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**REPORT OF THE
WORKING GROUP ON
HEALTH SYSTEMS RESEARCH,
BIOMEDICAL RESEARCH & DEVELOPMENT
AND
REGULATION OF DRUGS & THERAPEUTICS**

**11th FIVE YEAR PLAN
(2007–2012)**



सत्यमेव जयते

**GOVERNMENT OF INDIA
PLANNING COMMISSION**

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Preface

The Planning Commission had constituted a Working Group on Health Systems Research, Biomedical Research and Development and Regulation of Drugs and Therapeutics for the 11th Five Year Plan vide its order No.2(11)/2006-H&FW of 25th May, 2006 (copy placed as Annexure). The Director-General of the Indian Council of Medical Research was named the Chairman with 21 other members.

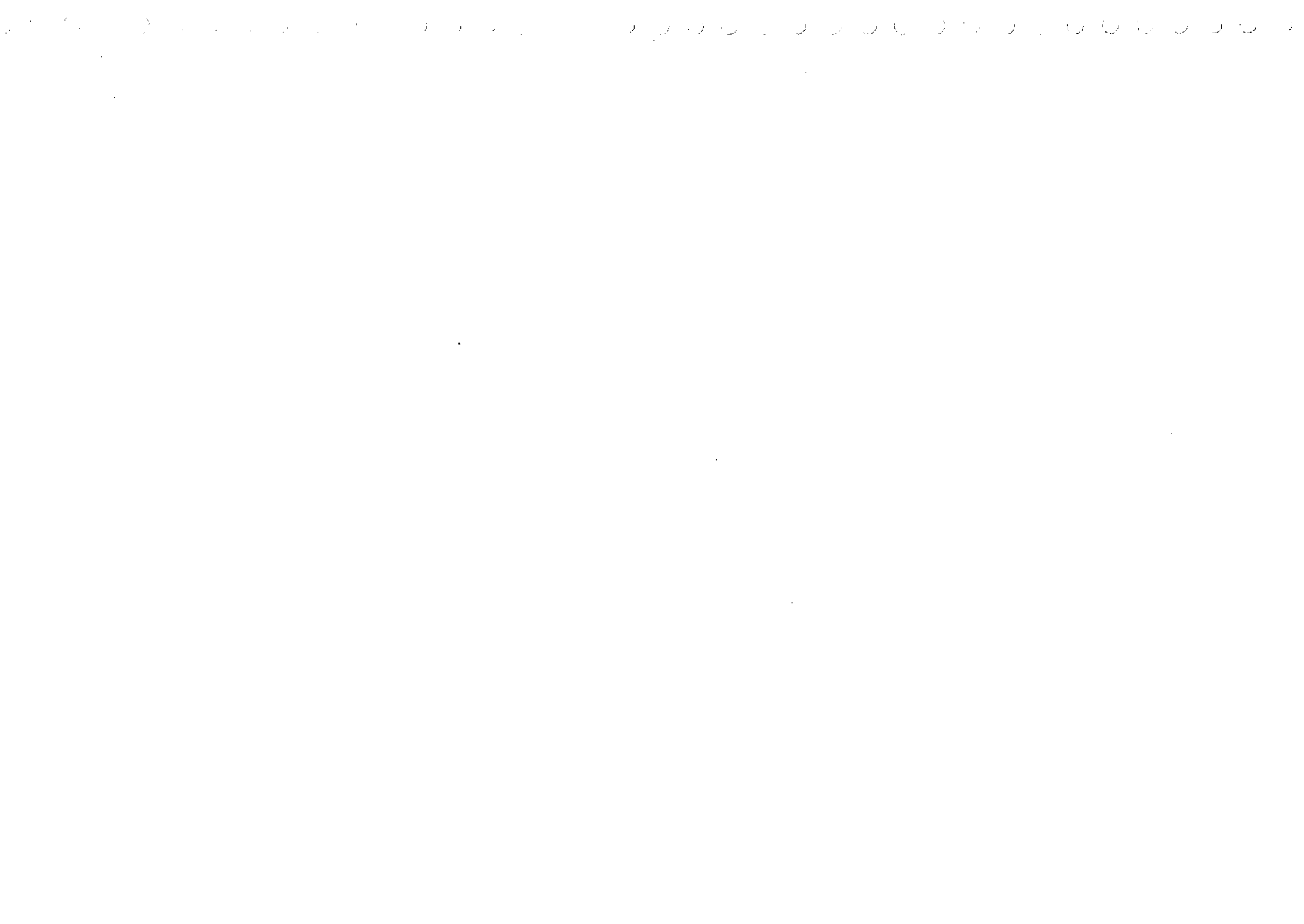
The membership included representatives of various Departments (CSIR, Health & Family Welfare, Science & Technology, Biotechnology, and AYUSH) Directors of relevant Institutes (Central Drug Research Institute and Industrial Toxicology Research Centre, Lucknow; Indian Institute of Health Systems, Hyderabad, Indian Institute of Technology, Chennai, Indian Institute of Science, Bangalore) Drugs Controller General of India, eminent scientists (Dr. Ranjit Roy Choudhary, Dr. Somnath Roy, Dr. Y. Atal), representative NGOs (Voluntary Health Association of India, Centre for Equity into Health & Allied Themes) and officials from Planning Commission and Ministry of Finance.

Dr. Gerald Keusch, Director, Global Health Initiative, Boston University, who was a member of the Performance Appraisal Board (PAB) of the ICMR, was in New Delhi during one of the meetings of the Working Group. He was also invited to interact with the members.

The Chairman had co-opted Prof. Indira Chakroborty, Director, All India Institute of Hygiene and Public Health, Kolkata and scientists/officials from the ICMR for their inputs in view of their experience and expertise (Dr. A. Pandey, Director, National Institute of Medical Statistics; Dr. Bela Shah, Sr. Dy. Director General, Division of Non-Communicable Diseases; Dr. V. Muthuswamy, Sr. Dy. Director General, Division of Basic Medical Sciences; Dr. D. Mukherjee, Chief, Division of Epidemiology; Dr. K.K. Singh, Chief, Manpower Development and Dr. Malabika Roy, Coordinator, Division of Reproductive Health and Nutrition).

The Working Group met twice. In the first meeting, the members deliberated on the *modus operandi* and offered suggestions. They agreed to provide their own and/or their parent organization's inputs on each Term of Reference. Based on these, a draft report was prepared and circulated to the members. The second meeting was taken by the Chairman to finalize the report.

This report is the outcome of invaluable contributions provided by the members. □



Health of a country depends to a large extent on the quality and reach of the health system as well as the support provided by the health research system to respond to the health challenges. With the development and use of sophisticated tools of modern biology, a better understanding of complex interplay between the host, agent and environment is emerging. This is resulting in the generation of new knowledge. One of the greatest challenges that the health community faces today is to find means of bridging this *know-do* gap. This scientific knowledge is to be used to develop drugs, diagnostics, devices, and vaccines which should find a place in the health systems of the country. A vibrant inter-phase between the research community, the industry and the health systems is the only way to facilitate this.

In order to make meaningful suggestions and recommendations for the 11th Plan period on the areas identified in the Terms of Reference, it is prudent to look at the existing scenario, the lacunae therein, and the future challenges. From this would emerge the areas that need strengthening as well as the new initiatives required. The Reports of the National Commission on Health and Macroeconomics, the Performance Appraisal Board of the ICMR, and several other national and international publications were reviewed.

As a result of the advances made by the country in various fields, the health of the common man has improved but it could have been better. It is not only the technological advances in public health and medicine that influence health of the population. The epidemiology of disease extends beyond biology. A sociological perspective is important to understand the occurrence, persistence and cure of a disease. The diseases are not rooted in biological causes above, but are multifactorial. This calls for an inter-disciplinary approach to health research. The 11th Plan, therefore, should mark a departure in its orientation. No amount of pure bio-medical research will be able to find solutions to health issues unless it addresses upfront the social determinants of health.

1. The absence of a national health research policy, weak health research system, neglect of health systems research, inadequate capacity to plan and implement, lax monitoring and evaluation system, priority setting not done on accepted scientific principles, inadequate budget for health and in turn for health research, narrow research base in medical colleges and other institutes, lack of policy, plan or management of human resource development for health research, neglect of translational research, and not-so-strong inter-agency collaborations all have contributed to the current state. Many of these factors have been repeatedly highlighted in reports of various committees the latest one being that of the National Commission for Health and Macroeconomics.

Several of these factors would be addressed once the decision of the Ministry of Health & Family Welfare to create a new Department of Health Research within the Ministry is implemented. This decision has been hailed as one of the most significant steps the Government is taking to elevate health research to centre stage of health promotion and care. It is hoped that with this initiative health research would be able to contribute effectively towards country's economic and human development.

Each agency involved in health research has worked out a detailed plan of activities for the 11th Plan period which they would submit to their respective Ministries. Some important cross-cutting generic issues which need attention are:

- enunciate National Health Research Policy
- develop a National Health Research System
- formulate a National Health Research Plan
- attach high priority to Health Systems Research
- inculcate a culture of research in medical colleges and other institutes by providing opportunities to participate in capacity building and infrastructure development programmes
- promote good governance of health research
- Strengthen partnerships at all levels-local, regional, national and international among all the stakeholders.
- identify current and future needs of human resources
- enhance allocation for health and health research
- facilitate translational research

New Institutes have been recommended to address some of the important areas. For example, Schools of Public Health, Clinical Trial Centre, Centre for Cardiovascular Disease, Diabetes and Stroke, Animal Resource Facility, Institute for Research on Ageing etc.

2. In order to address the issues surrounding development, testing and quality control of drugs and devices, the Government had set up several committees. Most prominent among them was Mashelkar Committee which was mandated to undertake a comprehensive examination of drug regulating issues including the problem of spurious drugs. This Committee has recommended creation of a well equipped and professionally managed CDSCO which could be given the status of Central Drug Authority of India. It also calls for strengthening of the State level regulatory apparatus, use of scientifically and statistical valid methods for quality checks, and amendment of Drugs and Cosmetics Act to check manufacture and sale of sub-standard drugs.

Specific recommendations have been made on ethical and IPR issues; regulation of recombinant pharmaceuticals, food including nutritional supplements, genetically modified foods; biologics, biobanks; stem cell

research and devices. The need for establishing clinical trial centers and a registry has been emphasized.

The AYUSH component has negligible visibility in terms of Drug Controllers, Drug Inspectors, Drug Analysts and other manpower required to regulate quality of formulations of indigenous systems of medicine. Though the Department of AYUSH has launched a scheme to develop Standard Operating Procedures of manufacturing process to enable maintaining of quality of these products, still lots of work needs to be done for standardization and quality control. During the 11th Plan period strengthening/upgrading of various drugs, testing laboratories, ensuring of availability of genuine raw materials, strengthening of drugs control department of states and at central level, development of herb garden/museum/herbarium are other priority areas that need to be addressed.

3. The human resources capacity for health research is a measure of country's capacity and capability to effectively address the existing and future research agenda. Though the ICMR and other agencies and Institute offer some very high quality training, but such opportunities are few and only a small number of scientists get trained. It is therefore, important to assess the current and future needs of scientific manpower in various disciplines using appropriate analytical methods. There should be an organized and focused effort towards formulation of a long term comprehensive human resource development policy and plan to address wide range of related issues. The career opportunities should be made more attractive for scientists. The compensation package being offered to scientists should be made generous to retain and attract bright brains.
4. Each agency engaged in health research has an elaborate peer review system of its research activities to address and monitor research in priorities areas. In addition, there are strategies to facilitate better utilization of results of research by the health systems. During the 10th Plan period, new initiatives to enhance inter-agency collaborations have been taken like the Golden Triangle (AYUSH-CSIR-ICMR) and DBT-ICMR MOU to work together on areas of mutual interest. There is significant scope of further improvement in inter-agency collaborations for addressing priority areas and to avoid duplication of efforts. An overarching National Health Research Management Forum is suggested. In this, all key stakeholders would be represented and it would advise on and evolve national health research policies and priorities and suggest mechanisms and action plan for their implementation; facilitate utilization of research results and review research management and recommend strategies to overcome problems in implementation of polices.

5. Access and utilization of health research information is critical for research. There are thousands of journals, reports, status papers and other documents that are produced every year. Many of these do not come in the realm of formal literature. Their availability is limited in the existing system of information and communication. To effectively search and retrieve the most relevant information the availability and use of appropriate technology like computers, computer readable data-bases, CD-ROM technology, and satellite based tools etc. is necessary to meet the requirement. ICMR and other agencies have taken very concrete initiatives to improve the access to national and international health information. MEDLARS Biomedical Informatics Programmes provides ready access to medical databases to researchers. Ground work on telemedicine in the country has already been laid with efforts of ISRO and Information Technology Department. The NCMH has already recommended setting up of a National Institute of Health Information System. A National Medical Education Institutions Network is also suggested for the country. This would act as a useful resource base for knowledge sharing for Medical Education, and Research. The country should also have a Digital Library and Medical Informatics Network. This would be a network of pooled information in the form of digital library of data bases and health information that can be accessed through internet/intranet and used for research purposes also. The libraries of medical colleges and other institutes should be modernized to bring them to a certain minimum benchmark in term of infrastructure, databases and services offered. Steps toward national resource sharing and networking of the libraries should be taken. This would also help to improve the accessibility of health information. □

Introduction

A sort of revolution in health research is underway. New insights have been gained into the human body. Humans are understood as social beings whose health is influenced by an intricate interplay amongst the biological, genetic, social, economic and environmental determinants of health. Outcomes of this revolution in health research are transforming the way diseases are diagnosed, treated, and prevented as also the methods for promotion of health.

Significant advances in better understanding of human health and disease are also being boosted by new ways of thinking, new technologies, new partnerships, and new industries. The complexity and scale of today's health research challenges increasingly require that researchers reach out beyond their own areas of expertise and establish partnerships that bring people who share a common vision and interests together.

Health challenges and disease know no boundaries. Public safety and security requires a health system and a research community that can respond quickly and appropriately to rapidly emerging health concerns.

While health research has made appreciable progress there remains an unacceptable lag time in translating the research outcomes into tangible health products or in application of the knowledge generated through research. Thus, the task is of how best to mobilize research to bridge the gap between what is known and what is done – the 'know-do' gap. Equally important is to ensure that the products of health research reach and are used for and by the people who need it most. Health research should be directed to provide ways and means of bringing about equity and improving access to health technologies.

The health of the population would not only be influenced by the technological advances in medicine and public health but also by the changes in structure of the society. Some of these changes are bound to happen like the demographic transition, (increasing in age-segment of more than 60 years), modification of life styles (increased consumption of alcohol and tobacco and consequent effects on health) and the changing environment (urbanization, occupational diseases, injuries and accidents). The 11th Plan should aim to create a healthy environment which can decrease the admissions to hospitals. This cannot be achieved by actions of health sector alone. Health is an outcome of interplay between various

variables like clean environment, potable and safe drinking water, sanitation, housing, infrastructure facilities, education and income. An inter-sectoral and inter-disciplinary approach would be critical.

The crude birth rate has decreased from 41.7 in 1951-61 to 24.8 in 2002-03, and crude death rate has fallen from 25 to 8 in the same period. Maternal mortality ratio has decreased from more than 5 to less than 2 and infant mortality rate has decline from 146 to 60. The total fertility rate has declined from 6 (1970-71) to 3 (2002-03). Small pox and guinea worm have been eradicated. Leprosy has been eliminated as a public health problem. Significant progress has been made in fight for polio eradication. It is believed that since the introduction of Directly Observed Treatment Strategy (DOTS) in the country over 500,000 deaths have been averted due to tuberculosis. The number of malaria cases have been contained at about 2 m a year.

The country is burdened with infectious diseases alongside the emergence of non-communicable diseases. Management of some of these is quite costly for example diabetes, vascular diseases, hypertension, mental health, cancers, injuries, respiratory infections etc. Contrary to popular belief, these *lifestyle* diseases do not spare the poor. The investment in public health is low and the state of health systems is unsatisfactory. Coping with these set of new diseases along with existing diseases calls for reforms in India's health system.

The Report of the National Commission on Macroeconomics and Health (NCMH) builds a strong case for investing in indigenous research and encouraging Indian companies and universities in partnership to engage in R&D for drugs, medical devices and vaccines relevant to the needs of India's poor. For developing a culture for research, the Report suggests that the Government should initiate steps to debureaucratize procedures, introduce greater transparency, provide incentives and adequate flexibilities to enable engaging and retaining the best minds to undertake research - both in public and private universities and research institutions. There is also a compelling need to build multidisciplinary research blending physical, medical and social sciences. Besides, there is also an equal urgency to establish regulations, strict ethical norms and transparency, standardize methodology and international standards of research. Such capacity is necessary for undertaking operational research as also large-scale trials of drugs of both modern and traditional systems of medicine.

The Planning Commission's Approach Paper to the 11th Plan provides the general directions, and the recommendations of the National Commission on Macroeconomics and Health the road-map to develop a blue print for health systems research, biomedical research and development, and regulation of drugs and therapeutics.

Future Challenges

Report of the National Commission on Macroeconomics and Health has provided a glimpse of the future challenges that the country is likely to face by the year 2015. This would provide the basis of development of research agenda.

Demographic Changes

At present, the elderly population in India constitutes approximately 7% of the total population. This is likely to increase to about 20% by 2050. India will have a population of 137 million of older persons in year 2020. Chronic diseases disabilities, mental illnesses, visual, locomotors and hearing impairment are major health challenges in this age group. It is important to ensure that living longer should mean living healthily. The focus of research should be on how to prepare for this change in demographic structure. It should not be adding years to life but life to years – how to ensure that years added to life are not the years of ill health and disease. In addition to equipping medical facilities to handle the disease profile of the aged, a healthy environment has to be created so that old age does not become a victim of surrounding million and become a resident of hospices and hospitals. With growing number of senior citizens, there would be substantial increase in health care needs. Increasing availability and awareness about technological advances for better understanding of these problems raise the expectation of the population for acceptable, affordable and sustainable interventions. Health research will have to gear up to make available necessary preventive, promotive, curative and rehabilitative strategies for growing population of senior citizens.

Disease Burden

I. Communicable Disease

1. HIV

Based on the surveillance data, it is estimated that there are 5.1 million adults with HIV infection between 15 and 49 years. An estimated additional 50 million people are likely to become HIV positive by the year 2025; and some 15-18 million by 2015. Women have a two-fold higher incidence, largely due to female sex workers as well as higher biological

susceptibility of women to HIV-1 infection. What is worrying is the projection of an increasing number of HIV infected women from among the low-risk category.

2. Tuberculosis

According to ICMR's Tuberculosis Research Centre, an estimated 3.8 million bacillary cases and 3.9 million abacillary cases, (totaling to 7.7 million) were suffering from TB in 2000. In this estimation the possible association of HIV and multi-drug resistant (MDR)-TB are not included. An estimated 400,000 die of the disease each year. This makes TB the single most important cause of death in India. While no future projections for TB in India are currently available, it is expected that an expanded HIV epidemic will greatly increase the numbers with active TB weakening the affected individuals' immune system in a population with high rates of *M.tuberculosis* infection.

3. Malaria

Malaria, dengue and some other conditions fall in the category of 'malaria and vector-borne diseases'. In 1998, these were estimated to account for 1.6% of India's total disease burden. This is likely to be an underestimate of the true disease burden of these conditions. Data show that the prevalence of reported cases of malaria (per 1000 population) declined in India during the period 1995 to 2003 but the proportion of *Plasmodium falciparum* cases, a serious form of malaria that is also expensive to treat, increased during the same period at the all-India level-from 38.8% in 1995 to 47.5% in 2003. With increasing resistance of the malarial parasite to available drugs, and without effective interventions, one may even see an increase in the disease burden from malaria in the future.

4. Emerging Re-emerging infections

During the last three decades, 30 new infections have been reported globally. India too had some experience of SARS and later of avian flu. Outbreak of encephalitis due to Chandipura virus was reported in Andhra Pradesh and Gujarat. Nipah virus outbreak happened in Siliguri, a new strain of *V.cholerae* 0139 emerged, diarrhea due to Group B adult rota virus was detected in Kolkata so was *V.parahaemolyticus* 03:K6. The threat is also posed by terrorist groups using natural or genetically engineered strains of microorganism with evil intent. Stepping up specialized disease surveillance is corner stone to emerging infectious disease threat. Laboratories with adequate biosafety levels would be needed and trained staff to work in them. Repositories of important microorganism would be needed to compare and study genetic changes. Animal facilities would be required to under take animal studies and development of diagnostics and other tools. Japanese encephalitis is spreading from rural to urban areas and dengue from urban to rural

areas. The annual number of cases are increasing and so is the number of deaths. And now Chikungunya is reported to be spreading.

II. Non-communicable Diseases

1. Cardio-vascular Diseases

Starting from a level of about 38 million cases in the year 2005, there may be as many as 641 million cases of cardiovascular disease (CVD) in 2015; and the number of deaths from CVD will also more than double mostly on account of coronary heart disease - a mix of conditions that includes acute myocardial infarction, angina pectoris, congestive heart failure and inflammatory heart disease, although these are not necessarily mutually exclusive terms. The rates of prevalence of CVD in rural populations will be lower than in urban populations, but will continue to increase, reaching roughly 13.5% of the rural population in the age group of 60-69 years by 2015. The prevalence rates among younger adults and women (in the age group of 40 years and above) are also likely to increase.

2. Diabetes

Diabetes, also associated with an increased risk for CVD, is emerging as a serious health challenge in India, even though it accounted for only about 0.7% of India's disease burden in 1998. It is estimated that there may be a significant load of diabetes cases in India-rising from 31 million in 2005 to approximately 46 million by 2015, and particularly concentrated in the urban population.

3. Cancers

In India, cancers account for about of 3.3% of the disease burden and about 9% of all deaths. These estimates will, however, surely change as many of the common risk factors for cancers, such as tobacco and alcohol consumption, continue to become more prevalent in India. It is estimated that the number of people living with cancers will rise by nearly one-quarter between 2001 and 2016. Nearly one million new cases of cancers will be diagnosed in 2015 compared to about 807,000 in 2004, and nearly 670,000 people are expected to die.

4. Mental Health

Nearly 65-70 million people in India are in need of care for various mental disorders in all age groups. This estimate excludes a large group of common mental disorders like phobia, anxiety, disassociative disorders, panic states, mild depression and substance abuse (varying spectrum of associated hazardous use). It is difficult to establish the true burden of all these disorders but has been estimated to be nearly 20.5 million people. Alcohol related problems are increasing in India nearly 62.

million people predominantly men - are likely to be current alcohol users with nearly 10.2 million being alcohol dependants and about 30 million alcohol users.

5. *Chronic and Obstructive pulmonary diseases and asthma*

It is estimated that there were roughly 15 million chronic cases of COPD in the age group of 30 years and above, and 25 million cases of asthma in 2001 in India. These numbers are projected to increase by nearly 50% by the year 2016, including 'severe' cases, some of whom may require greater levels of care, including hospitalization.

6. *Accidents and injuries*

Data from Survey of Causes of Death and Medical Certification of Causes of Deaths reveals that 10-11% of total deaths in India were due to injuries. It is estimated that nearly 8,50,000 persons die due to direct injury related causes every year in India during 2005, with 17 million hospitalizations and 50 million requiring hospital care for minor injuries. By 2015, the toll is expected to rise to 1.1 million deaths and 22 million hospitalization and 53.0 million minor injuries in the absence of any positive intervention. While official reports capture majority of these deaths, domestic and occupational injuries, falls, drowning, animal bites and injuries in disaster go unreported.

7. *Oral Health*

The number of cases of the various oral health conditions is expected to increase by 25% over the next decade.

8. *Suicide*

Suicide is major public health problem and is among the top ten causes of death in most countries. In India, total numbers of suicides were 38829 in year 1967, which has increased to 110851 in the year 2003 (National Crimes Records Bureau). The numbers of suicides (during decade 1993-2003) have increased at an annual compound growth rate of 3.11 per cent as against the corresponding population growth rate of only 1.9 per cent. Recently, suicides by students (pressures of examinations) and farmers (economic pressures) have brought into sharp focus the need for research in this neglected though important area. With increasing urbanization, the stress factor is likely to also increase and may prove to be a trap for larger number of suicides among the vulnerable population.

9. *Strokes and Neurological Disorders*

The estimates for the burden of NCD by ICMR indicated the prevalence rate of stroke to be 1.54/1000 in age group 20 years and more with a death rate of 0.6/1000 (2004). The number of cases of stroke in India increased from 0.79 million in 1998 to 0.93 million cases in year 2004,

whereas DALYs attributable to stroke increased from 5.8 million in year 1998 to 6.4 million in year 2004.

III. Problems of Urban Health

India's urban population is 285 million which amounts to nearly 30% of the total population. The urban growth will account for over two thirds of the total population increase in the first quarter of this century. Slum population growth will continue to outpace growth rates of India, urban India and mega cities. Demographers refer to this as the 2-3-4-5 syndrome; in the last decade, India grew at an average growth rate of 2%, urban India grew at 3%, mega cities at 4% and slum population increased by 5%. By 2030, the urban population is expected to reach 297 million. Official estimates do not account for unrecognized squatter settlement and other populations. Population projections postulate that slum growth is expected to surpass the capacities of civic authorities to respond to the health and infrastructure needs of the urban population.

Lack of water and sanitation and the high population density in slums facilitates rapid spread of infections. Poor housing conditions, exposure to heat or cold, air and water pollution and occupational hazards add to the environmental risks for the urban poor. The urban health is also vulnerable, as they do not have back up savings, food stocks or social support systems to help them during illness. Thus, even though there is a concentration of health care facilities in urban areas, the urban poor lack access to health care. Urban health initiatives in the country to date have been limited and fragmented. The challenge of increasing urbanization with growth of slums and low-income families in cities has made access to health care for the urban poor a matter of priority. It may be necessary to create a separate unit with multi-discipline expertise to address this issue.

IV. Nutritional Problems

The incidence of nutritionally poor population, particularly the rural poor, is quite high in Orissa, Bihar, Madhya Pradesh, Uttar Pradesh and Andhra Pradesh. Another related issue is the problem of *hidden hunger* - as the problem of micronutrient deficiency. While estimates suggest that 800 million people are undernourished, the number of people suffering from micronutrient deficiency is as high as 3.5 billion globally; a very high percentage of these are in India. In India, the magnitude of iron deficiency is perhaps the greatest. Thus, for example, 70% of pregnant women in India suffer from iron deficiency anaemia (IDA); and the figure for young children is also high. Between 10 and 20 million children in

India suffer from vitamin A deficiency (VAD) and 60,000 annually go blind because of VAD. The consequences of these deficiencies, in terms of impaired physical and cognitive development, disability and mortality are correspondingly staggering. There is a need to develop appropriate vehicles for these micronutrients. With the increase in the availability of processed food and development of food industry, food safety has emerged as an important issue. High levels of certain chemicals in ground water (like arsenic) and use of unacceptably large amounts of pesticides in agriculture, find their way in food stuffs consumed by people. There is an urgent need to develop technology to deal with such toxic agents in the food chain. Energy requirements for special groups like women who have to walk several kilometers to draw potable water or collect wood for fuel needs to be addressed by development of low cost technology.

V. Reproductive and Child Health (RCH)

According to the NRHM maternal, perinatal and childhood conditions account for a significant percentage of the disease burden. The IMR is about 66 per 1000 live-births, a substantial improvement over the levels nearly 30 years ago. The under-five mortality rate (U5MR) was estimated at 95 per 1000 live-births in 1998-99, and is declining at a rate similar to that of the IMR. Two-thirds of deaths occur within the first week of birth. About 35 babies of every 1000 childbirths die within one month; 30 before one year and 26 between 1 and 5 years of age. In India, the ratio of the neonatal death rate to the 1-5 year death rate is 1.3, against 10 in developed countries. Therefore, any strategy to reduce child deaths must focus on all three age periods, as focusing on any one may result in merely shifting the burden to the other. There is a reported decline of the maternal mortality rate (MMR) from about 580 per 100,000 live-births during 1982-86 to 540 per 100,000 live-births in 1998-99(NFHS-II).

Significant improvement has taken place in reproductive health of the population. The couple protection rate has increased from 1.4% in 1970-71 to 50-52% in 2002-03 and total fertility rate has declines from 6 to 3. However, there are problem areas which need to be tackled. Maternal mortality, infant and neonatal mortality are still very high. Main causes of maternal mortality are unattended delivery, obstructed labour, post-partum complications and unsafe abortions. Use of spacing method (about 6%) and male participation (7-8%) are very low. Unmet need for contraception is very high, particularly among young women below 20 years. (27%) resulting in high rate of unplanned and undesirable pregnancy, compelling them to resort to unsafe abortions.

In addition to the unmet need for reproductive health care, there are many of sociological factors which have contributed to the continued reproductive ill health.

Research would, therefore, be needed to, for example, how to alter gender perceptions, strategies to build rational and healthy sexual attitude and behaviour amongst adolescents and youths, approaches to ending discrimination and injustice, better understanding of barriers to girls education, empowerment and development, improve men's participation in reproductive health care, needs of under-privileged sections of population like the tribal, inequities related to poverty and access to health care.

Need for a different orientation to 11th Plan

Conventional response to persisting and new emerging health challenges would be to step up research in control method and improving the health systems research. epidemiology of the disease goes beyond biology. Sociological perspective is important to understand the occurrence of a disease and its cure so that the patient returns to normalcy and contributes to functioning of society.

It is now increasingly realized that this is not enough. No amount of pure bio-med research would be complete unless it is extended to social determinants of health. Many of them are embedded in the circumstances in which people live and work. All forms and shades of poverty, inequity, food insecurity, social discrimination, poor conditions of housing, unsafe working conditions, poor access and/or utilization of health services are some of the important social factors influencing disease burden. The 11th Plan, therefore, should mark a departure in its orientation to health research.

Health care does not end once the fever is down and stitches are out. Diseases are persisting, and/or emerging because of sociological changes, life-style changes, and social disruptions (riots, violence etc.). Diseases are not solely rooted in biological causes, but are multifactorial. This calls for a multi and inter disciplinary approach to health research.

Central to health systems research and biomedical research and development is improvement in public health and making available to them the 'goods' required for attaining positive health. This requires partnerships with various stakeholders viz. donors, pharmaceutical industry, IT industry,

engineering sciences, science and technology and biotechnology, social sciences, town planners, architects. It requires strengthening research capacity of medical schools, colleges, universities and institutions, development of skills and infrastructure. Human resource development, creating an enabling environment for researchers, setting up new infrastructure to address gap areas and creating effective networks are also priority areas. Undertaking these activities would translate into allocation of more funds for health and to health research. Underpinning all these principles are the attainment of targets laid down Millennium Development Goals (MDGs) meeting the objectives of the National Rural Health Mission, addressing the Government's Common Minimum Needs Programme.

Terms of Reference

- To review the position/progress/problems in basic, clinical, applied and operational studies during the 10th Plan period and to suggest priority areas for research in these areas, and mechanism to avoid duplication/overlapping and to bring about transparency and social control in research work including ethical issues during the 11th Plan.
- To review the current investment in bio-medical research and health systems research by various agencies and project requirements to address the identified priorities during the Eleventh Plan period.

Introduction

The group reviewed the present position, progress and problems in basic, clinical, applied and operational studies in biomedical research during the 10th Plan period. The major achievements in areas of health research of the ICMR, CSIR, DBT and Deptt. of Science & Technology were reviewed in the backdrop of the Planning Commission thrust areas of the 10th Plan period.

The thrust areas identified during the 10th Plan covered basic, applied and operational research in the area of health, family welfare, nutrition and the indigenous systems of medicine. During the 10th Plan period, based on these identified thrust areas, the different agencies involved in biomedical research have carried out significant work that has contributed towards achieving many of the objectives. These have been reviewed in detail in the 11th Plan document submitted by ICMR, DBT, DST and CSIR respectively.

The Group deliberated on the reasons for tardy improvement in the health indices for the country. Some of the major concerns include:

National Priority Setting

New policy initiatives in the health system are at times taken on inadequate evidence-base due to lack of adequate research in evaluating the policy experimentation. The work initiated by many state governments on Public-Private Partnership point to the fact that successes are announced and attempts made without undertaking rigorous research on such initiatives.

At present while one may talk about the dominance of the private health research funding upsetting the national health priorities, but the fact is that

the country has no transparent evidence based mechanism for priority setting in health research. Unless such a mechanism is set up, the institutions and researchers, and the ethics committees as local/institutional regulatory bodies, will not be in a position to resist the research proposals pushed by the multinational and Indian corporate firms looking for the markets abroad using the Indian biomedical research data. Therefore, it is imperative that the Government of India set up an expert group to make recommendations on the priority setting for the health research – particularly the clinical trials in biomedical research. This work of priority setting must be reviewed periodically say every three years so that the national health research priorities are updated on a regular basis. Due to lack of clear national priorities and committed resources for the health research, there has been an increasing influx of the foreign governmental, private foundation and corporate sponsored health research. There is a great danger that such research could distort the health priorities of the country.

Insufficient thrust on Health Systems Research

Even as India needs to contain and reduce prevalence of existing diseases, it is burdened with a growing emergence of non-communicable diseases (such as diabetes, cardio-vascular diseases, hypertension, mental health, cancers, injuries, respiratory infections etc) which are very expensive to treat. There is also increasing evidence that these 'lifestyle' diseases affect the poor due to low resilience to infections, poverty induced malnutrition and stress. Coping with these double burden diseases calls for reforms in India's health system. Health systems research is likely to provide feasible solutions.

The Group recognized the neglect of the health system research by institutions. The problem in health systems research in India is not that research on new topics is not conducted, but that there are system blocks in improving the health of people using the research outcomes. Thus, unless the health systems research is provided a prime place it deserves and its findings are used in shaping policies to remove system blocks in improving people's health, the expensive biomedical research would remain on paper or would be useful only to the health systems in developed world. Another worrying trend relates to the hiring of the for-profit market research and consultancy firms – Indian as well as from abroad or multinational, at times of questionable credentials to undertake health system research at very high cost. This has gradually led to financial and scientific undermining of the public and NGO research institutions undertaking health system research.

Need for Performance-based monitoring

No method is currently available within the health system to measure or assess on a concurrent basis the efficacy or utility of an intervention to identify critical problems and suggest corrective action. In the past, for every corrective system that was put in place, a more ingenious system of statistical manipulations evolved. Correcting this implies setting up a system of monitoring and review which are transparent and frequent such as, for example: (i) statistical sampling every quarter, and (ii) social audit.

Inadequate Capacity to plan and implement

According to the NCHM, there is an acute shortage of epidemiologists, biostatisticians and other personnel trained in public health. Specialists in certain disciplines often work as generalists in public health, which is an inefficient use of a scarce resource. Even generalist bureaucrats who serve as Project Officers for special programmes often lack the technical capacity to provide the desired level of comprehension and quality of leadership, proving to be a serious handicap. Lack of relevant technical expertise and non-availability of even the critical minimum at the Central and State levels are reasons for public health programmes lacking in focused design, non-development of national treatment protocols and standards, non-integration with other related sectors/programmes such as TB with HIV; HIV with maternal health, maternal health with malaria, health with nutrition or water, etc. The inability to provide required technical leadership to States and districts on the operationalization of interventions based on technical norms or the inability to assess and build the technical skills and human resources required by the programme is yet another reflection of the lack of technical leadership. More important is not utilising operational research for designing better targeted programmes in keeping with the wide social and geographical disparities that characterize this country has been a serious shortcoming.

Need for Regulation of quality of drugs and devices

The quality of drugs sold in the market has been a major concern. The common man often ends up buying spurious or sub-standard drugs. The Supreme Court of India, the National Human Rights Commission and MPs have time and again expressed concern about this and have urged the Government to improve the drug regulatory system. In the past, several committees have been constituted to examine the issue and have made many recommendations. Some of these have been implemented, but the core issue has remained unresolved. The NCMH's report has too flagged the need for strengthening of regulatory mechanism of not only drugs but also of devices. According to this report, there is no effective quality

regulation also on the sale of high-technology medical devices, with the existing BIS (Bureau of Indian Standards) mark norm limited to a small subset of low-cost medical equipment. Consequently, substandard second-hand medical devices are currently flowing into and floating around the country. The only regulation that currently exists is the protection relating to radiation. However, there is little or no control on what the equipment does relative to its claimed effects, its technical specifications, etc. Availability of good quality spare parts is also a serious problem faced by both public and private health service providers in India. While the problem is especially acute for older equipment, spare parts for which are no longer made by the original manufacturer, there are a lot of equipment suppliers who simply do not deliver follow-up services, making the search for alternative providers a costly exercise. There is severe shortage of technical experts for repairing medical equipment.

Narrow Research Base

Presently there are about 170 MCI recognized and 65 permitted medical colleges. About 20,000 to 25,000 students graduate every year. Medical schools are the cradle of health researchers of tomorrow. About 8000 of these do post-graduation in various specialties (38 PG degree courses, 32 PG diploma, 37 discipline for Ph.Ds and 24 super specialties). The quality of research in these medical colleges is low. Less than 10% are active in research, most of the papers resulting from research are published in non-indexed journals with low impact factor. More than half of the medical colleges (53%) had published less than 10 research papers in an indexed journal during 1990-94, and only 10% have 100 or more papers during that period. It is essential to inculcate a culture of research in medical colleges if the quality and quantity of health research is to be improved in the country.

Limited Human Resource

There have not been any organized and focused efforts towards human resource estimation for research or its development. It is not only an issue of numbers and skills, but also giving attention to generate a demand for research among policy makers. There has also been a ban on creation of new positions. This has further hampered human resource development. The only new blood that has been inducted has been against vacant posts. Rapid progress is being made in biomedical sciences. Fresh technologies are opening new vistas. But the country is unable to exploit them to the full in absence of adequate human resource. Cutting edge areas are being neglected.

Neglect of Translational Research

Translation of research to action involves using scientific knowledge to develop drugs, vaccines, diagnostics, devices and other interventions. There is a gap in using knowledge to inform policy and practice in health systems countries. Some challenges faced are limited access to technology and scientific information leading to scientific isolation, limited scientific career opportunities and the inability to synthesize existing knowledge towards improving interventions and performance of health systems. There is thus an urgent need for a health research system that would not only generate research outputs but also utilize scientific knowledge to inform policy and to promote knowledge based change in health system.

Recommendations

Setting up a Department of Health Research

The Group welcomed the decision of the Government of India to set up a Department of Health research within the Ministry of Health & Family Welfare. This Department would have the responsibility to address the shortcomings in the present system, and improve health research within the country.

National Health Research Policy

A clearly defined National Health Research Policy on the lines of Science & Technology Policy is the basis for maximising the return on investment in health research. The Government should therefore, enunciate a National Health Research Policy. The draft policy which has already been prepared by the ICMR should be quickly finalized and adopted.

This policy should aim to generate the evidence-base for Health Systems and Services, so that they will be significant promoters of equity and contribute to National Development; establish linkages between health research and national health programs to facilitate the operationalisation of evidence based programs and to obtain feedback for the optimisation of Health Research; encourage the development of fundamental research in areas relevant to health to ensure that a national critical mass of scientists who can contribute the benefits of modern technology to health research is developed. The proposed Policy would also ensure that the optimum benefits of modern technology are harnessed to promote national health; build and integrate capacity for research in National Health Programs, research institutions and in the private sector (profit and non-profit organisations) utilising as far as possible areas of excellence already

available in the country. The Policy would facilitate optimal use of information, communication and networking technology to ensure that the global knowledge base is available for national programs, and that research is channelled in relevant directions without unnecessary duplication; manage global resources and transactional collaborations optimally to ensure that collaborative health research primarily facilitates the development of national health systems and services. It would also ensure that health research is truly intersectoral and can harness the resources in areas such as social sciences, economics and traditional systems of medicine; optimum harmonisation of National Policies is essential to facilitate intersectoral collaboration and partnership, so that maximum developmental returns can occur from health research.

National Health Research System

Health Research in the country should be developed into a National Health Research System (NHRS) wherein all research agencies, cutting across ministries and sectors identify priority areas of research and coordinate with each other to avoid duplication, fragmentation, redundancy and gaps in knowledge, in order to enable the results of research to transform health as a major driving force for development. The NHRS would generate and communicate knowledge that helps to form the national health plan and guides its implementation, and thus contributes, directly or indirectly, to equitable health development in the country; adapt and apply knowledge generated elsewhere to national health development; and contribute to the global knowledge base on issues relevant to the country.

National Health Research Plan

A National Health Research Plan would be developed based on a transparent priority setting exercise involving all stakeholders. It shall be a rolling Biennial plan, to be reviewed and updated annually in the framework of a 5-year projection. A medium term (5 years) and a long-term (10 years) vision for health research would be developed for the entire country in consultation with all governmental agencies and others who provide funds for health research.

National Health Systems Research

A high priority should be accorded to support health systems research to generate the evidence for health policy to enable informed decisions for improved health service delivery. This would include assessing health needs of the country, the availability, acceptability and accessibility of health interventions, health technology assessments such as cost effectiveness of

interventions, the tracking of resources for health (including for health research) as part of the National Health Accounts, the availability and means of financing of health interventions. An interdisciplinary team would be set up to identify priorities for health systems research.

Recent studies of the economic impact of health research suggest that the health and wealth dividends from investment in research far outweigh the costs of the research. In partnership with other organizations, new concepts of both financial and non-financial benefits should be applied in the Indian context, to help build the evidence base and give a clear picture of the broad-ranging impact of health research.

Research which focuses on improving the health status of vulnerable populations, particularly Indians living in poverty; residents of rural areas; tribal populations; immigrants and refugees; people facing gender inequities; the homeless; children; seniors; the disabled and chronically ill; and victims of violence; and to support research on improving access to effective delivery of health services for these same vulnerable populations. Research that emphasizes the following should be encouraged:

- access to and equity in health services for vulnerable populations;
- biological, social, economic, cultural, and structural/environmental factors that influence vulnerability and disparities;
- identification, description and analyses of health disparities at the population level;
- Intervention research that informs the development of responsive programs, policies, and practices.

Research should also be supported on how social disadvantage is mediated by and interacts with other determinants of inequality, including poverty, social cohesion, gender and ethnicity, and how such factors influence health. There should be a continued need for research that will help to develop and evaluate ways to reduce social and health inequalities and to inform public health and social policy. A particular priority should be the impact of inequalities on women and children, rural populations, those belonging to underprivileged sections of society (like the SC, ST, and the OBC) their development and their long-term health.

The health system research is a multi-disciplinary social science, public health and policy research. There is a need to recognize (a) contribution of the social scientists and public health specialists in the research; (b) involve health system researchers before undertaking biomedical research and

clinical trials to ensure that there would be possibility of such research reaching to the people of the country and would not become only preserve of few; (c) sponsor multi-disciplinary intervention research to understand how the system can be improved and the new biomedical research could be disseminated.

Several priority areas for the health system research can be identified:

- Encouraging intervention research for seeking evidence useful for policy making: A wide range of intervention research projects may be financed in order to understand what works and what does not, and the reasons for the same.
- Many state governments have embarked upon the public-private partnership without creating good evidence based on its impact on the public health services, on the state finances, and whether they really bring about the equity in health access.
- *Studies on health insurance:* Increasingly, social health insurance is emerging as one of the major instrument for financing health care, and the private health insurance is also increasing. In both areas, major studies are needed.
- *Urban health:* Issues of health care access in urban areas despite high availability of private health care are not adequately studied. Besides, the health problems of urban poor, the migrants etc. need more attention.
- *Research on violence and health care in conflict situations:* This is a grossly under-researched area of health care despite increasing violence in the society.
- *Health care in disaster situation:* More work is needed in this area.
- *Gender and health:* The gender issues in disease prevalence, access to health care, and medical education, etc. must be paid priority attention.
- *Studies on the use and misuse of medical technologies:* While more and more health care technologies are being introduced in health care services, particularly in private sector, there is very little research on their relevance or appropriateness, misuse and irrational use, the additional financial burden on the users due to misuse etc. Such studies should cover prescription practices to the new medical technologies such as genetics, assisted reproduction, life prolonging technologies, organ donation and transplantations etc. etc.
- *Medical audit and audit of research:* Through research, we need to establish various ways of undertaking medical audit of health services at different levels.

- *Research on nursing practices:* The nursing is a much-neglected area of research in India. It is high time to encourage more nursing research by the nursing as well as social science and bioethics institutions in India.

Strengthening health research in medical colleges and other Institutes

The ICMR as a major funding agency of health research, should commit itself to strengthen India's health research communities by broadening, deepening and sustaining health research excellence. A skillful cadre of researchers working in state-of-the-art facilities with adequate and appropriate equipments and committed trainees, is the best strategy to ensure that India has the capacity and expertise to mobilize in order to address important health issues.

The best ideas of the researchers across the full spectrum of health research should get funded allowing them to pursue their own creative ideas for novel and significant research projects. At the same time, build on this foundation of research excellence through targeted research investments focused on emerging opportunities and challenges. Health research agencies should invest in strategic research initiatives designed to take advantage of new knowledge flowing from scientific progress, and to respond to the challenge of the health research priorities.

The convergence of disciplines should be encouraged that underlie the most exciting and important discoveries in health research, and to resolve ever-more complex health problems. Thus, the support for multidisciplinary and multi-sectoral teams of researchers as well as individual researchers working in medical colleges, universities and research institutes should be increased.

The right balance and mix of health researchers should be supported to realize its mandate and strategic objectives. It should continue to reach out through its extramural research programs and activities to those research communities that can contribute to health research. New investigators bring new ideas and ways of thinking and the energy of youth to health research. The ICMR should explore mechanisms to attract and encourage new investigators to establish themselves in health research.

Finally, attracting and mentoring the young to the exciting, relevant and important career in health research is key to ensuring the strength and vitality of India's health research system in the coming decades. This would involve creating a critical number of health researcher and positions in

medical colleges. The health research agencies should develop, in partnership with relevant stakeholders, a national initiative that reaches out to young students. Progress in research requires that the best researchers should be supported, work in stimulating and supportive environments. It may be necessary to set-up new departments like that of molecular medicine in medical institutes. Research would be given top priority in medical education. A formal programme of medical research should be incorporated in undergraduate and postgraduate level curriculum. Research should be made a core requirement for career advancement. Researchers should be suitably rewarded and appropriate infrastructure should be put in place. The ICMR should take up this challenge. This would require a substantial allocation of funds. The Working Group agrees with the recommendation of PAB of ICMR that the allocation for extramural research programmes should be about 50% of its budget.

Good governance of health research

The agencies, like the ICMR, should promote and provide guidelines on research governance issues, including good research practice, ethics and scientific probity. Thinking has to be reviewed within a continuously developing social and legislative context, and must respond to the moral and ethical questions that new scientific developments sometimes raise. One of the important tenants of good governance of health research is to promote the use of best available scientific evidence and results of research. The knowledge must be leveraged effectively to achieve better health. The generation, sharing and management of knowledge are necessary for its effective application. The agencies should give high priority to knowledge management. Consensus should be achieved through a continuing dialogue with the general public, users of health research, government, industry, the funding agencies, scientists and health service professionals. It may be necessary to accreditate certain facilities like the IVF clinics, research centres and clinics, stem cell research and therapy, clinical trial centres etc.

Partnerships

Partnerships are integral to the health research. As the challenges facing health sciences have become more complex and multi-disciplinary, the need for organizations to pool resources and expertise becomes increasingly important. Partnerships should be designed to meet the needs of a jointly agreed initiative whilst respecting the autonomy of individual participants. Partnerships are about shared vision, common objectives and alignment of priorities and programs.

By building partnerships amongst its stakeholders – those that have an interest and stake in health, the health system, and health research - India will be better positioned to support stronger research initiatives that produce quality results more quickly for the benefit of Indians.

Partnerships are critical in setting research agenda, share best practices in research, build research capacity, make more effective use of resources for research and eliminate redundancy in research activities and funding. Finally, partnerships are key to any successful knowledge translation strategy.

International collaborations

In recent years there has been an increasing number of new international partnerships in health research as organisations have come together to tackle some of the main scientific and medical issues of modern time. Initiatives would include partnerships with international research funders. National and international partnerships should be facilitated and nurtured in a variety of ways: through scientific workshops and meetings, bilateral interactions at agency level, and participation in consortia and other collaborations. Efforts should be made to:

- encourage and foster International collaborations based on equal partnerships, with mutual technology transfer, wherever appropriate
- Steer international collaborative health research to ensure that the country derives maximum benefit and the global goals are attained.
- Consider the possibility of extending resources and expertise to help other developing countries in their research efforts.
- Generate more financial resources as additionality to core funding to be used in research from various international agencies like BMGF, global fund for its TB and Malaria IAVI, GAVI and others.
- Set up North-South and South-South Global partnership by enhancing India's role in international health and by becoming an innovator and motivator for neighboring countries. South-South interactions should be made seamless and sufficient funds should be allocated for the purpose.

Translational research

Development of evidence-based medicine and healthcare by translating basic research outcomes into clinical evaluation is essential for their ultimate use into health policy and practice in the national health systems. A new initiative in clinical research should be developed in partnership with other research funders, industry and healthcare providers to. This will enable a

better assessments of the impact of research and the outcomes for patients. Such considerations will become integral to the research from the outset, and will ensure timely and effective implementation of new policy and practice.

An initiative should be launched to create greater opportunity to catalyze the development of a new discipline of clinical and translational science. Promising ideas for novel therapeutic interventions may encounter roadblocks in bench-to-bedside testing. While translation is sometimes facilitated by public-private partnerships, high-risk ideas or therapies for uncommon disorders frequently do not attract private sector investment. Where private sector capacity is limited or not available the public sector should step in to bridge the gap between discovery and clinical testing so that more efficient translation of promising discoveries may take place.

To make further progress in controlling major human diseases, initiatives should be launched to cultivate and train a cadre of clinical researchers with skills that match the increasing complexity and needs of the research enterprise.

Investing in interventions with high cost-benefit ratio cost-effective interventions

In a developing country like India, where a significant proportion of population is poor, a conscious decision has to be taken on the areas of investments in health research. It is important to keep in mind that key interventions that would yield the maximum improvements in population health outcomes should have the highest cost benefit ratio. According to a study, a worldwide demographic epidemiological advance between 1990 and 2020 would result in substantial decline in communicable diseases in importance among the poor and in relative terms, the significance of non-communicable disease would increase.

Modelling exercises have compared the impacts of interventions aimed at accelerated decline in communicable diseases with those targeting faster reduction in death and disability from non-communicable diseases. Such calculations indicate that an acceleration in overall progress against communicable diseases would bring about a significantly larger gain for the poor than would an acceleration of comparable magnitude achieved against non-communicable conditions. The additional 4.1 years of life expectancy that faster progress against communicable ailments would generate.

(compared to the base-line scenario) is almost 3 times as great as 1.4 year increase that faster decline in non-communicable diseases would produce.

Balanced Research portfolio for the 11th Plan

The potential to improve human health in areas where the burden of disease is most significant should be encouraged. Health needs influence the decisions about what research to support. However, the right balance has to be struck between short-term 'pay-offs' and promoting the longer-term development of fundamental science that will in time lead to improvements in health.

A number of health priorities have been identified in which new research is especially needed and where India can expect to make an impact, both socially and economically, in the years ahead. These range from well-known and long-standing causes of death and debilitation such as tuberculosis, malaria, HIV, cancer and heart disease, to problems that are on the increase, such as obesity, diabetes and respiratory problems including asthma. Infectious diseases continue to be a challenge, for example with the emergence of problems such as severe acute respiratory syndrome (SARS) and the ability of well-known viruses such as influenza to emerge in newly dangerous forms.

The research to be undertaken and supported should have an increasing relevance to health and disease, with equal emphasis on translational approaches at the basic/clinical interface.

The health research agencies, especially the ICMR should be committed to a research agenda that recognizes that future improvements in health and well-being will depend on research that:

- increases understanding of both the molecular and biological mechanisms underlying diseases as well as the psychosocial, economic and environmental determinants of health;
- supports efforts to develop new vaccines, diagnostic tools and cost-effective therapies;
- allows to understand and prevent the underlying social and behavioral causes of injuries and lifestyle diseases;
- links health with Science & Technology, engineering and related disciplines; and
- promotes healthy living and reduces risk behaviours.

There is a need to encourage harnessing of new knowledge of gene and gene functions, expand capacity for structural biology (structures of proteins and how different proteins interact). The complexity of the systems would demand development of bio-informatics as a major discipline. While fundamental and strategic research is critical, clinical research and translation of results of research into action should also be promoted. Clinical research capacity should be strengthened through training programme. To promote evidence-based decision making, the linkages with other health research agencies, academia and the industry should be strengthened.

The health research domains would be in accordance with the national health priorities, and address to known and emerging causes of morbidity and mortality:

- Communicable diseases
- Non-communicable diseases
- Maternal and child health
- Reproductive health
- Nutritional problems
- Environment and health
- Health issues of under privileged sections of society

To tackle problems in these priority areas, research approaches at many levels are needed: molecules, cells and tissues, animal models, whole organs and systems, individuals and populations.

The current level of knowledge provides exciting opportunities for multidisciplinary approaches. Many diseases have complex causes involving the interaction between genes and environmental factors, including, for example, exposure to chemicals, physical effects such as ultra-violet radiation, socio-economic status and lifestyle factors including diet, smoking and use of alcohol.

Development and use of modern biology tools (for example the micro-array, cryo-electron microscope, X-ray crystallography, magnetic resonance spectroscopy etc) and disciplines (like structural biology, stem cell research, computational biology, nanotechnology, nano-medicine, bio-informatics, genomics and gene therapy) should be facilitated for a better understanding of the biology of health and disease and devise interventions. The wealth of knowledge in traditional systems of medicine should be tapped.

Comparative therapeutic trials of traditional medicines with allopathic drugs should be undertaken.

A better understanding of the processes and mechanisms involved in disease causation and progression at molecular level holds the key to development of more effective tools for prevention and cure. The Working Group supports the priority areas identified by Department of Biotechnology. Some of these include:

- i. Molecular characterization of mechanisms of pathogen invasion to provide clues for identification of drug targets. Under this purview, infectious diseases like tuberculosis, HIV/AIDS, diarrhoeal diseases, encephalitis, and hepatitis, and malaria, tropical diseases like Leishmaniasis, Filariasis, Leprosy, and Dengue will be included. Pathogen virulence, disease progression and pathogenesis are governed by multiple factors that include the host genes, the genetic make up of the pathogen and immunological factors besides many others. Research into exploring the mechanisms used by the immune system to respond to bacterial, viral and parasitic diseases that will provide guiding principle for preventive, diagnostic and curative strategies should be encouraged. Research into host pathogen interactions should form a priority area within the infectious diseases research programme. For example, the interactions of HIV with host cells are an important issue as the course of the disease varies considerably among infected individuals. In this context, identification and elucidation of function of relevant host and pathogen genes are important. With the onset of AIDS, scenario for some other diseases has changed due to co-infections and increase in infection rates due to compromised immune status. In this scenario, co-infections of mycobacteria and HIV or HIV and *Leishmania* are a major problem. Studies on cells of the innate immune system that harbors the pathogens would be essential to provide clues to prevention of occurrence of such co-infections.
- ii. Identification of new lead molecules of potential therapeutic interest through a combination of approaches integrating traditional knowledge, recent advances and futuristic genomics-based predictions for infectious diseases would be an area of interest. The increasing emergence of drug resistance in pathogens is a relevant area of address. For this, research-encompassing basic mechanistic like how drug resistance is acquired and activated should be encouraged. One of the interesting areas under this is the design of novel inhibitors for decimating the pathogen. Many metabolic processes within the pathogens could possibly be inhibited by small-molecule inhibitors for which drugs are not available. Research into design of small molecule inhibitors and devising

- of means to increase the potency of these would form an area of interest. Development in the area of design of the inhibitors.
- iii. Vaccine development against viral, bacterial and parasitic diseases should be a priority area. Research initiative into the design, development, administration and efficacy studies in vaccines for a variety of diseases should be followed. Development of microbicides against HIV proteins relevant to HIV replication would be an important areas where research into developing bio-conjugates inhibiting replication proteins and assessment of their efficacy would be encouraged.
 - iv. Research to develop kits and reagents for diagnostic purposes should be supported for infections chikunguniya.
 - v. Developing systems for intracellular delivery of drugs or pharmacologically active agents selectively to specific cell types is an area which needs fortification in the context of infectious and other diseases and research in this area should be encouraged.
 - vi. Analysis of developmental cues that control the process of reproduction and development so as to provide clues for understanding genetic as well as environmental factors that lead to developmental defects in the systems.
 - vii. Autoimmune endocrine diseases, including those involving the thyroid (Graves' disease, Hashimoto's thyroiditis), insulin dependent diabetes mellitus (IDDM), and Addison's disease are among the most prevalent or common endocrine disorders. For autoimmune endocrine diseases considerable questions exist regarding the etiology, pathogenesis, and potential treatments directed at the autoimmune basis of these diseases. For IDDM, factors associated with autoimmune diseases including T-cell, and HLA markers have been implicated in disease initiation and progression. Putative role(s) played by various factors in eliciting and/or contributing to IDDM is not known. Clearly, a fuller understanding of the autoimmune basis of endocrine disorders is necessary to open the way for more effective immune (and other) system approaches to disease treatment and/or prevention. Research topics that should be considered relevant to this area would include the etiology, pathogenesis and treatment of endocrine diseases, including IDDM and autoimmune thyroid disease, the cellular and molecular basis of autoimmune endocrine diseases, the molecular basis for the increased prevalence of autoimmune endocrine diseases in women, the role of cytokines and growth factors in the etiology and/or path physiology of autoimmune endocrine diseases and potential therapeutic approaches to autoimmune endocrine diseases.
 - viii. Dissecting the specific molecular anatomy of a tumor is likely to be critical for the development of more specific, effective and safe treatments.

Research on understanding the cause and mechanisms of cancer, improving early detection and diagnosis, developing effective and efficient treatments should be addressed. Identifying and using specific targets for diagnosis and intervention would be critical.

- ix. Because of the potential of stem cells to alleviate many disease conditions, stem cell research would be an area of interest. Research on basic biology of mammalian stem cells, culture conditions for maximal growth and their potential to be used for disease treatments should be an encouraged.
- x. Research on molecular and cellular aspects of nervous system function in health and disease should be fostered. The research will illuminate the understanding of how nerve cells function and communicate in the brain, especially as they relate to the development of novel therapeutic approaches to neurodegenerative diseases.

Proposed New Institutes

Centre for Policy Research for Non Communicable Diseases

This Centre will target to systematically synthesize information relevant to comprehensive health care models and apply this knowledge in the Indian context. It would provide leadership in development and integration of policies and programs for prevention and control of non communicable diseases through partnership with relevant stakeholders at national level".

The Centre for Policy Research for Non Communicable Disease will use innovative processes to obtain authoritative, objective and scientifically balanced answers to unique problems in NCDs in India and translate this knowledge effectively into products of healthcare system so as to improve the health of Indians. The Centre would *inter alia* identify the NCD research needs of the country and obtain new knowledge, knowledge translation into products and action, supporting and developing measures for integrated surveillance of NCDs, developing a mechanism for incorporating NCD prevention in health care system, building research capacity manpower in the country establish centers for molecular medicine and creating partnership between medical institutes and universities.

National Centre for Cardiovascular Diseases, Diabetes and Stroke

This center will work out multi-pronged strategies to bring down the morbidity and mortality due the cardiovascular diseases, diabetes and stroke, thus making a significant dent in the emerging epidemic in the region. The Centre will support research efforts to promote new discoveries and enhance scientific progress through support of cutting edge basic and clinical

research related to cardiovascular diseases, diabetes and stroke, with a goal of rapidly translating research findings into novel strategies for prevention, treatment and cure of these diseases.

The Centre would among other objectives help to generate new knowledge by stimulating and sustaining interdisciplinary research for resolving complex issues in CVDs, diabetes and stroke, to undertake research activities which accelerate the translation of health research into action develop national clinical guidelines for prevention, management and control of CVDs, diabetes and stroke, create database of information on cardiovascular diseases, diabetes and stroke so as to act as national referral centre for these diseases. The Centre would be located at Chandigarh.

National Center for Disease Informatics and Research

This Centre would be set-up by upgrading the existing Coordinating Unit of the National Cancer Registry Programme at Bangalore. The proposed center besides working on collection and analysis of data on cancer would also work on establishment and running of registries related to diabetes, cardiovascular diseases and stroke. The data thus collected is expected to help in evaluation of control activities in the concerned areas. This would also provide a base for undertaking multi-disciplinary and multi-centric research projects. Surveillance programmes would also be supported by the activities of the Centre.

ICMR Schools of Public Health

For decision making in public health reliable data and information is often not available. Even if data and information is available, to use these effectively would require analytical skills which may not be readily available within the health system. There is an urgent need to enhance this very limited capacity in India for strengthening research and policy development in public health. To meet this demand trained human resources in the precept and practice of public health will have to be developed. The Government of India plans to raise public health specialists through establishing, initially two Schools of Public Health through the aegis of the Public Health Foundation of India. The ICMR plans to supplement this effort by setting up a chain of Schools of Public Health.

The National Institute of Epidemiology, Chennai would provide the core support to the regional institutions to be developed at National Institute of Cholera & Enteric Diseases, Kolkata, Post-Graduate Institute of Medical Education & Research, Chandigarh and the National Institute of Virology and

National AIDS Research Institute, Pune. These would offer specialized training facilities in partnership with other medical colleges and research institutes. Several international schools of public health have also agreed to partner in this effort (like School of Public Health, Boston, Swiss Institute of Tropical Diseases, Minnesota School of Public Health, and Aberdeen University).

National Animal Resource Facility for Biomedical Research

For combating the health challenges posed by persisting and emerging diseases, intervention tools like drugs and vaccine would be needed. It is essential that they are evaluated for their safety, efficacy and toxicity in animal studies. Such studies it is required by law to use animals of defined quality, of genetic and disease free status in order to obtain reliable and reproducible results. Currently there is neither a private centre nor any large breeding facility in the country which can supply quality animals. It is proposed to fill this gap by setting up National Animal Resource Facility for Biomedical Research at Genome Valley, Hyderabad. This would be a major central animal facilities for large, small, transgenic animals within the health systems. There is hence, a great demand of such animals and facilities in the country.

Institute for Research on Ageing

India will have a population of 137 million older persons in year 2020 as per estimates by the Registrar General of India (SRS-1991). The older persons face physical, psychological, social and economic difficulties due to various factors. They develop degenerative disorders such as those related to joint and cardio-vascular systems, suffer from mental health problems, visual and hearing impairments etc. This has direct implications for the health and social service sectors, which need to be augmented to take care of these health concerns as the population ages.

India has a National Policy on Older Persons, not though much headway has been made. Concentrated efforts have not been made to study the process of ageing, as well as the various health, psychological and other related issues. This needs institutional set-up with proper infrastructure.

Therefore, an Institute for Research on Ageing (IRA) is required to undertake multi-disciplinary studies. This multi-specialty centre should address to various research areas like epidemiology, morbidity profile, health care management, nutritional assessment, drug metabolism, molecular biology, neurobiology, socio-psychology and studies on health systems research

would be addressed. The Institute should encompass health, socio-behavioural, and rehabilitation areas.

Budget Requirement

The Working Group agrees with the observations of the ICMR's PAB that the funding for medical research in the country continues to be abysmal and is ridiculously low. India should be spending a great deal more on medical research if it hopes to even touch the fringes of medical problems which face the country. As prescribed in the National Health Policy, the Government must keep its commitment of increasing the funds for medical research to 1% of its health expenditure by 2005 and 2% by 2010.

Medical research is an interdisciplinary, multi-agency effort involving the government, academic institutions, and the private sector, and requiring progress in many diverse fields of science to succeed. Medical research competes annually with other worthy domestic spending priorities for its share of our national budget. Medical research is the responsibility of the national government, and one in which the government is uniquely positioned to take the lead. The health research is to a large extent funded by the Govt. of India through Ministry of health, the funding for health research depends on health budget, which itself is meager in the national budget. The current level of funding for health research is grossly inadequate. Ideally, spending on health research should be at least 2% of the total spending. Currently it is less than 1%. The ICMR has been able to increase its funding in last 4-5 years and utilized the same fruitfully. However, the funds available are about one third of the demand (allocation of Rs.970 crores as against requirement of Rs.25000 million for the 10th Plan period). The ICMR and its institutes have demonstrated ability to attract funds from the Government and other funding agencies both in India and abroad. In addition, the Council has demonstrated abilities to expend the allocated finances in a timely fashion reflective of good project management practices. However, the Council needs large infusions of funds to undertake large scale expansion and embark on mission mode projects.

The Working Group reviewed carefully the budget submitted for the 11th Plan by the Council and other agencies along with their proposed strategies of action. The Group endorsed the plan of action of the Council and departments and recommended that their budget provisions are appropriate for the activities that are envisaged.

ICMR

Total Budget Required	Rs. in crores
Intramural	3504
Extramural	1496
ICMR Hqrs	
TOTAL	5000

New Posts Required	Numbers
Scientific	500
Technical	0
Administrative	0
TOTAL	500

The Working Group approved the new activities suggested by the ICMR for the 11th Plan period.

In addition, special and ear-marked funds should be made available for:

- i. addressing neglected diseases and disorders; and
- ii. health systems to interact with industry to develop products that the health systems need.

The budgets of CSIR, DST and DBT have presented to the appropriate controlling authorities by the respective agencies.

Product Development & Evaluation

Terms of Reference

- To review the current situation regarding development, testing and quality control of drugs and devices, both in the modern system of medicine and AYUSH and suggest priority areas for research and institutional strengthening during the 11th Plan period.

Introduction

With the introduction of product patent laws in India, there is a compelling need for investing in indigenous research and quality control for drugs, medical devices and vaccines relevant to the needs of India's poor. The development of new drugs from the knowledge and information possessed by a community must ensure that part of the financial benefits from the use of these drugs flows back to the community that initially owned the knowledge. The NCMH has recommended that an R&D policy needs to be formulated for assuring drug, medical technology and vaccine security and investing funds for upgrading public sector research institutions at Kasauli, Conoor and research institutions of the ICMR, DST, CSIR, DRDO, DBT, Universities etc.

Besides stepping up health systems research, there is also an equal urgency to establish regulations, strict ethical norms and transparency, standardize methodology and international standards of research for tapping the global market for clinical research. India has the possibility of becoming the international hub of clinical trials. With its quantum of well-trained physicians, pharmacologists and clinical pharmacologists, the availability of a large untreated naïve population providing numbers, the relatively low cost of conducting trials, and the recent patent regulations. India has a huge comparative advantage that gives it an opportunity to be at the forefront of drug discovery, besides earning valuable foreign exchange and providing employment to many.

Among the limitations plaguing new drug discovery are lack of GMP compliant facilities, few centres for undertaking pharmacokinetic studies and poor quality study of animals. An area in which India could make significant contribution is drugs for chronic diseases. Significant knowledge is available on traditional systems of medicine. This could be taken as a mission-project.

The research has to be innovative which can only be done by encouraging basic research in cutting edge areas. Good quality clinical trials are not

being undertaken. This is so primarily because of lack of trained personnel. Training courses in clinical epidemiology, clinical pharmacology, GCP, GLP, Quality control, toxicology, pharmacokinetics etc. would need to be expanded. Simultaneously a mechanism of accreditation of clinical trial centres should be put in place. The action of drugs at molecular levels would have to be studied along with pharmacokinetic studies (using biomarkers). Monitoring quality of these drugs would also be an important aspect which needs to be addressed.

During the 10th Plan period, the Government had set up various Committees to address several of the issues listed in this Term of Reference. The Group reviewed these Reports and recommendations made therein. The members supported these recommendations and hoped that they would be soon implemented.

The Central Drugs Standard Control Organization (CDSCO), under Drugs Controller General (India), DGHS, Ministry of Health is responsible for ensuring the safety, efficacy and quality of drugs and therapeutics as per the provision under Drugs & Cosmetics Act, 1940 and Rules 1945. The regulatory requirements pertaining to safety efficacy and quality is currently effectively implemented through:

- The State and Central Drug Regulatory Authorities
- States and the Central Drug Testing Laboratories with infrastructure and facilities to ensure speedy analysis of drug samples.
- Good Manufacturing Practices (GMP) mandatory for all pharmaceuticals production houses.
- Stringent quality regulatory process for import of drugs Le Import Registration process.
- Publication of Essential Medicine List.
- National Pharmacovigilance Programme to ensure self sustaining and viable adverse drug reaction monitoring programme.
- Regulation in respect of licensing of import as well as manufacture of 10 sterile medical devices in place since October 2005. Subsequently, guidelines have been issued for import and manufacture of medical devices.
- At present, there is an indirect control like licensing for the products exclusively for export giving for NOC for the export drugs to regularize the same in addition to manufacture, sale and distribution in India.

Regulation of Drugs and Pharmaceuticals

There has been a wide-ranging national concern about spurious/counterfeit/substandard drugs. The Drugs and Cosmetics Act has not been reviewed in a comprehensive manner since its inception although the Rules have been amended from time to time. The Report of the Expert Committee under the chairmanship of Dr. R.A. Mashelkar on a comprehensive examination of drug regulatory issues, including the problem of spurious drugs has submitted its report in November 2003.

The Committee concluded that the problems in the regulatory system in the country were primarily due to inadequate or weak drug control infrastructure at the State and Central level, inadequate testing facilities, shortage of drug inspectors, non-uniformity of enforcement, lack of specially trained cadres for specific regulatory areas, non-existence of data bank and non-availability of accurate information.

The report of the Committee deals comprehensively with the issue of implementation of all the rules and regulations, which guide, monitor and control the activities of the providers of the healthcare system in the country and the way to bring them up to international standards. It provides the design of Central Drug Administration (CDA), its size, functions and the sharing of the responsibilities vis-à-vis the States including directions for licensing of manufacturing units by a central authority. It also deals with the regulatory health food/dietary supplements/therapeutic foods, Indian system of medicines and herbal products, over the counter drugs, medicines & diagnostics. It addresses the issue of drug development and clinical research in India with special reference to the drug regulatory agency including modern biotechnology.

Major recommendation of Mashelkar Committee include:

- Create a well equipped and professionally managed CDSCO, which could be given the status of Central Drug Administration (CDA) and strengthen the State level regulatory apparatus with complementary roles of the Centre and the States, while at the same time ensuring uniform and effective implementation,
- A scientifically and statistically valid methodology should be used to evaluate and quantify the extent of the problem of spurious drugs at various levels in the supply chain at the Regional and National levels.

- The Drugs and Cosmetics Act should be suitably amended and the maximum penalty for sale and manufacture of spurious drugs causing grievous hurt or death should be enhanced from life imprisonment to death.

During the 11th Plan, it is proposed to establish a Central Drug Authority of India as per recommendations of the Mashelkar Committee.

Regulation of Recombinant Pharmaceuticals

A Task Force on Recombinant Pharma, was appointed by Ministry of Environmental & Forestry in 2004 to suggest a new regulatory framework for recombinant pharma products. Headed by Dr R A Mashelkar, Director-General, Council of Scientific and Industrial Research (CSIR), the Task Force has submitted its report.

The Task Force has laid down the Procedure for Regulation of Recombinant Pharma Products derived from Living Modified Organisms (LMOs). Taking into consideration the regulatory objective of GEAC, which, is confined to regulation of LMOs, two protocols have been recommended: (i) products derived from LMOs but the end product is not a LMO and (ii) product derived from LMO where the end product is a LMO.

- Where the end product is a LMO (which has the potential for propagating/replicating in the environment), a higher level of regulation is needed as compared to end products which are not LMO.
- The magnitude and probability of environmental risk depends on the extent of use of LMOs within the R&D and production units. In case of imports of finished products. The risk is not there, especially in cases of therapeutic proteins in finished form.

The Task Force has also recommended that the regulatory procedure need to be rationalized for the various scenarios regarding LMOs and other linked issues. It has proposed establishing of an Independent Institutional Mechanism National Biotechnology Regulatory Authority/ Commission. This is a complex issue and it has been recommended that an inter-ministerial group be established to examine the model proposed by Secretary DBT among various others administrative Departments/ Ministries, for functioning of the proposed authority and make specific proposals with respect to the implementation including the budgetary requirements.

AYUSH Formulations

AYUSH systems are based on experience and interaction with nature and natural resources. Scientific evidence to prove the rationale of using these formulations in health care is essential not only to develop and preserve the cultural heritage but also to make them acceptable at large.

Even though Research Councils under the Deptt. of AYUSH have undertaken clinical and health care research programmes, the multi institutional support with AYUSH based approach in research at other centres was evidently lacking. Active participation of AYUSH in service oriented surveys, surveillance programme, and community health care research programme is yet to be achieved in R&D sector.

Though a number of pre-clinical and clinical studies are carried out on medicinal plants used in ISM including isolation and purification of active principles, scientific evaluation of Ayurvedic therapies and medicines based on Ayurvedic pharmacological principles and clinical parameters deserves to be carried out. The scientific evaluation of Ayurvedic drugs through placebo controlled clinical trials have to be reviewed for its appropriateness in Ayurvedic system. The comparison should be done with standard care available in modern medicine. It is, therefore, proposed to re-analyze the clinical drug trial data base incorporating Ayurvedic parameters and evaluate the hypothesis for Ayurveda driven drug studies for proving their 'equivalent efficacy and comparative safety'.

In the research front multiple agencies like CCRAS, CCRUM, CCRYN, CCRH, ICMR, S&T, CSIR and its units, various University Departments, AYUSH teaching institutions etc. are attempting to solve the same problems and creating same kind of data over the years. Such duplication should be avoided. There should be a well co-ordinated programme for execution at different institutions in accordance with their mandate. Similarly, the documentation and validation of traditional therapies being practiced in various parts of the country is required to be taken up on priority. It is desirable that ICMR in collaboration with AYUSH research councils should take up R&D on ASU drugs that could be included in the National Disease Control and health programmes

Quality Control Regulation of Drugs in AYUSH

One of the priority tasks of the Department of AYUSH is to publish pharmacopoeial standards for Ayurveda, Siddha and Unani and Homoeopathy (ASU&H) medicines both for single and compound drugs. Pharmacopoeial standards are important and are mandatory for the

implementations of the drug testing provisions under the Drugs and Cosmetics Act, 1940 and Rules there under. These standards are also essential to check samples of drugs available in the market for their safety and efficacy. The Department of AYUSH launched a Central Scheme to develop Standard Operating Procedure of manufacturing processes, to develop pharmacopoeial standards and shelf life studies of Ayurveda, Siddha & Unani Compound drugs under 10th Five Year Plan and achieved significant results, but still lots of work have to be done in the field of standardization and quality control. For this strengthening / upgrading of various drugs testing laboratories (Government /autonomous / states/other accredited laboratories), ensuring of availability of genuine raw materials of commonly available drugs as well as rare and endangered drugs of plants/animals/minerals origin, substitutes of similar species have to taken up in the 11th Plan to handle the task of drugs quality control. New area relating to drugs e.g. strengthening of Drugs Control department of States and Central, Developing Herb garden/Museum/herbarium are essential requirement for quality medicines.

It is necessary to develop the Quality Standards along with their Safety Profile for the extracts of the most common drugs used in ASU system. It is also necessary to develop pharmacopoeial and quality standards for Indian medicinal plants used for the purpose of food and cosmetics and official substitutes of non-available drugs/ plants/animals. This work should be give priority in the 11th Plan.

Other priorities for the 11th Plan are :

- i) To publish SOPs and Quality standards, shelf life monographs for at least 100 compound formulations per year to complete the work on 500 ASU drugs.
- ii) Revise and update the various volumes of pharmacopoeias and Formularies.
- iii) Capacity Building : The new GMP provisions require regular testing during the process of manufacturing as well as for the products. Therefore, there is a need of developing and supporting large number of DTLs for ASU&H systems.
- iv) Centre for Safety Evaluation/Toxicity studies for AYUSH Drugs: However, there is a felt need to establish the safety of various single drugs as well as formulations containing poisonous ingredients in various dosage forms.
- v) National Herbarium, Museum, Herbal Garden for ASU Drugs: There is a need to establish/strengthen a couple of medicinal plant garden

containing all the medicine plant species used in ASU&H system. These gardens will act as Demonstration Garden as well as source of authentic raw drug samples.

- vi) Training and provisions of Scholarships/Fellowship in ASU&H Pharmaceuticals, Quality Control and standardization : Degree, Post Graduate and Post Doctorate training is required in ASU&H drug sector.
- vii) There is lot of scope and urgent need to work on different aspects of preparation, standardization, safety, efficacy, doses forms and pharmacology of metal based Bhasmas and Ras Aushadhis.
- viii) ASU drug industry is a green industry, cause minimum pollution, make use of all indigenous material and giving job opportunities for needy people.
- ix) Support the R&D based production of classical and P&P drugs, there is a need to allocate ASU&H "Pharma Industries Support Corpus" fund of Rs.100 crores to meet the bank interest (amount of interest difference between the bank rate and soft loan rate of interest) which will be recoverable in 10 year period. Similar scheme was implemented by DST earlier.
- x) Scheme to supply authentic raw material for ASU&H Drug industry
- xi) Strengthening of Drug Control Division in Centre and States : There is utter lack of infrastructure, human resource expertise and other requirements to regulate the provision of Drug & Cosmetics Act at Centre and State. The AYUSH component has negligible visibility in terms of Drug Controller, Drug Inspectors, Drug Analysts and other manpower required to regulate the provision of Drugs and Cosmetics Act. There is an urgent need to strengthen Centre and State Licensing and Regulatory Authorities. There is a need for comprehensive review of regulatory provisions of AYUSH products. To begin with, regulatory changes can be started by implementing a system of registration on AYUSH products on the basis of proper product dossier with State licensing authority on the basis of proper guidelines developed by the Central Government. There is an urgent need to support technical experts in Drug Control section of AYUSH along with supporting staff.
- xii) Repository for plants used in Traditional Medicine: A national well stocked repository of drugs from the traditional medicine source in order to house crude drug samples of authenticated parts of the plants, used as medicine is highly essential. This referral facility could be accessible to pharmaceutical industry, traders, medicinal practitioners, natural product chemists, students and academics. This may provides an accessible repository of quick overviews of particular herbs and pointers for further research , describes methods for studying specific activities of plants in vitro and in animal models as well as in humans,

includes regional reviews from an international group of contributors , allows to compare and contrast information specific to geographical areas and between geographical areas and also may contains an up-to-date summary of available knowledge on plants tested for specific disease activity. The increasing prevalence of various metabolic disorders world-wide is an issue of major socio-economic concern. Scientific interest in plant-derived medicine is steadily rising, yet there is often a wide disparity in the caliber of information available. A detailed compilation of scientific information on traditional medicines plants may highlight the potential role of dietary and medicinal plant materials in the prevention, treatment, and control of various diseases and its complications.

Regulation of Food Including Nutrition Supplements

There is increasing evidence that many food based materials have potential health or medicinal benefits. Such products fall into a grey area between foods and medicines and have been described as “functional foods” or “nutraceuticals”. It needs to be verified whether these so-called “health foods” really are safe for human consumption and offer the purported health benefits.

Some nutraceuticals are already in the U.S. supermarkets – eggs with fish-derived fatty acids to lower the risk of heart disease orange juice fortified with calcium to fight osteoporosis, herbal teas with anti-oxidants that may lower cancer risks : and margarine laced with a wood pulp ingredient that lowers cholesterol by 10%.

Several products are in the pipelines, Investigators are now busy using a combination of traditional plant breeding, genetic engineering, and just plain chemistry to produce foods enhanced with compounds they hope will lower the risk of many diseases. Those focusing on cancer are looking at compounds such as lycopene in tomatoes, beta carotene in carrots glucosinolates in broccoli, and isoflavones in soy. Soy protein extracts, sweeter carrots with greater concentrations of beta carotene and higher lycopene containing tomatoes, besides mushrooms, garlic are potential candidates for this food based medicine approach.

A major challenge for those involved in the research and development of functional foods is the scientific validation and substantiation of a claim in the eyes of the law. It is already clear that in some areas, manufacturers will need better clinical evidence of the overall relationship between diet and

disease, and they may need to carry out specific clinical trials on their products. The issue of substantiation of claim covers not only the safety and efficacy of the food component(s) themselves, but also the finished food as it would be used by people. In future, nutritional assessments of novel foods will need to be carried out against a background of rapidly advancing knowledge on the role of diet in the causation and prevention of many diseases, from classical nutrient deficiencies to illnesses that are major causes of morbidity and mortality, such as coronary heart disease and some types of cancer. For parts of the food industry, this is a move toward greater use of biomedical sciences, more akin to the pharmaceutical industries.

The evidence and commercial criteria for a growing inter-face between the two industries are under constant review. Whatever happens in the commercial environment the use of specific nutrients and ingredients or combinations thereof that are claimed or perceived to be beneficial to health will stimulate the reformulation and repositioning of existing products as well as product and process innovation. Key areas of interest include antioxidant substances (e.g. beta-carotene, vitamins C and E), minerals (e.g. calcium, magnesium, zinc, selenium), phytochemicals (e.g. flavonoids), probiotics (e.g. bifidus and lactobacillus), fatty acids and lipids (e.g. fish oils), and a range of macromolecules (e.g. dietary fibers and oligosaccharides).

The Indian Food Safety and Standards Bill 2005, introduced recently is aimed to consolidate the laws relating to food and to establish the Food Safety and Standards Authority of India for laying down science based standards for articles of food and to regulate their manufacture, storage, distribution, sale and import, to ensure availability of safe and wholesome food for human consumption and for matters connected therewith. The new rule is expected to boost the level of science behind products, as it will define the scope of acceptable health and nutrition claims. Such claims will need to be based on clinical trials, protocols, or scientific studies conducted as part of their R&D and product development. All of these need strengthened during 11th Plan.

Regulation of Genetically Modified Foods

Current issues are:

- Whether testing of GM foods is necessary as regulatory exercise once, the product has been cleared for use (from the point of view of food safety) and labelling provisions are in place to advise the consumers.

- If testing is necessary then the nature of the protocols to be developed for testing both imported and domestically produced foods.
- Whether capacity needs to be built up in, Central Food Laboratories (CFLs) or specialized laboratories need to be identified where capacity is being developed and there can be networking of these laboratories, given the large resources needed.
- The development of protocols for risk assessment and generating data under the existing regulatory framework, to facilitate the manufacturers/importers to easily comply with regulatory requirements without delay or duplication of efforts
- To address the labelling concerns at the earliest and identification of an institution under concerned Ministry which could be resource centre for collection and documentation of information on GM foods.

Currently, there is no appropriate regulatory mechanism for monitoring marketed imported GM Foods and also for sale of GM Food produced in the country. The Ministry of Health and Family Welfare is responsible for making regulations for sale of safe foods including GM Foods under PFA Rules 1955. Thus, there is a need to incorporate regulatory provisions for GM Foods:

- Labelling of GM food, may however be one of the practical option for regulating post-marketing of GM Foods on one hand and on the other it would provide information to consumers who have the right to choose whether or not to consume GM food based on the information provided on the label.
- Keeping in view the current scenario, it may not be feasible to decide on the threshold level of GM foods, therefore, the Ministry of Health should consider incorporating the labeling provisions under the PFA Rules.

Based on these recommendations, notifications on labeling of GM Foods were issued in May 2006.

Regulation of Biologics

The term "*Biologics*" generally refers to any biological product that can only be made using a living system or organism, usually DNA, proteins, bacteria or other microorganisms. *Biologics* are inherently different from chemical drugs, which are synthesized from raw chemicals using more predictable and replicable processes. Since the production of *Biologics* occurs in a living cell, the process is subject to considerable variability. The 21st century heralds the "biotech revolution" where biologic medicinals promise cures for

some of the most complex diseases. Currently, over 370 innovative biologic products are being tested, targeting more than 200 diseases, including cancers, neurological disorders, heart disease, diabetes, multiple sclerosis, AIDS and arthritis. The biopharmaceutical industry represents one of the fastest growing segments of U.S. healthcare. The *regulation* of follow-on *Biologics* is a rising concern for the biotech industry since many *Biologics* are approaching the end of their patent life, and as a result, will open the market for more affordable generics. Due to the complex processes that are used to produce *Biologics*, creating an exact copy of the original, pioneer biologic is often very difficult. The many sources of variability in the process, from bio-environmental factors such as gene splicing and culture media to physical factors such as temperature and chemical make-up of petri dishes, can lead to variability in the product as well. Biotechnology is used when the desired drug product is a large molecule that is difficult to produce through chemical synthesis. Because of simpler, more straightforward processes used in the production of chemical drugs, exact copies of the original drugs can be produced and marketed as "generics". Brand manufacturers argue that science is not capable of detecting changes in protein structure between the brand biologic and the generic. Furthermore, the brand industry contends that biologics are impossible for generics manufacturers to successfully reverse-engineer without the proprietary good manufacturing practice (GMP) and good laboratory practice (GLP) protocols of the innovator company. The policy issues surrounding the approval of *Biologics* must consider the need to balance the rights of innovator companies with the economic needs of healthcare consumers, while ensuring high quality healthcare. Promoting innovation requires the right combination of incentives, safeguards, and effective regulation to secure maximum benefit from new medical technologies, while assuring mechanisms for equitable access to the treatments.

With the recent developments in clinical research and business process outsourcing it is proposed to develop strategies to regulate the import and export of biological material at this juncture for the social benefit and economic development of our country.

Biobanks

Human tissue is critical for new areas of research that promise to revolutionize medicine like *genomics* and *proteomics*. The samples are important for various types of studies like population genetics, human diversity studies, and even in forensic medicine. The samples reveal the types of genetic changes or protein "signatures" associated with a particular disease and experiments on human tissue are there is enough scope for the findings to be translated into new diagnostic and prognostic tests. Human

tissue has its greatest potential benefit when there is associated clinical data for analysis because genomic and proteomic research may then reveal associations between genetic or protein patterns and response to therapy, or toxicity. Biobank sample collections are used for various purposes, namely for clinical, research, and industrial uses. Council has already prepared a draft guideline on ethical, legal and social issues for National repository of genetic resources and database in the year 2006.

Regulation of Stem Cell Research

The stem cell research holds great promise of improving human health by control of degenerative diseases and restoration of damage to organs by various injuries; but at the same time it also raises several ethical and social issues such as destruction of human embryos to create human embryonic stem (hES) cell lines, potential for introducing commoditization in human tissues and organs with inherent barriers of access to socio-economically deprived and possible use of technology for germ-line engineering and reproductive cloning. The research in this field, therefore, needs to be regulated to strike a balance. The Council has prepared draft *Guidelines for Stem Cell Research and Therapy in collaboration with DBT*. These guidelines emphasize a separate mechanism of Review and Monitoring is proposed for Research and Therapy in the field of human stem cells, one at the National level called as *National Apex Committee for Stem Cell Research and Therapy (NAC-SCRT)* and the other at the institutional level called *Institutional Committee for Stem Cell Research and Therapy (IC-SCRT)*. These guidelines will be debated in different parts of the country before finalization.

Regulation of Devices

India has stunting growth of medical devices industry due to inadequate regulation. Only low technology devices (thermometers, weighing machines etc) are being made because these do not require a pre market certification, and optional QC is provided by agencies like Bureau of Indian Standards. The Drugs and Cosmetics Act was not covering the critical medical devices(pace makers, implants, internal catheters or other critical in vitro testing devices) resulting in near zero indigenous production. Absence of such a regulatory body has resulted in India becoming dumping ground of outdated or third rate western devices which have actually been discarded in the west due to information about their harmful effects. That information is withheld from Indian users who have no other way of knowing the harmful effects because of lack of a regulatory and surveillance body. Formation of such a governing body having regulatory and surveillance responsibility pertaining to the medical devices is, therefore, very essential.

The wide range and huge number of medical devices that are being constantly introduced in comparison to the few drugs every year make the traditional pre market approval approach impossible to implement. As devices are based on a number of advanced technologies having a great diversity in mechanism of their action, they can also fail because of a myriad of mechanical faults, electrical component failure, or biocompatibility problems. An implantable device may fail after many years of its use at an unpredictable time period. Hence, besides product regulation, its correct use must also be ensured to assure safety of device.

There is no doubt about this out country definitely needs a system to ensure that our public is not exposed to poor quality products, especially in this rapidly growing market segment. Also, the advantages of having a device regulation to the various segments of the developmental chain – the R&D groups, the manufacturer, the clinicians and finally the patients have to be clearly elucidated. This medical device regulation will be advantageous to one and all, provided that it is well implemented and administered like in Europe and other developed countries

Recently, the Ministry of Health and FW under Gazette notification S.O. 1468 (E) dated 6.10.05 declared the following sterile devices to be considered as drugs under Section 3 (b) (iv) of the Act : Cardiac stents; Drug Eluting Stents; Catheters; Intra Ocular Lenses; I.V. Cannulae; Bone Cements; Heart Valves; Scalp Vein set; Orthopedic Implants; Internal Prosthetic replacements;

These guidelines have become effective from 1st March 2006. These cover purpose, procedures for Import of Medical Devices, Registration of Medical Devices for Import, Manufacture of Medical Devices in the country and sale of Medical devices in the country

Ethical Issues in Animal Experimentation

The Ministry of Environment and Forests has notified the Breeding of and Experiments on Animals (Control and Supervision) Amendment Rules, 2005 in Jan 2006 in continuation of the Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998 and its amendment in 2001. This amendment emphasizes :

- i) personnel using experimental animals shall be responsible for the welfare of animal during their use in experiments;

- ii) investigators shall be responsible for the aftercare and rehabilitation of animal after experimentation, and shall not euthanise animals except in defined situation;
- iii) costs of aftercare and rehabilitation of animal after experimentation shall be made part of research costs and shall be scaled in positive correlation with the level of costs involved in such aftercare and rehabilitation of the animals;
- iv) rehabilitation treatment of animals after experimentation shall extend till the point the animal is able to resume a normal existence by providing a lump-sum amount as costs for rehabilitation and care of such animal to cover its entire statistical expected life span; and
- v) the establishment undertaking experiments or duly licensed and authorised animal welfare organization under the control of the Committee may, on payment of lump-sum amount, undertake rehabilitation of animals.

These draft rules if approved will result in extra costing of the research projects aiming at New Drug Developments for which provisions have to be made by all the funding agencies. There is also need for establishing Centres which can develop alternatives to animal experimentation.

Ethical Issues in Drug Development Involving Human Subjects

The Ethical Guidelines For Biomedical Research On Human Subjects, released by ICMR in 2000 have been drafted for Legislation and were forwarded to the Ministry of Health and Family Welfare, and Ministry of Law and suggestions have been incorporated. The Bill entitled "*The Biomedical Research on Human Subjects (Promotion and Regulation) Bill, 2006*" is now ready to be placed before the Parliament for notification.

There is a need at the present time for a strong centralized regulatory regime which can guide high quality development of ethical capacity with extra vigilance with an informed understanding of acceptable risk.

Clinical Trial Registry

A number of clinical trials are carried out for which results are not published either because the company decides not to market its product, or because the results are negative or neutral or because the trial was terminated. Information about a drug that does not demonstrate efficacy in a controlled trial or that demonstrates significant hazards that are important for making health care decisions. Failure to publish results of such studies could compromise patient safety. To ensure that systematic reviews are unbiased,

the need for an international trial register of all controlled clinical trials has been highlighted in many scientific fora.

Recognizing the importance of a clinical trial registry, the ICMR is piloting the establishment of a Clinical Trial Register that is web based and designed to be compatible with international clinical trial registry. Once established, a full fledged National Clinical Trial Registry should be established during the Eleventh Plan period.

Research and Development

The India Pharmaceutical industry in the last six decades has grown substantially and has the capabilities to manufacture APIs through different technology like Chemistry, Biotechnology, Biology and also has developed technologies to manufacture various doses forms like parenterals, oral, aerosols etc. This also includes capacity to manufacture immunobiologicals like vaccines for prophylactic and therapeutic use in human and animals. Industry's focus is on Chemistry based, R & D and in the last decades substantial effort are being made for their presence in drug discovery research.

Potential growth in Pharma Sector

Process development still will be a focus area for growth and research in APIs. India has been recognized as a single source for carrying out research in existing molecules as well as molecules under patent. This has huge potentials to encase the opportunity in the 11th Plan. Another important emerging area is to prepare dossiers for submission of R & D application concerning the approval of generic drugs in USA, EU, Japan etc. India has a huge potential of highly qualified post graduates in pharmaceutical chemistry, analytical chemistry, instrumentation etc. This needs support from Government during the 11th Plan to capture the growth opportunities

Pharmaceutical Formulations

In the field of biotechnology, there is a need to focus on the Research & Development, of all cell lines for existing as well as newer vaccine for self-sufficiency. In this area, already a lot of work has been done at the International level for developing therapeutic drug and biotech products for treatment of Cancer, Infectious disease, Heart diseases, inflammatory disorder, allergies etc. India has become a choice for research and clinical trials as the country has all the requirements for carrying out the same. The government should explore the possibilities to support the R & D work that can help local CROs and attract the global pharmaceutical industry. Also

potential scope to create R & D facilities for producing drug products for clinical trials.

Human Resource Development

There is a need to produce highly qualified Doctors/Scientist in this field of science to meet the growing demand in R & D. Institutes of excellence which can liaison with the industry and government must be developed. Focus should also be on continuation of education through training programmes by a well defined training module and also infrastructure.

Indian pharmaceutical companies have been competing for their share in global generic market by creating state of the art manufacturing facilities. It is therefore, imperative to capture the opportunities in contract manufacturing by building large number of units with global standard this would encourage the local industry to manufacture the product as per cGMP norms in order to boost export of their products. This would also generate employment opportunities of technically skilled and unskilled personnel.

In order to meet the global standards, R & D efforts needs to be focused on the various ancillary requirements i.e. primary packaging material, automation in equipments.

Integration of information technology in the field of Pharma and Biotech industry, self-sufficiency in manufacturing of analytical and other ancillary equipments for manufacturing of quality drugs is also an important requirement of the industry.

Intellectual Property Rights (IPR) and Technology Transfer

Closely linked to development of drugs, diagnostics, devices and vaccines are issues of IPR and technology transfer.

Improving public health is one of the most effective means to reduce poverty in developing countries and access to safe, effective and affordable drugs and vaccines is essential to achieving improved health. This has been demonstrated in the battle against such illnesses as tuberculosis, AIDS, malaria and life-threatening diarrhea etc.. Programmes addressing reproductive health and non-communicable diseases also are dependent on modern drugs, too. There is a widening gulf between developed and developing countries with respect to access to advanced health technologies. Primarily either due to inability of developing countries to

generate enough intellectual property for the development of new drugs or there is just not enough money even to buy the generic drugs available. Also, not many pharma companies are willing to invest on R&D on drugs afflicting the poor countries and it is for us to address these issues. There are several strategies being adapted to address this issues both at the global and at the national levels through several mechanisms and public-private partnerships etc.

Besides sufficient and sustained support for research and development (R&D) for the creation of candidate products for the poor, there is also a need to establish policies and systems for improved management of IP to help bring candidate products for the poor to reality, especially since the public sector's experience with handling IP is limited. There is enough evidence to show that better management of IP can be quite powerful in enhancing product development and availability for the poor.

IP is a complex subject which vary by product type, by country, by proposed partner, by the nature of the further development work needed, *etc.* But the following are a few high-priority, highly feasible and complementary tasks.

- Training scientists and officials at universities and research institutes to manage IP.
- Identification and implementation of best practices of IP management to help public sector develop new IP management norms.
- Advising developing and developed country groups concerned with research and product development.
- Promoting coordination and synergy in public sector product R&D through partnerships with the private sector.
- Research on the quantitative relationship between IP and health product availability and cost.
- Collaborate with other countries and other stake holders on issues of TRIPS and other international treaties to facilitate formulation of national policies and strategies for India and other developing countries.

New initiatives

- Centre for Clinical Research including clinical trials research: A Clinical Trial Centre is needed to provide leadership in this field. It should be a facility for human resource development using internationally recognized curriculum related to clinical trials, management of data, designing clinical data base, quality control and assurance. The Centre should help to train clinicians in the concept of scientific and evidence

based medicine. It could also undertake large single or multi centre clinical trial and take part in national and international collaborative trial group and contribute expertise to trials run by others. It could offer advice on trial design or operation, randomize patients or analyze data for groups wanting to run their own trials. The Centre should be committed to promoting the quality and efficiency of clinical trials through ethical considerations, scientific expertise, quality assurance and education.

- Centres for carrying out pharmacokinetic studies in India.
- Toxicology Centre for carrying out regulatory toxicity studies on *Lead* compounds.

Terms of Reference

- To review current status of inter-agency, inter-ministry collaboration in priority areas of research and to suggest mechanism of improvement during the 11th Plan period.
- To review the situation regarding research agencies addressing priority areas of research identified by service providers and implementation of major suggestions emerging from research studies and to suggest mechanism for improvement of these during 11th Plan period.

Present status

The Committee reviewed the existing mechanisms and strategies in each of major organizations.

The ICMR has an elaborate peer review system to oversee its research activities. Its Scientific Advisory Board (the highest technical body of the ICMR) includes eminent scientists from different disciplines and Agency/Departmental representatives from DGHS, DBT and DGAFMS. Each Technical Division has its Scientific Advisory Group. Each of the 26 ICMR Institutes has its Scientific Advisory Committee, on which the Programme Managers of Central/State Health Department / Directorates, Representatives of other ICMR Institutes, and non-ICMR scientists are involved. These are intended to provide the ICMR with the directions for research to be pursued without unnecessary duplication, in clearly identified priority areas. Likewise, ICMR is represented in the Scientific Committees of other agencies such as DST, DBT, DSIR, CSIR, Research Councils of CSIR Institutes working in areas related to biomedicine, DGHS, State Councils for S&T, NIHFWS etc. The ICMR has been using the following strategies for better utilization of the results of research:

- Involvement of officials of MOH&W, DGHS, National Programme Advisors from the planning stage till the final review meeting.
- Involvement of officials of Government of India in the high-level policy making committees like the SAC/SAG/SAB of ICMR.
- Dissemination of research results to all concerned in MOH&W and DGHS.
- Holding workshops, symposia, and conferences for dissemination of research results.

- Participation of ICMR officials in the meetings of Health Ministry and DHGS in order to focus its research on the problems and priorities and help the national policies and programmes.

At present, inter-scientific-agency dialogue exists, sometimes on formal basis but mostly on informal basis. For example, ICMR has linkages with the CSIR laboratories and DBT is increasingly trying to forge collaboration with ICMR for efficacy evaluation of products developed by the investigations through the support of DBT, in human subjects. Thus, it was noted a mechanism at informal level exists, through which exchange of information between agencies occurs. However, it was felt that the persons who participate in inter Agency / Institution meetings may very often give personal views and not institutional 'considered opinions'. This result in a lack of true representation in each other's Committees, and the inputs provided by them do not really reflect the Agency's perspective. Therefore such informal 'collaboration' leaves much to be desired, in terms of policy directions, identification of research priorities and ensuring the avoidance of duplication of health.

New Initiatives taken in the 10th Plan

Ministry of Health

A Joint Monitoring Group has been set up under the Chairmanship of DGHS to monitor situation of avian flu in the country. This Group meets every fortnight, but in case of an outbreak meets daily. The members of the group include representatives for Animal Husbandry, the NICD, ICMR and WHO country office.

A high level Task Force chaired by Secretary (Health) also meets on avian flu every fortnight. It includes representatives of Department of Animal Husbandry also.

CSIR

The Department of AYUSH, CSIR and ICMR have entered into the Golden Triangle collaboration for research on traditional systems of treatment. The Bhasmas and Rasayanas would be systematically and scientifically studied for their role in management of identified conditions like joint disorders, bronchial allergy, fertility and infertility, cardiac disorders, irritable formal syndrome, diabetes, malaria, filarial and kala azar. The CSIR would the QC and predinical studies which the ICMR would assist in clinical evaluation.

DBT

The DBT and ICMR have signed a Memorandum of Understanding to work together on areas of mutual concern. HIV/AIDS and Microbides are examples of two areas where a 'call for proposals' for joint funding has been issued. A Centre for Translational Research is coming up.

Recommendations

Realizing the importance of sociological studies, it is recommended that the ICMR-ICSSR (Indian Council for Social Sciences Research) Joint-Panel be revived. Links with other Institutes like the Indian Institute for Philosophical Research should be established.

It is important to understand the varied type of social phenomenon in medicine, if the health care services are to function better. For example, study the different attitudes and values which various segments of population have towards health, illness, and medical care, social organization of health personnel; social structure and functioning of hospitals; social rates played by patients and health personnel as they interact in different settings; social processes through which health personnel acquire the outlook, standards, and competence for providing satisfactory professional service; social and psychological factors concerning different kinds of disease; studies are also needed on medical students, nurses and doctors; what medical personnel expect of patients, and on types of behaviours that patients expect of medical personnel.

As suggested by PAB of ICMR an overarching National Health Research Management Forum should be put in place wherein all existing and the prospective players in health research will have a space of their own. In this representation of all key stakeholders will be ensured. The ICMR would act as its Secretariat, and would have the following functions:

- To advise on and evolve national health research policies and priorities and to evolve mechanisms and action plans for their implementation;
- To review the output from the National Health research System annually and provide suggestions;
- To promote the development of health research activities in the country;
- To review biomedical & health research management, and suggest strategies to overcome problems in implementation of policies;

- To suggest mechanisms to nurture a scientific environment to attract talent, and to develop human resources for biomedical and health research; and
- To facilitate utilisation of research results.

The National Health Research Management Forum would be chaired by the Minister of Health, Secretary-DG ICMR with Secretaries of Health, DST, DBT, CSIR, AYUSH, DG-DGHS one representative each of private sector and industry, and about three eminent health scientists of the country.

Create a coordination structure with other Ministries, S&T agencies and other partners (like ICSSR) where technologies developed by other organizations are assessed and if found suitable are moved into the system.

Create several public-private platforms analogues to some of the existing ones in other departments (like NIMITLI) in down stream health technologies which are not being addressed currently,

Terms of Reference

- To review the manpower position and infrastructure available for research in research institutions, universities, medical college and service institutions and to suggest mechanisms for optimal utilization of these human resources and facilities during the 11th Plan.

Introduction

The human resources capacity for health research is a measure of country's capacity and capability to effectively address to existing and emerging health concerns of the country. Further strengthening of efforts is required to bridge the existing gap in the availability of trained human resource in health research not only within India but also for the South Asia region and beyond. It is important to select appropriate analytical method that would best identify current and future needs. The policy goals should be laid down clearly in the order of priority. The strategies that will support their realizations should be identified.

Human Resource Development

The ICMR should formulate a HRD development plan which should focus on developing policies, procedures, and partnerships to ensure the competitiveness of Indian science in health research. Skilled and talented people are undoubtedly the most important resource for the delivery of high quality science and its translation for the public's health. Current recruitment policies preclude staffing changes that will be conducive to the conduct of research at the cutting edge of science. There should be a recruitment policy to attract and retain the right calibre of staff to meet the country's evolving needs. The aim should be to employ highly qualified staff to deliver outstanding results. While primarily considering qualifications, knowledge, skills and personal qualities it should also evaluate the capacity to adapt and evolve over the longer term. The career opportunities should be made more attractive not only for current employees but also for scientists abroad. It may be necessary to restructure the compensation package offered to scientists to very generous levels by adopting an aggressive approach. At the minimum the pay structure would be on par with those of other S&T organizations in the country such as the CSIR and DBT, including introduction of appropriate number of positions at Scientist G and H levels. All efforts should be taken to retain distinguished scientists and should consider offering a Rs. 26,000 scale also. Similarly the career opportunities and compensation packages of technical staff should also be reexamined.

There should be an organized and focused effort towards formulation of a long term comprehensive human resource development policy and plan to address wide range of related issues. For almost twenty years, many Institutes/Organizations in social sector like the ICMR have had a ban on creation of new positions which is continuing. Only openings available have been on superannuation or resignation of staff. It has not been possible to address cutting-edge areas of modern science adequately. Retraining and re-deployment has helped but not much. Consequently several Institutes of ICMR are sub-critically staffed. There is thus an urgent need for assessing the requirements and creation of adequate number of new positions. For example, the Performance Appraisal Board of ICMR has recommended creations of 500 new scientific positions.

The objective of the Policy should be to ensure the conduct of quality and relevant health research by recruiting, training, managing and retaining a sufficient number of health research personnel based on identified priority areas of research needs and within sustainable resources.

Development of research capacity

The human resource and skills required for meeting the current demands and future challenges is abysmally low. In a billion populations, In a billion populations only a very small number is engaged in health research. The ICMR should liberalize its policy of institutional fellowships like SRFs and RAs. These Fellows could be mentored by senior scientists. As happens in other international research agencies, like the NIH, those who do good work could compete for regular positions as and when advertised.

Examples of some of the ICMR schemes which are currently in operation:

- ICMR Fellowship Programme for Sr. Research Fellow and Research Associate.
- Jr. Research Fellowship Programme in collaboration with PGIMER, Chandigarh.
- MD, Ph.D. programme in collaboration with Sanjay Gandhi Institute of Post-Graduate Institute, Lucknow.
- It provides support for MD thesis in priority area.
- Supports Indian scientists (Jr. and Senior) for training abroad, as well as scientists from developing countries to come to India.

The ICMR also offers some regular training courses:

- Super-Specialization (DM in Haematology)
- Post Graduate Courses
 - ▶ Masters in Applied Epidemiology
 - ▶ M.Sc.
 - Applied nutrition
 - Virology
 - Entomology
 - ▶ Diploma
 - Occupational Health
 - ▶ Certificate course
 - Nutrition

In addition, the ICMR provides short term training courses in nutrition, virology, animal sciences, epidemiologic technique, outbreak response, transfusion medicine, vector control, occupational health, genetics, ethics etc.

The NCHM has recommended that along with domestic resources, external aid, WHO assistance etc. be fruitfully utilized for developing such capacity by earmarking fellowships every year to institutes of excellence abroad and within India. Of the total 25% must be at the doctoral level and the rest at the Master's level. It should be our target to have a pool of at least 500 persons with a combination of such critical skills by the end of 2012. Such fellowships should be open for competition and not be confined to central government employees of the Ministry of Health. This will help develop capacity and expertise outside government and be available for policy advice in an objective manner. The working Group supports this recommendations.

Specific disciplines for human resource development

One of the important areas in which there is an acute shortage of human resource is social scientists to work on social determinants of health. Social scientist can bring a social science perspective to practice of medicine, making doctors socially responsible, sensitize them about the role of culture and social relationship in causing and treating disease. Well trained social scientists are needed who can undertake researches in an interdisciplinary perspective to contribute to the social science of medicine and health and assist in improving health people of the community. Very little research has been done in India on sociology of sickness and on medical anthropology, encouragement should be provided for development of human resource in

the field by creating opportunities for training and teaching. A special effort should be made to develop and nurture this expertise.

Some of the other areas in which human resource is needed include:

- Epidemiology, Public Health
- Clinical trials
- Toxicology, animal technologies
- GCP, GLP
- Quality control and Quality assurance
- Genomics and gene therapy
- Bioinformatics
- Health information technology
- Geriatrics
- Health economics
- Socio-behavioural sciences
- Bio-ethics
- Biotechnology
- Molecular Biology
- Stem Cells research and stem cell therapy
- Genetics

Terms of Reference

- To study the current status of access to research information from India and abroad to researchers in India, suggest mechanism for research information dissemination and central clearing house for facilities for research information.

Introduction

Information is central to the growth and development of medicine – the practice, teaching or research. In the present times, when new information is growing at an exponential rate, professionals are finding it difficult to cope with the deluge of information. Informatics is also playing a vital role in discovery research. The different kind of data that are required in managing a drug discovery is enormous. The challenge is to make different sets of knowledge bases to complement each other. In the post-genomic era, the research paradigm has shifted towards more rational models. Added to this are the ever growing genomic, proteomic, and transcriptomic databases. Even to find and read the meaningful and relevant content from myriad publications today. There is need for computational text mining. Suitable information tools to churn and extricate useful information need to be developed to complement the explosion of data. The entire spectrum of information ranging from three dimensional protein structures to clinical data is now available. There is an urgent need for an integrated informatics platform which fosters various facets of drug discovery research. With the rapid generation of information, new journals are being started to cater to such needs. The number of scientific journals is growing at a steady 5-7 percent per annum. Despite an occasional discontinuation, the number of journals doubles every ten years. There are an estimated 50,000 in biomedical sciences.

In addition, numerous of reports, status papers and other documents are produced. There are also documents, which give data relating to various parameters such as population, health indicators, mortality and morbidity statistics *etc.*, which are equally important for researchers, policy makers and other decision makers. Availability of such information is also very limited in the existing system of information and communication.

This growth of the literature has made virtually impossible for information-seekers access literature from primary sources such as the printed journals.

Secondary information sources such as abstracting/indexing journals have come into existence to provide ready and rapid access to the content of journals. But to effectively search and retrieve the most relevant information, the use of appropriate technology is essential. This is where the information technology such as computers, computer-readable databases, CD-ROM technology, satellite-based communication systems etc. provides the necessary tools to fulfill the requirement.

IT based Information services have thus become an essential infrastructural requirement for supporting medical community whether they are practicing physicians, teachers of health care providers at the community level or researchers in medical colleges. Unfortunately, the existing health science information infrastructure is rather inadequate to meet the complex needs of the health professionals. In order to make health science libraries more responsive to the growing demands of the health team and to meet the challenging needs of information and documentation, it is imperative that the existing resources and services for health science libraries are strengthened.

The new electronic technologies have also come to be regarded as powerful agents for helping the libraries to achieve speedier access to information. They have, in fact, revolutionised every function of the library and information science to the benefit of both the library profession and the users especially in the West. And the advent of computerised databases has largely helped researchers to now easily update their knowledge fast with a variety of tools and technologies of information retrieval. Information highway, info- routes, cyberspace- all of these terms point to the same future: the "information revolution" – a result of progress made in telecommunications and computing, along with the expansion of mass media. More and more medical researchers are now beginning to rely on the World Wide Web and the Internet.

While the new technologies have made the access of information faster and easier, this has benefited only those scientists located in the metropolitan cities and/or those working in well funded Government laboratories. Information access to scientists/teachers in most Medical Colleges/Universities/Research Institutes etc. is still poor as they are deprived of these very basic facilities; this may be one of the reasons why quality of science/research from these areas is not really up to the expected standard.

Information Technology is now one of the major components of the technological infrastructure for health management. All sub-sectors dealing with the generation, transmission and utilization of demographic and

epidemiological data such as bio-informatics, bio-statistics, HMIS and the decision support systems (DSS) are finding increasing use in health planning and management. The nationwide network of NICNET provides rapid reporting mechanism for health information, MEDLARS Biomedical Informatics Programmes provides ready access to medical databases to post graduates and research workers as well as practicing physicians. Planning Commission has provided additional central assistance to the UHSs in Karnataka, Andhra Pradesh, Tamil Nadu, Punjab and Maharashtra for strengthening of libraries and networking them through IT. This effort has to be augmented and all medical colleges need to be brought into the network.

Following are the major initiatives taken by of ICMR

- The Indian Journal of Medical Research (IJMR) was made available full-text free on the website www.icmr.nic.in from 2004. New sections such as Editorials, Commentaries, Letter to the Editor have been introduced from January 2004.
- A series of four Lancet-ICMR Workshops on Medical Paper Writing for Publication conducted in February 2005 at Vellore, Kolkata, Mumbai and New Delhi. Junior and middle level scientists from medical colleges participated in these workshops. Received very encouraging feed back.
- ProQuest full text electronic database which contains about 550 + full text medical journals subscribed. The Council has installed only two sites of ProQuest for NICED, Kolkata and NIN, Hyderabad during the year 2002-03 and later, due to increase in demand, four sites more were installed at NJIL & and Other Mycobacterial Diseases, Agra; RMRC, Dibrugarh; ICMR Hqrs, New Delhi; NIMR, Delhi.
- JCCC@ICMR subscribed. JCCC is customized e-journal gateway-cum-database service.
- The ICMR-NIC Centre for Biomedical Information's website has been ranked the top Indian health website by Google since November 2003 and has won several awards for the content as well design. The webpage provides links to the Centre's services in addition it also acts as a portal to National Library of Medicine's (NLM) databases as well as other resources available over the Net. A Meta search tool, MetaMED, was designed to search NLM's PubMed and the Centre's IndMED database in one click.
- medIND database (a full-text version of IndMED journals) was launched in August 2003 at [www.medind.nic.in.\(extramural\)](http://www.medind.nic.in.(extramural))

- A prototype Open Archive, OpenMED@NIC, was launched for Medical and Allied Sciences where authors/owners can self-archive their scientific and technical documents.

Recommended initiatives for the 11th Plan

The 10th Plan *inter-alia* had focused on building up a fully functional accurate health management system, utilizing available IT tools, so as to enable the real time communication link to send data on births, deaths, diseases, requests for drugs, diagnostics and equipment, facilitate decentralized district planning, implementation and monitoring.

A web based, one point interactive health research information system should be developed which would provide information about the health and biomedical research projects carried out in medical colleges, research institutes, universities, government departments, NGOs, private sector etc. This information could be used by policy makers, planners, programme managers, researchers etc. This would provide access to national and international biomedical databases and health research websites. The system would act as an information portal for published and un-published work. The Health Research Information System would need to be linked with policy and decision-making

A National Institute of Health Information System, as already recommended by NCMH, should be established. For this purpose, CBHI should be properly upgraded with necessary supports from public health, statistics and national health programmes to play the role effectively. This institute will also be responsible for Human Resource Development and research studies. NIMS, ICMR may be involved in taking up evaluation studies and operation research periodically. The recommendation of National Statistical Commission to upgrade the CBHI as a full fledged Directorate of Health Statistics as a nodal agency to provide sufficient inputs on health statistics should be seriously pursued. The Monitoring and Evaluation division of the Department of Family Welfare which is responsible for collecting and collating all Family Welfare information including RCH should be merged in the proposed National Institute of Health Information System. Keeping in view the recommendations of NRHM, the synergy between the Health and Family Welfare Information System need to be made and this Institute should be responsible for Monitoring and Evaluation of all health related programme including RCH.

Telemedicine

With the area of 3.3 million sq km, population of 1.1 billion, urban-rural divide, inaccessible hilly regions, islands and many tribal areas, India is an ideal setting for telemedicine assisted health care delivery. Growing number of medical, paramedical colleges and schools with lack of adequate infrastructure, learning materials and teachers needs is a matter of grave concern. E health technology has the potential to create a national level GRID which can form the backbone to be shared by healthcare providers, trainers and beneficiaries. A strong fiber backbone and indigenous satellite communication technology in place with large mass of human potential trained in IT and local presence of telepathy industry, e-health application and implementation should not be a problem technically. Further, a number of pilot projects over last five years with successful outcome stand to its testimony. A ground work on telemedicine in the country has already been laid with the efforts of ISRO and Information Technology department partnering with many State Government and specialty Institutes/hospitals. Policy standardization and infrastructural issues have already been researched.

A strong formulation for telemedicine in the country has been laid by ISRO and the Department of Information & Technology partnering with many State governments, hospitals and specialty hospitals. Issues of policy, standardization and infrastructure have been delved into by them. Professional societies on telemedicine/ e-health are actively engaged in its development.

Telemedicine aims at equal access to medical expertise irrespective of the geographical location of the person in need. Recent developments in Information and Communication Technologies (ICT) have enabled the transmission of medical images in sufficiently high quality that allows for a reliable diagnosis to be determined by the expert at the receiving site.

Access too many different sources of medical data, usually geographically distributed, and the availability of computer based tools that can extract the knowledge from that data are key requirements for providing a standard healthcare provision of high quality.

Developments in the integration of bio-medical knowledge, advances in imaging, new computational tools and the use of these technologies in diagnosis and treatment suggest that Grid-based systems can make a significant contribution to this goal. In addition to enhancement of improved

access by integration of information, the benefits are raised to a new level, over a Grid because of multi dimensional access to the information.

It is understood that the *National Task Force* has recommended a National Telemedicine Grid which will contain the following major functions / constituents. The Task Force is already looking into the connectivity, hardware, software requirements for projection under the 11th Five Year Plan which could be incorporated in the Report of the Health Informatics Working Group. Essentially the following is already under consideration of the Task Force:

- A health portal at the Ministry of Health & Family Welfare providing all information related to health informatics, telemedicine, disease surveillance data, medical care details and other educational material or information related to specific Indian healthcare system not available in the internet or hyper link to the internet data repository. This portal will be a constituent of the national grid for repository of information and guidance.
- An All India Medical Institution network connecting the various recognised medical institution, national institutes like PGIMER, AIIMS, JIPMER, SGPGI etc., and major super specialty hospitals (Government and Private) in the country for medical education, exchange of knowledge, CME etc.
- An All India Network connecting the various selected district hospitals in the country to be connected to major super specialty hospitals (Govt. /Trust/ Private) for specialist referrals for consultation and treatment and also medical informatics, disease information and health promotion aspects from different states of the country. (super specialty hospital network).
- A national network for medical training connecting various agencies in the country and also establish/integrate similar networks at state levels. (National Medical Training Network).

State Telemedicine/e-Health Grids (STG)

As a part of e-health program and digitalisation of health records, some of the states have been operating Telemedicine Networks initiated by ISRO and other agencies like Department of Information Technology (DIT) under Closed Usage Group (CUG) concept e.g. Chhattisgarh, Karnataka, and Kerala. Many more states are planning to implement such state level networks. There is a need to formalise the state Telemedicine networks into standard State Grids for specific purposes of application and usage like; providing State Health Information, Monitoring and Surveillance of

Disease/Epidemic outbreak, identification and mapping susceptible areas and population etc., as mandated by MoH&FW for health governance.

National Medical Education Institutions Network (NMEIN)

A National Medical Education Institutions Network if created would act as a useful resource base for knowledge sharing for Medical Education, Research and training including CME. The teaching and practical sessions can be configured in live or recorded video, audio and information data broadcast, accessed on the grid, for an effective learning experience.

Association / Society / Health portals Network (ASHPN)

Several associations/agencies are hosting and maintaining diverse health portals like DOCTORYANYWHERE.COM in health care services.

It is necessary to pool the resources available with the various autonomous/government/trust medical associations like Indian Medical Association (IMA), Cardiology Society of India (CSI), Neurological Society of India (NSI), Federation of Gynaecological and Obstetrics Society of India (FoGSI) etc and form an Association/society /health portals Network.

Digital Library & Medical Informatics Network (DLMIN)

It is required to establish a Digital Library & Medical Informatics Network, that will be a network of pooled information in the form of digital library of data bases and Medical/Health Information that can be accessed through Internet / Intranet and used for administrative/research and / or clinical purposes.

Some of databases of immediate value would include, but not limited to:

- Manuals of illness, diseases, symptoms, and diagnostic tools.
- National registry of specialty hospitals and specialists: names, contact information.
- Health education programs and curricular materials.
- Medicines: description, side effects, location, costs.
- Online journals, abstracts, preprints.
- Environmental profiles by state/region
 - Locations of safe water supplies.
 - Location of polluted sources (symptoms and treatment).
 - Location of emergency food supplies.
 - Location and description of health services.

- Location of disease outbreaks.
- Changing environments.

Disaster Management Support Network (DMSN)

It is required that the health care services in times of disaster can be effectively provided through establishment of Disaster Management Support (DMS) Network. This network is required to integrate identified disaster Monitoring Stations (current and proposed) across the country and provide periodic and timely information both statistical and remedial to the central station for necessary advice/action through the power of medical informatics and digital connectivity.

Capacity building: Thrust of health informatics education should be use of health information standards, storage of health information in electronic health records and research and extra collation of health information for better healthcare. Clinicians, healthcare managers, technologists, researchers would all need to specialize in various aspects of healthcare technologies. The course for skill development to include, certificate course in computer application, education framework for general, para-medical and nursing staff. These courses would need to be certified by Medical Council of India.

System of statistical data and collection

In India, health information exists at various levels, forms and systems. There is a wide variety of data that are collected by several agencies, mainly government, both at the Central and the State levels through routine data collection and periodic sample surveys. There is a plethora of information concerning the health sector but in a highly fragmented manner. The health management information system at the ground level especially tends to be duplicated by various agencies.

A major problem of health information is the reliability of data and consequent utilization for decision-making. In some respects, the reliability, relevance, timeliness and quality of the data are questionable. There is therefore a need to review national health information systems at various levels — Central, State, district and block— by various agencies — different ministries and departments in the government — method of data flow, gaps in data, utilization of the data, organisational set up, accessibility of information to various persons at various levels are aspects to be examined. Such a review would help in improving data collection techniques and quality, selectively expanding and examining the data load at various levels,

different types of information sources, biases in data management, reporting of data transmission, vertical, horizontal, utility and use of information, protocols for monitoring and evaluation of health information systems on a routine basis.

These shortcomings are known and have been spelt out by the Statistical Commission of India. It is recommended that action be taken to implement the recommendations made therein with regard to the particular needs of the health sector. Non availability of good quality data and reliable baseline estimations are responsible for lack of clarity in policy design and strategies being adopted.

Other steps to improve information access and flow include i) commitment for sharing information and using electronic media; and ii) standardizing formats for information exchange.

Action Plan for Research Information Dissemination

The current state of library and information network in medical colleges continued to be poor. There is thus a great need to upgrade these facilities to bring them, at least to a level at par with other libraries in sister disciplines using IT. Students and teachers in these disciplines get adequate exposure to the new information technology and are quite comfortable using these new facilities in these libraries some of which are near global level. There is no reason why the same cannot be done in medical colleges.

Policy makers have also shown inclination towards a comprehensive and wholesale upgradation of such facilities and the recognition that without modern information technology there cannot be any real progress in the quality of medical education. It is important to motivate the library personnel to take up the new challenge, as new IT would help them provide better services to their user. A systematic approach is called for to chalk out a strategy for the revamping exercise. As a starter an in depth, evaluation is required to know the existing facilities of these libraries in terms of existing availability of hardware and software and plan means of strengthening the libraries. In fact, the ICMR has just started steps to modernize its network of libraries and upgrade them to modern information centres. In view of the massive exercise involved, it has been proposed to take up this in a phased manner to enable both the information providers and users come to grips with the new developments. A similar exercise is needed for the revamping of these libraries, especially those in medical colleges.

Some Suggested Strategies/recommendations

Some of the action points to help the overall improvement of the medical college libraries including the use of IT in these exercises to provide easy and speedier access to relevant information for all health personnel and other users are given below. Some of these have been suggested in the 10th Plan but could not be implemented.

- As seen, the present IT infrastructure of the medical colleges/ biomedical institutions libraries in terms of user needs and the potential for growth. Undertake this modernization in a phased manner to bring all the libraries of the medical colleges / biomedical institutions to a certain minimum benchmark in terms of infrastructure, databases and services offered in the first phase.
- Create computer-readable indexes of the holdings of these libraries. Automate in a phased manner routine library operations like indexing, issue and return of books, reminder system, inventory control of purchases *etc.* through computerization.
- Switch over as far as possible from printed versions of alerting/journals/reference sources like *Current Contents, Index Medicus, Tropical Diseases Bulletin*, and some core medical journals, to the electronic form as CD-ROMs, to improve the accessibility of literature, save reader's time and save shelf space in the library. Train users to access these facilities themselves.
- Train the library staff on a continuing basis to get familiar with the rapidly changing technological developments in the area of computer-based communications to access/provide these new facilities to users. Involve IT professionals in library activities.
- Plan steps towards national resource sharing and networking of the libraries. To begin with, libraries can network with institutes/universities, which are closer in terms of proximity. They should also be encouraged to join networks of other libraries with the current IT infrastructure in India thus should be possible.

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Government of India
Planning Commission
(Health, Family Welfare & Nutrition)

Yojana Bhawan
Sansad Marg
New Delhi
25th May, 2006

ORDER

Subject: Working Group on Health Systems Research, Biomedical Research & Development and Regulation of Drugs and Therapeutics for the Eleventh Five-Year Plan (2007-2012)

In the context of formulation of the Eleventh Five Year Plan (2007-12), it has been decided to set up a Working Group on Health Systems Research, Biomedical Research & Development and Regulation of Drugs & Therapeutics under the Chairmanship of Director General, ICMR, New Delhi. The composition of the Working Group will be as follows:

1.	Director General, Indian Council of Medical Research, New Delhi	Chairman
2.	Representative, Deptt. of AYUSH, Ministry of Health & Family Welfare, New Delhi.	Member
3.	Representative, Deptt. of Health and Family Welfare, New Delhi	Member
4.	Representative, Deptt. of Science & Technology, New Delhi.	Member
5.	Representative, Deptt. of Bio-technology, New Delhi	Member
6.	Representative, Directorate General of Health Services, New Delhi	Member
7.	Representative, Council of Scientific and Industrial Research, New Delhi.	Member
8.	Drugs Controller of India, DGHS, Ministry of Health & Family Welfare, New Delhi	Member
9.	Director, Central Drugs Research Institute, Lucknow	Member
10.	Director, Industrial Toxicology Research Centre, Lucknow	Member
11.	Dr. C.K. George, Director, Institute of Health Systems, Hyderabad.	Member
12.	Dr. Y.K. Gupta, Professor of Pharmacology, All India Institute of Medical Sciences, New Delhi	Member
13.	Prof. V.R. Muraleedharan, Indian Institute of Technology, Chennai	Member
14.	Director, Indian Institute of Science, Bangalore	Member
15.	Shri Rajeev Lochan, Director, (Health), Planning Commission, New Delhi	Member

16.	Shri K.M. Gupta, Director, Ministry of Finance, New Delhi	Member
17.	Dr. Ranjit Roy Choudhary, New Delhi	Member
18.	Dr. Somnath Roy, Emeritus Professor, New Delhi	Member
19.	Dr. Y. Atal, Ex-Principal Director, UNESCO, Gurgaon	Member
20.	Dr. Mira Shiva, Voluntary Health Association of India, New Delhi	Member
21.	Dr. Amar Jessani, Centre for Enquiry into Health & Allied Themes, Mumbai	Member
22.	Deputy Director-General, Indian Council of Medical Research, New Delhi	Member-Secretary

2. The terms of reference of the Working Group will be as under:
- (i) To review the position/progress/problems in basic, clinical, applied and operational studies during the 10th Plan period and to suggest priority areas for research in these areas, and mechanism to avoid duplication/overlapping and to bring about transparency and social control in research work including ethical issues during the 11th Plan.
 - (ii) To review the current situation regarding development, testing and quality control of drugs and devices, both in the modern system of medicine and AYUSH and suggest priority areas for research and institutional strengthening during the 11th Plan period.
 - (iii) To review the manpower position and infrastructure available for research in research institutions, universities, medical college and service institutions and to suggest mechanisms for optimal utilization of these human resources and facilities during the 11th Plan.
 - (iv) To review current status of inter-agency, inter-ministry collaboration in priority areas of research and to suggest mechanism of improvement during the 11th Plan period.
 - (v) To review the situation regarding research agencies addressing priority areas of research identified by service providers and implementation of major suggestions emerging from research studies and to suggest mechanism for improvement of these during 11th Plan period.
 - (vi) To study the current status of access to research information from India and abroad to researchers in India, suggest mechanism for research information dissemination and central clearing house for facilities for research information.
 - (vii) To review the current investment in bio-medical research and health systems research by various agencies and project requirements to address the identified priorities during the Eleventh Plan period.
 - (viii) To deliberate and give recommendations on any other matter relevant to the topic.
3. The Chairman may form sub-groups and co-opt official or non-official members as needed. The Working Group will submit its report by 31st August, 2006.

4. Shri Rajeev Lochan, Director (Health), Room No.463, Planning Commission, Yojana Bhawan, New Delhi will be the Nodal Officer for all further communications.

5. The expenditure on TA/DA in connection with the meetings of the Working Group in respect of the official members will be borne by the parent Department/Ministry to which the official belongs as per the rules of entitlement applicable to them. the non-official members of the Working Group will be entitled to TA/DA as permissible to Grade-1 officers of the Government of India under SR 190 (a) and this expenditure will be borne by the Planning Commission.

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To : The Chairman and all Members of the Working Group.

Copy to :

1. PS to Deputy Chairman/MOS
(Planning)/Members(KP)/(AS)/(VCL)/(BLM)/(BNY)/(AH)/(SH)/Member-Secretary, Planning Commission, Yojana Bhawan, New Delhi
2. All Pr. Advisers/Advisers/HODs in Planning Commission
3. Prime Minister's Office, South, Block, New Delhi
4. Cabinet Secretariat, Rashtrapati Bhawan, New Delhi
5. US (Admin.I) / Pay & Accounts Officer/Accounts-I Section, Planning Commission/DDO, Planning Commission
6. Information Officer, Planning Commission

(Rajeev Lochan)
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List of persons who attended the meeting of Working Group on 23rd Sept, 2006

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