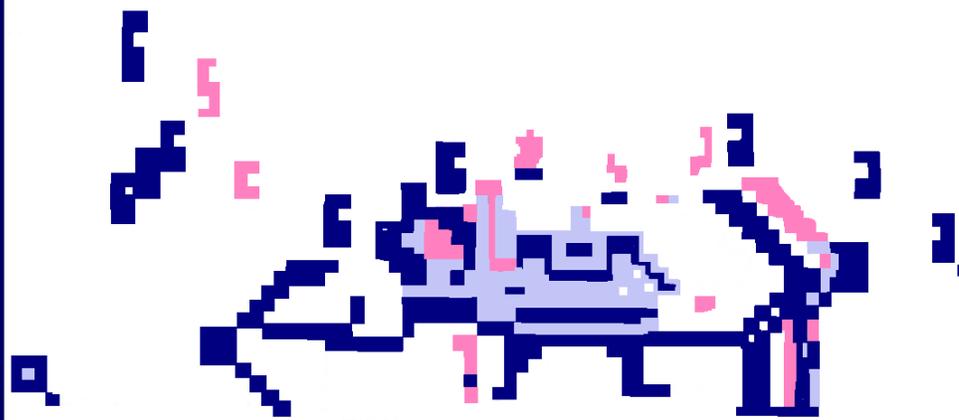


# Health Research Policy-ICMR

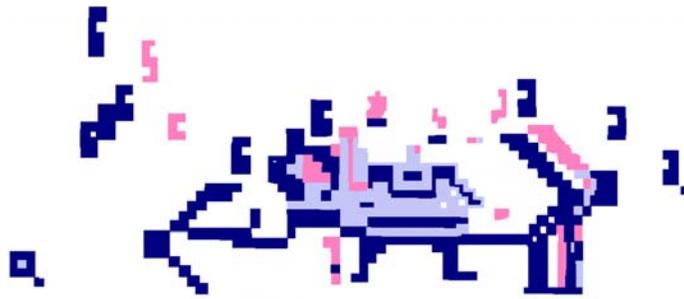


October-2007



**Indian Council of Medical Research  
New Delhi**

# Health Research Policy - ICMR



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## **Preface**

Though history of health research in India goes beyond 1911, when the Indian Research Fund Association the precursor of Indian Council of Medical Research (ICMR) was established, the country has not had a policy laying down the principles to guide decision making.

Why has a need of Health Research Policy arisen now ?

It is being increasingly realized that better health is not only a consequence of economic development, but also a critical input and a means to achieve it. The discovery, development and refinement of cost-effective interventions can drastically improve the landscape of disease control and health of Indians. Better use of existing health interventions is critical in improving access to these tools and must be given high priority. Equally important is to simultaneously invest in the development of new, improved and equitably and affordable interventions.

There are many players in health research, the public and private sector, autonomous organization and NGOs, bilateral and multi-national agencies. The players in health research are increasing and so is the funding. Better coordination would be the key to judicious use of resources. The other policies enunciated by the Government of India (Population Policy 2000, Health Policy 2002, Science & Technology Policy, 2003) have equivocally stressed the importance of health research to improve health of the nation.

A Committee of Experts reviewed the situation, and its sub-committee drafted this Health Research Policy. The draft has been widely circulated to individuals and has been put on Council's website for a wider readership for comments and suggestions. The final revision is informed by public opinion and incorporates all the comments and suggestions received. I thank all those who contributed to give it the final shape.

It is hoped that the policy would facilitate the generation of evidence-base for health systems and services, so that they will be significant promoters of equity and contribute to national development. The policy will help to meet the multi-faceted challenges including those of creating and managing of national health research system, capacity-building and networking, dissemination of results including their translation into action.

This policy is expected to serve as a beacon to guide health research in India which should contribute towards attainment of better health for all Indians.

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Our grateful thanks to all those who participated in discussions, read the drafts and gave their comments and suggestions, upon those critiques, ideas and thoughts this Policy has evolved.

The policy was finally drafted by a sub-Committee headed by Prof.V.I. Mathan with valuable inputs from Ravi Rangachari, DCS Reddy, CAK Yesudian, and Ambujam N Kapoor.

The credit for editing and publication of this policy goes to K. Satyanarayana (ICMR Hqrs.). Rakesh Chand assisted in giving shape to the document and Lalita Anand and Rajiv Kumar provided secretariat assistance.

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## **1. Preamble**

India is a significant contributor to knowledge on health, with research outputs ranging over the full spectrum, from epidemiology and clinical care to biotechnology and genomics. A large number of Government Departments (Health, Science and Technology, Atomic Energy, Human Resource Development, Social Welfare etc.) support health research. Work is carried out in National Institutes, Autonomous Research Institutes, Universities and other Academic Institutions and by a variety of private organisations, including the Pharmaceutical Industry. The Indian Council of Medical Research, an autonomous council established in the Ministry of Health, is the agency responsible for research in the nodal ministry. In addition, the Department of Science and Technology (DST), the Department of Biotechnology (DBT), The Council of Scientific and Industrial research (CSIR) and the University Grants Commission are some of the other major agencies financing health research. There are also other Councils of Research in the Health Ministry for Ayurvedic and other systems of Medicine.

Health has been accepted as a fundamental right of all people by the Constitution of the World Health Organisation and in The International Declaration of Human rights. The fundamental right to life enshrined in the Constitution of India, includes the fundamental role of health as an integral component. India is making significant investments in health and health research, but so far a Health Research Policy has not been formulated. In view of the importance of Health and the need for research to provide the evidence, for the maintenance of health and for formulating rational health care policies, it essential that a Health Research Policy is laid down to channel efforts and funds the right direction. In order to formulate the policy it is necessary to examine relevant existing national and international policies and review briefly the current status of health research in India.

### **1.1 National Health Policy**

The first National Health Policy of 1983 was a response to the commitment to the Alma Ata declaration to achieve "Health for All by 2000"<sup>1</sup>. It accepted that health was central to development and had a focus on access to health services, especially for rural populations. While much was achieved in health services infrastructure development, the health service system continued to be plagued by widening inequities in access to health care and the quality of care. The need for an evidence base was not recognised fully. The poorly regulated health system has undergone dramatic changes since 1983, with an emerging for profit corporate health care system, which has further marginalised the development of the public system.

The National Health Policy 2002 (NHP2002) reviewing the current scenario recognised that, while there has been significant improvement in demographic trends, control of infectious diseases and growth of infrastructure, between 1981 and 2000, health indicators are still far from optimal<sup>2</sup>. Inequity in health care access is still continuing at a time when 'Health Tourism' is being promoted. The Public investment in Health is still comparatively low and in fact has declined from 1.3% of GDP in 1990 to 0.9% in 1999. Only about 1%

of the health budget is set apart for Health Research. NHP 2002 envisages that by 2010 the public investment in health would reach 2% of the GDP. Ideally 2% of the Public Health Budget should be invested in research. A public private partnership in health research is envisaged by providing financial inputs and public funded health research would primarily be translational and operational. It is, therefore, timely that a Health Research Policy is enunciated to ensure that these goals are met.

## **1.2 Science Policy Resolution**

The Scientific Policy Resolution of the Govt. of India, released on the 4th March 1958, clearly identified the role that science and technology can play in the growth and development of the nation, and the advancement, materially and culturally, of the people<sup>3</sup>. The stated aims of the policy, "to foster, promote and sustain, by all appropriate means, the cultivation of science, and scientific research in all its aspects -pure, applied and educational", with a focus on human resource and infrastructural development and scientific freedom, is equally applicable to Health Research, although it was not specifically mentioned.

## **1.3 Health, Health Research & Development**

Health is a key factor in national prosperity. "It is a truism that disease is no respecter of national boundaries... At the same time major scientific breakthroughs hold the promise of more effective prevention, management and treatment for an array of critical health problems. Poor health- and more broadly poverty and vulnerability- have never received as much genuine political attention as in the recent past. The inherent danger in the powerful and inexorable forces of globalization, and similarly with the revolutionary applications now arising from new genetic understanding, is their potential to accentuate inequality. While their fruits are enjoyed by those nations and groups with the means of access, they are generally not available to the world's poor who, instead, progressively crowd the margins behind barriers that are ever more difficult to penetrate."<sup>4</sup> Despite overall gains in health since Independence in 1947, in many instances, health inequities between rich and poor have widened. New and re-emerging diseases have undermined gains, and accidents, injuries, mental health problems and non-communicable diseases pose new challenges even as we are trying to cope with the long standing challenges of maternal and infant mortality. Globalisation, trade reforms and the focus on intellectual property rights are additional pressures for India to face. "This, therefore, may prove a metaphor for the twenty first century: the choice between an inclusive worlds focussed on health problems that afflict the vulnerable, or a growing marginalisation of those with the greatest burden from the means to improve their situation."<sup>4</sup>

Over the past decade or so, there is substantial evidence to suggest that national governments of several countries increasingly recognize that health research has the potential to help reduce the impact of many of the health problems faced by their populations, and thus contribute to national development. This was emphasised in the World Bank, 1995 World Development Report<sup>5</sup>. *In India, this recognition has been there from even before Independence in 1947 AD, and governmental support to a limited*

*extent has been available.*" It is timely as we are entering a new century and millennium and India is poised to take its rightful place in the global village that a policy spelling out the critical role of health research in the countries development is adopted.

#### **1.4 Health Research and Evidence based Health Policies**

It seems quite obvious and apparent that any policy or strategy should be evidence based, especially as scarce resources are to be utilised in implementing the policies. There are several examples of Indian research providing the evidence for the formulation of strategies, policies and programs (Vitamin A prophylaxis, Vector Borne Diseases Control Programme, National Immunisation days, DOTS regimen for treatment of Tuberculosis). The contributions made by these essentially Indian discoveries to national welfare is unquestionable, but in some instances they had to be rediscovered by international agencies before they were nationally implemented. There is therefore an urgent need for a Health Research Policy aimed primarily at generating information coordinating all concerned stake holders and using it for determining national priorities for implementing health programs.

#### **1.5 International initiatives outlining rationale and need for Health Research Policy**

In 1990, the Commission on Health Research & Development proposed a set of strategies through which the potential of research could be harnessed to accelerate health improvements and to overcome health inequities throughout the world<sup>6</sup>. The concept of Essential National Health Research (ENHR) was enunciated by the Commission to describe the health research (and the health research capacity) on which each developing country should concentrate. This incorporated two approaches (i) research on country specific health problems necessary to formulate sound policies and plans for field action; and (ii) contributions to global health research aimed at developing new knowledge and technologies to solve health problems of general significance, which are also relevant to the population of the country. The Commission also recommended that at least 2% of national health expenditure should be invested in ENHR, and that at least 5% of project and program aid for the health sector from development aid agencies should be earmarked for research and research capacity strengthening. As a consequence of the above recommendations, the World Health Assembly, in 1990, adopted Resolution WHA 43.19 calling for Member States of the WHO to undertake health research appropriate to national needs.

As a follow-up of the 1993 World Bank Report a Conference in Ottawa, co-sponsored by IDRC, WHO and the World Bank, resulted in three major initiatives, one of which was an examination of issues relating to and redirecting investment in equity oriented development to health, led by the World Bank. World Bank assisted projects initiated in the 1995 in India reflect the Commission's as well as the Bank's current philosophies.

Another initiative emerging from the Ottawa Conference was an *ad hoc* review of health research priorities (with WHO as the Secretariat), which resulted in a five-step systematic approach being suggested for resource allocation for

strategic health research. The third initiative was the establishment in 1997 of the Global Forum for Health Research (GFHR). The GFHR has since identified the inequities in health research financing, where 90% of the investment in health research addresses the problems of 10% of the world's population (the '10/90 gap').<sup>4</sup>

A relatively recent development is the growth in the number, size and financial outlay of "philanthropic" Foundations and International NGOs. While their stated aims and objectives cannot be faulted, in several instances there is cause for concern on their limited or narrow agenda, the likelihood of their diverting national focus or influencing the thrusts and direction. This could be to the detriment of national interests, thus reinforcing the need for national policies.

The Report of India's 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<sup>8</sup>. For developing a culture for research, the Report suggests that the Government should initiate steps to de-bureaucratize 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.

In India while most of the agencies funding research have plans in general linked to the National 5 year plans, a coordinated national health research policy which could guide the planning and implementation is not yet in place. Some of the conflicts and failures of Indian health research can be attributed to the absence of such an overarching policy.

In the 60<sup>th</sup> World Health Assembly, May 2007, one of the Resolutions adopted was WHO's Role and responsibilities in health research (WHA 60.15)<sup>9</sup>. It urges the Member States to draw up or strengthen health research policies.

## **1.6 Objectives of the Health Research Policy**

The broad objectives of the National Health Research Policy are given below and are discussed in detail later:

- i. Identify priorities for health research so that the results of the research would enable the achievements of the objectives of NHP 2002 by ensuring that the results of health research are translated by policy makers into action
- ii. Foster inter-sectoral coordination in health research including with the science departments within the Government, Private Sector and the Academia. The establishment of the proposed Department of Health Research would facilitate this.

- iii. Focus on the vulnerable and the disadvantaged sections of the society such as Scheduled castes, Scheduled Tribes, communities of the north-east, children, women and the elderly.
- iv. Strengthen networks between research institutes, and between academia and research/ service institutes
- v. Put in place strategies and mechanisms for assessing the cost-effectiveness and impact on health systems on the outcomes of health research
- vi. Develop human resources for health research

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## 2. Current Status of Health Research in India

### 2.1 Achievements of Health Research in India

A common criticism of scientific activities in India in general, and of medical research in particular, has been that no significant achievements have occurred, particularly in the post-independence period. Major breakthroughs of the Nobel Prize winning kind require an investment and infrastructure that has been unaffordable by the country. However, there are several instances over the past fifty years that clearly indicate that, in spite of the handicaps and difficulties, contributions have been made in the health sector through research done in India by Indians, which have significantly changed the health scenario. Some examples of such contributions would include: the identification of emerging or reemerging infections (Kyasanur Forest Disease, *Vibrio cholerae* 0139, resurgence of leptospirosis, adult variants of measles); development of diagnostics (Japanese encephalitis, Dengue, Hepatitis A, Group A Rotavirus, Malaria, Kala Azar, 0139 cholera, Hepatitis C, *Chikungunya*); development of vaccines (KFD, cholera, leprosy, Hep E, MVA based HIV vaccine, Japanese encephalitis); major field evaluation of vaccines (leprosy, TB, typhoid, Phase I HIV vaccines, aerosol measles vaccine Phase I, Vi antigen based typhoid vaccine, rota virus); development and operationalisation of treatment regimens (short course chemotherapy for TB, supervised chemotherapy- now called DOTS- for TB, multi-drug therapy for leprosy, oral rehydration solution-ORS- for diarrhoeal diseases, Vitamin A prophylaxis for children to prevent nutritional blindness, iron and folic acid supplementation for pregnant women); new drug development (Centchroman, Artether); development of strategies for delivery of services (pulse polio, DOTS, Integrated disease vector control, rheumatic fever / rheumatic heart disease); development of nationally appropriate guidelines (for tubal sterilisation, assisted reproduction ); generation of data (on dietary intakes, and nutritional status leading to formulation of recommended dietary allowances for Indians, nutritional value of Indian foods, magnitude of the problems of blindness, hearing impairment, cancer & mental illness, haemoglobinopathies); discovery of a rare blood group (the Bombay Group); preparation of a Genetic Atlas of Indian Tribes; demonstrating the safety, efficacy and cost-effectiveness of *Kshaarasootra* (an Ayurvedic Medicated Thread) technique as a non-surgical ambulatory technique for management of fistula-in-ano; providing the basis for formulation of new programs for non-communicable diseases (cancer, blindness, deafness, mental health) and developing the Ethical Guidelines for Biomedical research on Human Subjects in India(1980 and 2000).

The contributions of the pharmaceutical industry in making available at affordable cost almost all drugs required by the Indian population, is the direct result of the considerable investment in research on alternate processes which are cost effective.

These achievements are not the result of any single agency's efforts. Coordinated efforts of a number of agencies of the Government, especially in the Ministry of Health (Indian Council of Medical research) the Ministry of Science and Technology (Council of Scientific and Industrial Research,

Department of Biotechnology, Department of Science and Technology, etc.), the Ministry of Human Resource Development (University Grants Commission) and others including the private sector have worked together to achieve these results. Clearly a policy driven investment in infrastructure and manpower development and a climate of scientific freedom that fosters initiative as envisaged in the National Science Policy will increase the contributions of health research and will ensure that Health acts as a major catalyst of development. This coordinated effort has developed a number of health research infrastructures, which can form the nucleus around which further capacities can be developed.

## **2.2 Constraints and Concerns**

The achievements of Indian health researchers could have been greater but for some identifiable constraints. These are a matter of concern and it is necessary to identify them in order to give the necessary impetus to enable Health research to be a vehicle for national Development.

- Policy makers do not readily recognise the developmental importance of national health research. In fact important current health programs like the National Immunisation days and DOTS, while they arose from the results of Indian health research, they were only implemented when they were given the seal of International acceptance.
- National coordination of the considerable investment in research in the health sector is currently not done. There is no National plan or consensus on priorities.
- A 'research culture' and a climate that fosters health research are not present. In fact many scientists feel that they subserve a beurocratic agenda and procedures.
- Capacity development for Human resources and Infrastructure is not recognised as a priority.
- The medical educational system does not foster a research culture. The glamour of curative care often works as the career guiding principle of medical students.
- A clear research career structure and productivity related incentives are not in place.
- Intersectoral linkages are weak and serve primarily for information and not for coordinated action.
- The tools of modern information technology and biotechnology are relatively inaccessible to the majority of health professionals and researchers.
- The links between health research and health services and programs are weak and ill defined.

## **2.3 Challenges facing Health Research in India**

Given the achievements made, the constraints faced and the concerns felt, the challenges before the country in so far as health research is concerned are:

- How can health research contribute to reducing the inequities in health between various segments of the Indian people?
- How are the priorities to be determined, at what level (national, state, district), and how often?
- How are certain current issues to be addressed, such as Demographic and Epidemiological Transition and its implications for human health, Modern Biotechnology (including Genomics, Human Genetics, New Drug Development), Environmental and Ecological impact on human health), as also emerging and re-emerging diseases?
- How can the health research system be more integrated with the national health development plans?
- Are the guidelines for ethics in human subjects research adequate in India? If not, how can they be improved and harmonised with internationally accepted guidelines? How can the principles of ethics be put into practice?
- How can the Indian health research system contribute to global, regional and other national research systems?
- How can India attain and retain a critical mass of researchers in various disciplines affecting health?
- How can a demand for research be generated among policy makers, health workers, community groups and others?
- What targets can be set for financing of health research, and what are the actions that would be required to be taken to achieve these targets, from both internal and external sources?
- How can the resources available for research (human, financial, infrastructure) be accessed and used judiciously to address the national priorities?
- How can rapid processing and red-tape-free release of research grants be ensured so that good research ideas can be funded in real time?
- How would allocations be made and monitored?
- What actions would be required to increase the access to national and international research literature and knowledge base, both as contributors and as users?
- How can closer links be ensured between the research community, health services and policy makers, in order to facilitate the utilisation of research results in practice and policy formulation?
- What are the threats posed and opportunities offered by Globalisation? How are these to be addressed?
- How can a research culture be developed wherein policy makers and communities are sensitised to the value of research, and the research environment is supportive of scientists and science?

### 3. Strategic Vision for Health Research in India

In order to achieve intersectoral coordination and to make national priorities for health research a new architecture of national health research system is envisaged.

#### 3.1 National Health Research System (NHRS)

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 shall be managed by a **National Health Research Management Forum (NHRMF)**.

#### 3.2 Goals of the NHRS

- To 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;
- To adapt and apply knowledge generated elsewhere to national health development; and
- To contribute to the global knowledge base on issues relevant to the country

#### 3.3 Underlying values

The NHRS can only be viable if there are strong underlying values which recognizes that health research is an investment which is equitable based on ethics, owned by the people and leads to development of research culture and self reliance. This system must be intersectoral and accountable. These values are explained in Appendix-1.

#### 3.4 Operating Principles

- **The National Health Research Plan**

A National Health Research Plan shall 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. This shall be the major responsibility of the National Health Research Management Forum.

- **Priority setting**

A Priority Research Agenda will be developed based on national needs for health to be a vehicle of equity and development and the following principles.

- ◇ **Responsiveness**

Current and emerging issues such as Demographic and Epidemiologic Transition, emerging scientific developments such as Modern Biotechnology (Genomics, Human Genetics, New Drug Development, Stem Cell research), Health system research, Health Economics, Behavioural and social issues, Emerging and re-emerging infections, etc. and the priorities of the National Health plan will guide the Research Agenda.

- ◇ **Integration**  
The integration of the National Research Plan with the priorities and aspiration of society is essential for the ready utilisation of the results of research. The linkages of the health system with communities, District and State Governments and the Central government is essential for developing the data bases necessary for research and service priority setting and decision making. The generation of this data shall be a priority.
- ◇ **Multidisciplinarity and Linkages**  
Health Research, in addition to the field of Health, intersectorally encompasses Education, Environment, Ecology, Social and Behavioural Sciences, Population, Agriculture, Trade, Commerce, in addition to the physical, chemical, biological and mathematical sciences. This multidisciplinarity will be reflected in the National health Research Plan
- ◇ **Social and Behavioural Sciences and Health Economics**  
In order to make meaningful health policies, plans and programs and to make medical technology useful and accessible to the community, it is essential to understand the community's perception of health problems, health services and health care providers. Social and Behavioural sciences and Health Economics are integral to health research and will be actively fostered.
- ◇ **Focus on vulnerable and disadvantaged populations**  
Equity in services and development shall be the cardinal principle undergirding the Health Research System. There shall be a special emphasis on vulnerable groups like scheduled castes, tribal populations, unorganized labour, women, children, adolescents, and the geriatric populations who remain in the periphery of society and the larger health sector. Data on expenditure on health on these sectors, problems on delivery of health care and the potential impact of innovations in public sector financing / resource generation such as user fees, and the economic burden of disease in vulnerable groups and its impact on national development are key issues.

- **The Private Sector in Health Research**

The private sector, Pharmaceutical Industry, Biotechnology and Biomedical technology oriented Industries, private educational institutions, hospitals and nursing homes, research foundations and institutions, private practitioners, NGO's and CBO's working on a not-for-profit basis etc. are now major stakeholders in Health care research and delivery. The National Health Research System recognises their important role in health research and shall foster their participation in the system as partners.

- **International Linkages**

In the current global scenario International collaborative efforts are recognised as one of the factors in successful research because of the complementarity of technology transfer, capacity building and access to diseased populations. There are a large number of potential partners and in the choice of partners the priorities of the National Health Research Plan and national interest shall

be paramount. Linkages with International Developmental partners and WHO and other UN Agencies shall be further developed and strengthened.

- **Ethical Research**

The Ethical Guidelines for Biomedical Research on Human Subjects (ICMR 2000), along with the guidelines being developed by the Dept. of Biotechnology for Human Genetics Research and the Animal ethical guidelines of the Government of India, shall be mandatory for all research. The Health Research System shall review the Guidelines from time to time, and harmonise them with International Guidelines. Facilitation of training in ethical research shall be the responsibility of the System.

- **Targeted Financing**

The National Health Research System shall be responsible for ensuring equity in resource mobilisation and allocation of public funds. It shall endeavor to ensure that the allocation/ expenditure on health research is at least 2% of the allocation / expenditure on health. International funds will also be mobilised in keeping with the priorities. A mechanism needs to be put in place to track the resources available for health research within the country. Though a minimum of 2% of health expenditure has been recommended, this may be too small a figure considering that the allocation for health itself is meagre in relation to the population and health concerns of the country.

- **Monitoring and Evaluation**

To ensure that resources are used efficiently and in line with agreed priorities there is a need for continuous monitoring and evaluation. The health research system will develop explicit policies and procedures for reviewing proposals, and for monitoring and evaluating the output and impact of those that are funded. Indicators will be developed to monitor the development and effectiveness of the health research system. Indicators would also be defined for assessing health status, health system effectiveness, efficiency and affordability, in order to capture the contribution of research in reducing inequities. Direct indicators of National Development, would serve as indirect indicators of the efficacy of Health System research as a vehicle of development. A detailed strategy for the assessment of the health research system is give as Appendix-2.

### **3.5 Currently Identified Research Priorities.**

The Planning Commission's Approach Paper to the 11<sup>th</sup> Plan provides the general directions, while the road-map to develop a blue-print for health research is provided through the recommendations of the National Commission on Macroeconomics and Health, Planning Commission's Working Groups for 11<sup>th</sup> Plan on Communicable and Non-communicable diseases and on Health System Research, Biomedical Research and Development and Regulation of Drugs and Therapeutics along with the Report of the Performance Appraisal Board of the Indian Council of Medical Research.

This will form the basis on which the National Health Research Management Forum will update the priorities from time to time. For the period 2007-12, the priorities identified for the 11th Five Year Plan shall guide the national health research system. (See *Annexure 1 and 2*)

## **4. Suggested Architecture of the National Health Research System (NHRS)**

### **4.1 The Present Status**

A large amount of research is carried out in India by a multiplicity of organisations and Institutions and sponsored by a variety of governmental agencies and International sponsors. There is no agency for coordination of this large endeavour and avoidable duplication and unhealthy competitiveness is an unfortunate feature. The Ministry of Health is the nodal Ministry for Health and is primarily considered as a "Social sector ministry" and not a "science sector" one. The reality of the necessity for a scientific evidence base for the optimum delivery of health care requires that research is essential. Further the rapid advances in Modern Biotechnology in the health field means that unless India is able to respond effectively the role of health being an engine of development will remain as a dream in our country. The key to future success in this field is dependent on a coordinating role for the Nodal Ministry with the willing cooperation of all others concerned to develop a National Health Research System. Efficient coordination, planning and financing of the NHRS requires the establishment of a National Health Research Management Forum.

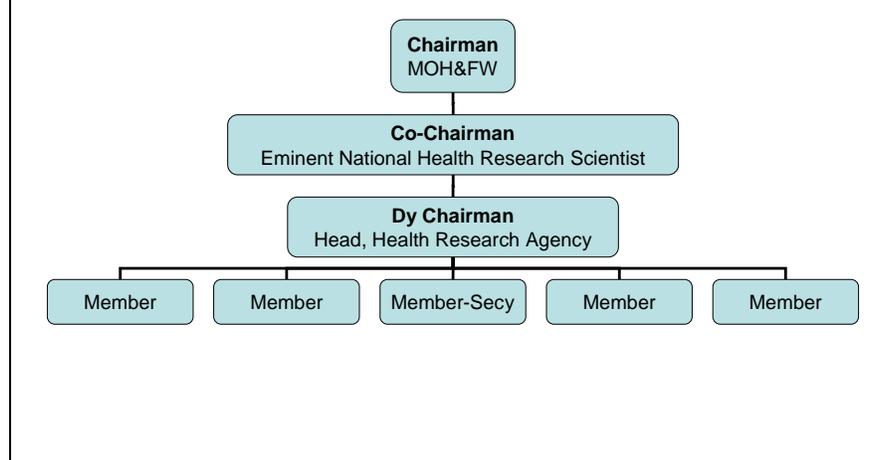
### **4.2 The National Health Research Management Forum (NHRMF)**

The National Health Research Policy envisages a System wherein all present and prospective players have their own space. However, an overarching National Health Research Management Forum is proposed, having representation of all key stakeholders, the ICMR as its Secretariat, and the following functions / terms of reference:

- i) To advise on and evolve national health research policies and priorities and to evolve mechanisms and action plans for their implementation;
- ii) To develop a 5 year projection of the plans for health research and to prepare a biennial rolling National health research plan;
- iii) To review the output from the National Health research Plan annually and prepare the plan for the next biennium;
- iv) To promote the development of health research activities in the country;
- v) To review biomedical & health research management, and suggest Strategies to overcome problems in implementation of policies;
- vi) To suggest mechanisms to nurture a scientific environment to attract talent and to develop human resources for biomedical and health research; and
- vii) To facilitate utilisation of research results.

The NHRMF will be Chaired by the Minister of Health and Co-chaired by an eminent National health Researcher. The Secretariat shall be in the Indian Council of Medical Research and the Director General of the ICMR shall be the Secretary. The NHRMF shall take all steps are necessary to discharge its functions based on the underlying values and principles referred to in Section 3, and explained in Appendix-1.

## Structure of National Health Research Management Forum



The NHRMF will have special responsibility for the following functions.

### **Stewardship**

This would encompass a range of activities for the national health system intended to ensure quality leadership, productivity, strategic direction and coherent action. Sub-functions would include Strategic Vision, Policy Formulation, Priority Setting, Performance and Impact Assessment" Promotion and Advocacy, and the setting of norms, standards and frameworks for the sound practice of research.

### **Financing**

The essential functions of the System as regards finances would be to address issues related to resource generation, targeted allocation and judicious utilisation. On the basis of recommendations of the National Health Research Management Forum, funds would be allocated in ways that are generally consistent with national priorities. External Partners would be apprised of these priorities, while a national capability to monitor where and how research funds are being spent, and the quantities involved, would be created and put in place. Efforts would be made to invest at least 2% of national health expenditure in research and research capacity strengthening.

### **Knowledge Generation**

The research system would generate knowledge relevant to the Indian health situation, appraise the measures available for dealing with health problems, and suggest the actions likely to produce the greatest improvement in health.

### **Utilisation and Management of Knowledge**

The Research System fully endorses the principle that the research process does not end with Knowledge Generation, but includes the translation of results into policy or action, or absorption into the existing knowledge / technology base. For

this to happen, links will be strengthened between researchers, policy makers, health and development workers, non-governmental organisations, and communities. Vertical and horizontal connectedness will be improved upon. More specifically, for better utilisation and management of knowledge, an information culture would be fostered, supported by enhanced use of information technologies currently and likely to be available.

### **Capacity Development**

A long-term approach to the development and maintenance of research capacity will be adopted. Efforts will be focussed on both the quantity and quality of skills available / needed, including research techniques, research priority setting, research management, use of research ('demand' side), policy and systems analysis, communications, development of partnerships. A situation analysis followed by a phased and realistic plan would be prepared to ensure constructive and sustained capacity development. Thus, both the 'Supply' and 'Demand' sides of the research system needs will be addressed.

## 5. THE HEALTH RESEARCH POLICY STATEMENT

Health is a fundamental right of all people. An evidence base developed by appropriate research should be the basis of Health Systems and Services. The global imbalance in the allocation of resources for Health research, the 10/90 Dis-equilibrium, has resulted in a low priority for research on the pressing health problems of much of the Developing World. India is fortunate that significant resources are allocated for research and that funds are available in a diversity of fields and disciplines to be used for Health Research.

Health is also now recognised as a fundamental issue in National Development and a factor that promotes equity. A clearly defined Health Research Policy therefore is the basis for maximising the return on investment in this important field. This policy aims to:

- i. Generate the evidence base for Health Systems and Services, so that they will be significant promoters of equity and contribute to National Development.**

*Health is not merely the absence of disease and a healthy population is the basis of National Equity and Development. The aim of research is to produce the evidence base necessary for optimum Health Systems and Services. In addition to active in- country research, this would involve critical review of the global evidence base, its adaptation for National conditions and communication to Policy makers.*

- ii. 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.**

*The evidence available for health strategies should be operationalised. The operational research necessary for this, based on a full understanding of National Programs, is one of the responsibilities of the researchers.*

- iii. Foster translational research to ensure that the products of basic research can be appropriately utilized in health systems and services.**

*Findings of basic and laboratory research have to be translated so that they can be applied to promotion of public health. This would require a diversity of expertise in addition to basic science such as epidemiology and clinical research.*

- iv. Encourage the development of fundamental research in areas relevant to Health, such as Physiology, Biochemistry, Pharmacology, Microbiology, Pathology, Molecular Sciences and Cell Sciences, to ensure that a national critical mass of Scientists who can contribute the benefits of modern technology to Health research is developed.**

*A critical mass of health researchers can only be built up by developing a research culture in the educational institutions. This would require strong links between medical colleges and research institutions and close supervision by the National Health Research System.*

- v. **Facilitate priority setting to guide the direction of health research and prepare rolling planning and strategy documents.**  
*Priority determination in health research is an on-going process and has to be done at intervals. Groups of experts would have to be convened in individual areas (example communicable diseases, non-communicable diseases, maternal and child health) and also multidisciplinary experts groups including social sciences, health economic etc. these groups would identify priorities linked to setting goals to be achieve in a time bound fashion.*
  
- vi. **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 technological, information and research excellence already in the country should be recognised and should form the basis of a major capacity building process to enhance the quantum of relevant research carried out in the country. Where essential, International resources should be judiciously used for capacity building.*
  
- vii. **Ensure that the global knowledge base is available for National programs, and that research is channelled in relevant directions without unnecessary duplication by the optimal use of Information, Communication and Networking technology.**  
*There is a large volume of research results available globally and it is essential to ensure that national research does not unnecessarily duplicate available evidence which only requires operational research to be implemented in national programs. The optimal use of modern I, C & N technology are essential for this. A beginning has been made by the National subscription to the Cochrane Review and the access to consortium of e-libraries.*
  
- viii. **Manage global resources and transnational collaborations optimally to ensure that collaborative health research primarily facilitates the development of National Health Systems and Services.**  
*The world is developing into a global village, but there is a danger that in all research sponsored transnationally, priorities may not be focussed on National needs. The policy would require that the paramount nature of the priorities of the National Health System and Services is ensured.*
  
- ix. **Ensure true intersectorality of health research and harness the resources in areas such as Social Sciences, Economics and traditional systems of Medicine.**  
*Health is not just the concern of modern Medical Science. Health Research should be holistic and ensure that resources in Anthropology, Sociology, Economics and Education are optimally used to solve the real problems of the people.*
  
- x. **Optimum harmonisation of National Policies in a variety of areas (Education, Social Sciences, Population, Agriculture, Nutrition, Trade,**

**Commerce, etc) is essential to facilitate intersectoral collaboration and partnership, so that maximum developmental returns can occur from Health research.**

*Health as a developmental mechanism is truly intersectoral and harmonisation and coordination is essential for realising its full potential.*

- xi. Develop a mechanism for research on policy issues that impinges on health**

*This is essential to facilitate decision making by the policy makers*

- xii. A National Health Research Management Forum should be established as the body responsible for evolving, harmonising and evaluating the implementation of the National Health Research Plan.**

## **Underlying Values of National Health Research System**

- **Health Research as an investment**  
Health Research should be considered as a necessary investment for health as well as overall development. Its value as an investment for a healthier population and as a cost- beneficial entity is recognised and acknowledged.
- **Equity**  
A commitment to addressing the problems of the vulnerable segments of the population, in order that the benefits of research are accessible to them.
- **Ethics**  
A commitment to the ethical practice of health research. The current guidelines will be periodically reviewed and given the force of law.
- **Self-reliance**  
Self-reliance in financing, human resource development and upgradation of infrastructure and the sovereign right to determine priorities and set out strategies.
- **Ownership**  
All stakeholders in the research process will have the right to participate in and have access to the outcomes of the research. These rights of individual citizens to be aware of and participate in the fruits of research shall be protected.
- **Solidarity**  
A spirit of solidarity will be promoted among all the stakeholders in the Indian Health Research System
- **Development of a Research Culture**  
It is essential to inculcate a research culture among all concerned with the health sector, in order that the value of research and of researchers is recognised, and a supportive environment for research is created at all levels.
- **Intersectorality**  
The essentiality of intersectoral cooperation in health and development will be recognised, and made more effective and meaningful.
- **Partnerships**  
Partnerships within the country, and outside would be essential to derive the maximum possible benefit from research endeavours. While strengthening and expanding partnerships the sovereign rights of the country will be protected.
- **Accountability**

Researchers, managers, policy makers and decision-makers will be accountable. The criteria for accountability will not only relate to monetary matters, but also include the translation of research into action.

## **Strategy for Assessment of the Health Research System**

In view of the plurality of the health research system, the strategy for assessment must have a much broader perspective in dealing with multiple stakeholders of research funding agencies, leaders, managers and research investigators in the system. The proposed research architecture is expected to contribute to the strategic vision and goals of the health research system that can be assessed against a set of criteria. The following criteria are proposed :

**Robustness:** The architecture of the health research system should be such that it should advance health research for development. All the organizations within the health research system should pay attention to the goal of equity. The National Health Research Management Forum should ensure the comprehensiveness of the national research architecture.

**Competence and Effectiveness:** The structure should allow the formulation of a coherent strategy for achieving reasonable scientific goals. The system should have competent technical advisory committees and ethics committees to ensure the achievement of the goals and means. For quality research, there should be mechanisms to review protocols objectively through peer review processes. There should be research committee to monitor the progress of the research. Further, every research organization must have its own research, administrative and audit system adapted from well-tested practices and experiences of others. Apart from using research for policy and programs, emphasis should be given to publication of research findings in internationally peer-reviewed scientific journals.

**Credibility and Accountability:** The research system should be responsive and sensitive to the concerns of various stakeholders. For this, appropriate mechanisms would be developed to get feedback and disseminate evidence among stakeholders of the health research system. The research system should hold forth the promise of achieving the goals of equity and development through not only good quality research, but also cost-effective research. There should be good financial auditing of research to ensure fiscal responsibility and accountability. The health research system should provide a high standard of stewardship.

**Ability to Champion the cause of Health Research for Development:** The research structure should be able to articulate effectively the significance of health research for development at various levels. Such an effort should start at the National Health Research Forum and move down to community level.

**Ability to Generate Research Funding:** There should be a conscious effort to set aside a significant proportion of funds of health programs for health research. Research organizations should be able to attract funding through their credibility from international funding agencies. Government should provide tax and other incentives for the private sector setting aside research funds.

**Research Governance and Management:** A responsive and responsible governance and management structure needs to be developed in every research institution. This may be in the form of governing bodies or oversight bodies or auditing mechanisms. While facilitating the goal of development and equity, it should also show the responsibility and accountability to the stakeholders in terms of quality of research and financial accountability. Such a body will also strictly monitor the ethical aspect of health research.

**Cost-effectiveness:** Stewardship, quality assurance, administrative and financial audit should be in place to ensure increased yields in research productivity and financing as well as in meeting the broader goals of health research for development and equity. Timeliness of conducting research should be ensured.

***Relevant extract from National Commission on Macroeconomics and Health, Planning Commission's Working Groups for 11<sup>th</sup> Plan on Communicable and Non-communicable diseases and on Health System Research, Biomedical Research and Development and Regulation of Drugs and Therapeutics along with the Report of the Performance Appraisal Board of the Indian Council of Medical Research***

**India's Future Health Challenges**

**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 undertake 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 numbers 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 64.1 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 the 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 foodstuffs 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 [PUT FIGURES OF NFHS 3]**

According to the National Rural Health Mission, 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 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.

## **Other Challenges**

### **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. 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.

### **Shift from Medical to Health Research**

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 and normalcy and contributes to functioning of society.

No amount of pure bio-medical 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 influence disease burden.

Health care does not end once the fever is down and stitches are out. Disease 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 research 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 in Millennium Development Goals (MDGs) meeting the objectives of the National Rural Health Mission, addressing the Government's Common Minimum Needs Programme

***Relevant extract from National Commission on Macroeconomics and Health, Planning Commission's Working Groups for 11<sup>th</sup> Plan on Communicable and Non-communicable diseases and on Health System Research, Biomedical Research and Development and Regulation of Drugs and Therapeutics along with the Report of the Performance Appraisal Board of the Indian Council of Medical Research***

**Health Research Priorities**

**Good governance of health research**

There is a need to 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 rise. 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. High priority should be given to knowledge management.

**Health System Research**

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 include Intervention research for seeking evidence useful for policy making; Creating good evidence based on impact of public-private partnerships on the public health services, and whether they really bring about the equity in health access; studies on health insurance; urban health; violence and health care in conflict situations; health care in disaster situation; gender and health; 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.

**Strengthening health research in medical colleges and other institutes**

It is essential 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 address important health issues.

The best ideas of the researchers across the full spectrum of health research should be funded allowing them to pursue their own creative ideas for novel and significant research projects. At the same time, this foundation of research excellence should be built through targeted research investments focused on emerging opportunities and challenges.

Thus, the support for multidisciplinary and multi-sectoral teams of researchers as well as individual researchers working in medical colleges, universities and research institutes would have to be increased.

Research should be given top priority in medical education. In consultation with the Medical Council of India, a formal programme of medical research would have to be introduced in undergraduate and postgraduate level curriculum so that research is made a core requirement for career advancement.

### **Strengthening of Research Networks**

There are areas that have enormous potential in upstream research markets and need to be exploited utilizing both the vast geographical reach and the pool of talent available within research institutions/ colleges and Universities in the country. Launching network projects would enable emerging areas to be gainfully exploited. The focus is on adding value through sharing of resources and the expertise of individual institutes in multi-disciplinary projects. Some examples of research networks are ICMR Schools of Public Health, Tuberculosis Network, Networking of Virology laboratories, HIV Network, Vector borne diseases Network

### **Emergency Outbreak / Disaster Response Fund**

A rapid outbreak / disaster response fund to strengthen response to infectious disease outbreaks or a natural or manmade disaster through timely research and intervention has to be established. The Fund would ensure rapid mobilization of response. At times crucial days are lost in trying to mobilize funds for sending teams, purchase of diagnostics kits or reagents or vaccines or a piece of equipment. It becomes difficult to divert funds from already committed resources. Rapid detection, identification and response are key to saving lives. This delay could mean the difference between a limited number of affected population or a major epidemic with large casualties.

### **New emerging and re-emerging infectious diseases**

Research plays a critical role in dealing with emerging and re-emerging diseases. It could help to identify the agent, develop diagnostic tests, formulate case management modules and preventive strategies. Knowledge needs to be generated through research and interpreted, evaluated and transferred to improve practices for prevention and control of emerging infectious diseases. Most research is incremental, building on existing knowledge to find useful advances. Entire range of emerging infectious diseases and factors influencing them need to be understood in the Indian perspective by understanding:

- ▶ *environmental factors* which facilitate emergence, maintenance and transmission of these diseases especially the vector borne and zoonotic infections.
- ▶ *evolution of pathogenic infectious agents* resulting in changes in infectivity, virulence, transmissibility and adaptations based upon identification of changes at molecular level especially in genetic composition of the organisms
- ▶ *host factors* that facilitate emergence of infections and their spread include use of antimicrobial and immuno-suppression drugs and that of protective factors in a host
- ▶ *social inequalities and behavioural factors* that influence distribution of emerging diseases, their course and populations that are affected most
- ▶ *impact of environmental changes* and climatic variability on the emergence of microbes

A chain of laboratories with appropriate levels of biosafety would have to be set-up so that new, exotic and dangerous organisms could be handled without posing threat to the scientists, technicians and the environment. This would be needed for animal studies and development of diagnostic tools which can support rapid and accurate diagnosis even in field conditions. To tackle this threat it would be necessary to enhance biomedical applications of new technology such as remote sensing and GIS to improve ability to predict future infectious diseases outbreaks; mathematical models that can facilitate transmission dynamics and vaccines and other interventional tools.

### **Translational research**

To develop evidence-based medicine and healthcare translating basic research outcomes into clinical evaluation and ultimately into health policy and practice in the national health systems is essential. This will enable a better assessment 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.

Promising ideas for novel therapeutic interventions may encounter roadblocks in bench-to-bedside testing. Effective public private partnerships could facilitate translational research.

### **In-country Partnerships**

Partnerships are integral to the health research. They are about shared vision, common objectives and alignment of priorities and programs. 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 would be designed to meet the needs of a jointly agreed initiative whilst respecting the autonomy of individual participants. By building partnerships amongst its stakeholders – those that have an interest and stake in health, the health system, and health research – it will be possible 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.

### **Mission-mode Projects**

Mission projects akin to those seen in other sectors such as agriculture, atomic energy and aerospace will have to be undertaken. These mission projects would have to be identified with care taking into account core competencies of research institutions, its comparative advantages, the strength of its national and international linkages and finally sustainability. Some examples of Mission mode projects that could be undertaken are in on Capacity building for epidemic forecasting and investigations, diagnostics for viral diseases, Stem cell research, development of predictive markers for diseases, use of Nanotechnology in health research, development of clinical trial sites etc.

### **International collaborations**

As globalization increases, international collaborative research will also increase. International collaborative health research must extend beyond clinical trials. Without effective international cooperation there would be limited access to breakthrough scientific knowledge generated by researchers in other countries; the quality of the scientific knowledge generated locally would decline and; industries would not be able to obtain innovative technological information needed to maintain their competitive edge. Institution to institution collaboration involves long term linkages between two institutions, characterized by multidisciplinary involvement and providing opportunities for development of variety of projects. Recent interest in promoting private-public partnerships has led to the expansion of linkages between scientists in research institutions and pharmaceutical companies. These projects are aimed at accelerating the translation of research in to usable products through innovative partnerships. Collaborations developed through international network or global consortiums have also been encouraged. Groups of scientists having a common interest in a specific research area (e.g. diabetes) are brought together through these networks. They are helpful in providing access to scientific information, and data bases mutual support technical assistance. The future of the health system depends on having a critical mass of health scientists with the international knowledge and intercultural skills necessary to meet globalization's challenges.

### **Environment and Health**

Human health risk assessment is essential to provide a qualitative and quantitative characterization of the relationship between environmental exposures and effects observed in exposed individuals. Research to improve human health risk assessment is based on the assumption that major uncertainties in risk assessment can be reduced by understanding and elucidating the fundamental determinants of exposure and dose and the basic biological changes that follow exposure to pollutants leading to a toxic response. The focus of such research need be on including harmonizing human health risk assessments, predicting aggregate/ cumulative risk, and protecting populations.

### **Human Resources Development for Health Research**

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 would have to be identified.

The human resource and skills required for meeting the current demands and future challenges is abysmally low. In a population of a billion, only a very small number is engaged in health research. Strengthening research capacity is an area of priority. Some of the areas in which human resource is needed include social sciences as related to health, 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, Drug Chemistry etc.

### **Investing in interventions with high cost-benefit ratio and 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 baseline scenario) is almost 3 times as great as 1.4 year increase that faster decline in non-communicable diseases would produce.

### **Critical Infrastructure Protection**

Prior to the recent focus on bio-terrorist attacks, little thought has been given to the protection of critical health research infrastructure. Previously the only threat facing infrastructure came from natural disasters, and malfunctioning of appliances. To adequately address infrastructure protection an analytical process has to be implemented to identify vulnerabilities. As not all critical infrastructure can be protected from all threats appropriate risk management techniques would be used to determine relative duration, and the level of protective security. As bioterrorism preparedness is expensive, priorities would have to be set for allocation of resources and the application of the best mitigation strategies.

## BACK COVER

### **Health Research Policy**

A clearly defined Health Research Policy on the lines of Science & Technology Policy is the basis for maximising the return on investment in health research.

This Policy aims 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 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 Policy also ensures 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.