F.No. T.11014/01/2020-HR
Government of India
Ministry of Health & Family Welfare
Department of Health Research
*****

2nd Floor, IRCS Building
New Delhi-110001
Dated: 03.11.2021

Public opinion

The Government of India is in the process of formulating the 'National Health Research Policy' (NHRP) for the next 10 years which will be an enabler and a driver for the national health research efforts that has a positive impact on national development – whether in terms of health of our people, performance of healthcare services delivery, health equity or for more general social and economic development.

2. After holding number of in-house brainstorming sessions of Core Committee (CC) and Working Group (WG) and taking into account suggestions of stakeholders, draft NHRP has been prepared (copy enclosed). It provides a blueprint for putting in place a robust system for health research which would include capacity building in terms of human resources and infrastructure, training, involvement of private sector, list of priority areas which would be dynamic to align with and serve the state priorities and mechanism to put health research outcomes into the public healthcare systems.

3. It is requested that suggestions on different aspects of NHRP may be provided to this Department so that it could become a comprehensive document to cater to the requirement of health research sector of the country. Since it is a time bound exercise, shall be grateful if you could provide your suggestions by 15.11.2021 on email id-nhrp.dhr@gmail.com.

(Vinod Kumar)
Deputy Secretary

National Health Research Policy- 2021

Department of Health Research

Ministry of Health & Family Welfare

Government of India

New Delhi

Contents

ABBREVIATIONS

CBO	Community Based Organization
COPD	Chronic Obstructive Pulmonary Disease
CSR	Corporate Social Responsibility
CSIR	Council of Scientific and Industrial Research
CVD	Cardiovascular Diseases
DALY	Disability Adjusted Life Year
DBT	Department of Biotechnology
DHR	Department of Health Research
DST	Department of Science and Technology
EDP	External Development Partners
GCP	Good Clinical Practices
GDP	Gross Domestic Product
GLP	Good Laboratory Practices
ICMR	Indian Council of Medical Research
IC&N	Information Communication & Networking
IDA	Iron Deficiency Anemia
IMR	Infant Mortality Rate
IHR	International Health Regulations
IEC	Institutional Ethics Committee
IPR	Intellectual Property Rights
KFD	Kyasanur Forest Disease
HIV	Human Immunodeficiency Virus
MCI	Medical Council of India
MDG	Millennium Development Goals
MDR-TB	Multi-Drug Resistant Tuberculosis
M & E	Monitoring and Evaluation
MoHFW	Ministry of Health & Family Welfare
MP	Member of Parliament
NCD	Non Communicable Diseases
NCMH	National Commission on Macroeconomics and Health
NGO	Nongovernmental organization
NFHS	National family Health Survey
NHP	National Health Policy
NHRP	National Health Research Policy

NHRPB	National Health Research Policy Board
NHRS	National Health Research System
NRHM	National Rural Health Mission
NUHM	National Urban Health Mission
ORS	Oral rehydration solution
PPP	Public Private Partnership
R & D	Research and Development
STI	Science, Technology & Innovation
U5MR	Under 5 Mortality Rate
UK	United Kingdom
UN	United Nations
US	United States
VAD	Vitamin A Deficiency
WHO	World Health Organization

DEFINITIONS

Health Research: It refers to the process for systematic collection, description, analysis, and interpretation of data that can be used to improve health.

Health Research Systems: The people, institutions, and activities whose primary purpose is to generate high-quality knowledge that can be used to promote, restore, and or maintain the health status of populations. It can include mechanisms adopted to encourage the utilization of research.

Biomedical Research: The area of science devoted to the study of the processes of life, the prevention and treatment of disease, and the genetic and environmental factors related to disease and health.

Basic Research: Research conducted to increase the base knowledge and understanding of the physical, chemical, and functional mechanisms of life processes and disease.

Clinical Research: It embraces a continuum of studies involving interactions with patients, diagnostic clinical materials or data, or populations in any of the following categories: (1) clinical knowledge, detection, diagnosis and natural history of disease; (2) therapeutic interventions including development and clinical trials of drugs, biologics, devices, and instruments; (3) prevention (primary and secondary) and health promotion and (3) community-based and managed care-based trials.

Public Health Research: It aims to shed light on the influence of the determinants of health, i.e. factors (genetic, environmental, social, etc.) which determine population health.

Operational Research: It is the discipline of using models, either quantitative or qualitative, to aid decision-making in complex problems.

Implementation Research: It is the scientific enquiry into questions concerning implementation. The basic intent of implementation research is to understand not only what is and isn't working, but how and why implementation is going right or wrong, and testing approaches to improve it.

Translational Research: Interdisciplinary branch of biomedical science that the application of scientific observations to the human condition, a process that involves many steps from conception of the problem to its ultimate application.

Health Systems Research: that seeks to understand and improve how societies organize themselves in achieving collective health goals, and how different actors interact in the policy and implementation processes to contribute to policy outcomes.

By nature, it is interdisciplinary, a blend of economics, sociology, anthropology, political science, public health and epidemiology that together draw a comprehensive picture of how health systems respond and adapt to health policies, and how health policies can shape − and be shaped by − health systems and the broader determinants of health.

Private sector: It represents part of the economy, which is operated by an individual or group with the underlying objective of maximizing profits.

Monitoring: It refers to ongoing assessment of our progress. It should be set up as part of our routine programme management and is ideally done by both programme and community members together. It uses the record systems we have built into the programme.

Evaluation: It refers to a systematic review of the programme outcomes and impact often at the end of a funding cycle. It often involves an outside evaluation team.

Open access: It refers to the practice of making scholarly outputs freely available with unrestricted re-use online for everyone.

Modelling: Modelling studies are used widely to help inform decisions about health care and policy and their use is increasing. A model is "an analytical methodology that accounts for events over time and across populations, that is based on data drawn from primary or secondary sources…" and in the context of health care-evaluation "…whose purpose is to estimate the effects of an intervention on valued health consequences and costs". Its value lies not only in its results, but also in its ability to reveal the connections between its data and assumptions and model outputs.

Bench to bedside research: A term used to describe the process by which the results of research done in the laboratory are directly used to develop new ways to treat patients.

Research dissemination: It refers to the process of sharing research findings with stakeholders and wider audiences. Dissemination is essential for uptake, and uptake and use of research findings is crucial for the success and sustainability of practice-based research networks (PBRNs) in the long term.

Health economics: Health economics is a branch of economics concerned with issues related to efficiency, effectiveness, value and behavior in the production and consumption of health and healthcare.

Health technology assessment: Health Technology Assessment engages in explicit and evidence-based priority setting of health resources towards providing universal

health coverage for all individuals. It helps to bridge the evidence to policy gap and ensures alignment of academic and policy interests through HTA towards the common goal of improving decision-making for health resource allocation to improve the health of the population.

Integrated Approach: An integrated research approach involves multidisciplinary stakeholders from the start and guides them through the entire process.

1. Introduction

The health-care system across the world has witnessed a major revolution with rapid strides in technological advances. The increased longevity of the human race today has been the result of decades of medical research worldwide, resulting in improvements in diagnosis and treatment. No wonder, medical research assumes huge significance globally. Given the fact that India contributes to a fifth of the world's share of diseases, the health research output needs to be substantially increased in order to meet the challenges ahead. Research is an integral part of learning, development and innovations in any subject. It is one of the key areas which help in advancement of science. In Medical Sciences, it is important to produce documents with evidence-based medicine, which helps in better understanding of the subject. Research helps to refresh and update the entire knowledge of the subject and thus, pave the path for further addition, improvement. Medical education and medical research are non-separable components of healthcare. Health research is of paramount importance as it provides knowledge regarding the health status, diseases relevant to our soil, changing pattern of disease prevalence, treatment strategy to be adopted, impact of various health programs initiated by Government, etc. To remain globally competitive, the need-based clinically oriented research useful to patients in particular and general public at large is crucial and hence, quality research is the need of the hour focusing on health research.

Further, the approach of conservation of resources and resource sharing needs to be adopted which will contribute to understanding the role of resources in research use, resistance to research use, and potential strategies to enhance research use. Resources (and a lack of them) may account for the observed disparities in research uptake across health systems. Resource sharing is a complement to other means of improving biomedical science. Adopting a culture of transparency and openness will help advance science and, by reducing the number of nonreplicable findings, accelerate the identification of knowledge to inform clinical and population-level interventions to improve health.

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 number of Government Departments namely Department of Health Research, Department of Science and Technology, Department of Bio-Technology, Department of Atomic Energy, The Council of Scientific & Industrial Research, Indian Council of Medical Research, National Institutes, Autonomous Research Institutes, University Grant Commission, Universities and other Academic Institutions and variety of private organisations, including the Pharmaceutical Industry support/carry out/fund health research in the country. 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 right to health as an integral component. India is making significant investments in health and health research, but so far a Health Research Policy could not be 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 is essential that a Health Research Policy is laid down to channel efforts and funds in 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.

The National Health Research Policy to be formulated should include economic development, social inclusion and environmental sustainability for achieving an “Atmanirbhar Bharat", emphasizing upon promotion of knowledge system, developing indigenous technologies and encouraging start up new technological innovation which will be cost saving with maximum efficacy.

COVID-19 pandemic has underlined the need for undertaking collaborative medical research by Research and Development (R&D) institutions, academia and industry to make India self-sufficient with a dynamic Health infrastructure to fight any such pandemic situations in the future.

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". It accepted that health was central to development and had a focus on access to health services, especially for rural population. While much was achieved in health services infrastructure development, the health service system continued to be plagued by widening inequities in access to healthcare and the quality of care. The need for an evidence base was not recognized 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 a sound public health care system addressing health care issues of all segments of the society thereby helping to achieve the objective of health for all.

The National Health Policy 2002 (NHP 2002) reviewing the current scenario recognized 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. Inequity in health care access is still continuing at a time when ‘Health Tourism’ is being promoted.

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 about1% of the health budget is set apart for Health Research. NHP 2002 envisaged 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, need of the hour that a Health Research Policy is formulated to ensure that these goals are met.

Subsequently, the National Health Policy 2017 aimed to inform, clarify, strengthen and prioritize the role of the Government in shaping health systems in all its dimensions- investments in health, organization of healthcare services, prevention of diseases and promotion of good health through cross sectoral actions, access to technologies, developing human resources, encouraging medical pluralism, building knowledge base, developing better financial protection strategies, strengthening regulation and health assurance (insurances).The policy envisages as its goal the attainment of the highest possible level of health and well-being for all at all ages, through a preventive and promotive health care orientation in all developmental policies, and universal access to good quality health care services without anyone having to face financial hardship as a consequence.

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. 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.

The new Science, Technology, Innovation (STI) Policy aims to bring about profound changes through short-term, medium-term and long-term mission mode projects by building a nurtured ecosystem that promotes research and innovation on the part of both individuals and organizations. It aims to foster, develop, and nurture a robust system for evidence and stakeholder-driven STI planning, information, evaluation and policy research in India. The policy identifies and addresses strengths and weaknesses of the Indian STI ecosystem to catalyse socio-economic development of the country and also make the Indian STI ecosystem globally competitive.

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 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, have the potential of further accentuating 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. Despite overall gains in health sector 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 longstanding 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 world-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.

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. The following table shows budgetary allocations to the Department of Health & Family Welfare and the Department of Health Research:

(in Rs. Crore)

Year	Budgetary allocation to D/o Health & Family Welfare	Budgetary allocation to D/o Health Research	Allocation to DHR as % of allocation to DoHFW
2015-16	32819.00	1012.60	3.08%
2016-17	38343.33	1344.80	3.51%
2017-18	51550.85	1743.39	3.38%
2018-19	54302.50	1742.73	3.21%
2019-20	62659.12	1950.00	3.11%
2020-21	78866.00	4062.30*	5.15%*
2021-22	NA	NA	

**Due to additional allocation of Rs.2100 crores in 2020-21 for Covid-19.*

The United Nations in 2015, set 17 Sustainable Development Goals (SDGs) and 169 targets aimed at building a more prosperous, more equal, and more secure

world by the year 2030. These have been adopted by 193 Member States, including India. The SDGs are the result of an exceptional consultative process that brought international community together to adopt the path to sustainable development for the next 15 years.

The present situation of COVID-19 which was declared a pandemic on the 11th of March 2020 also emphasizes on the need for clearly defined health research projects. The WHO has also emphasized the need for Health Research in the World Health Assembly document.

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 are 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.

Unlike medical research, health research is comparatively a new concept. It goes beyond illness to include the research into the various determinants of illness as well as health. Health research, therefore, is systematic generation of knowledge that can be used to promote, restore, maintain and/or protect health of individuals and populations. 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. 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.

Establishment of Department of Health Research (DHR) in the Ministry of Health &Family Welfare (MoHFW) in 2014 was a step by Government of India to underscore the key role that health research should play in the national health sector including policy formulation, generation of evidence based drugs, devices, vaccines, medical procedures etc. The Department has been mandated to

undertake Studies related to Health research and clinical Trials. For fulfilling its mandate, the Department of Health Research has formulated the following schemes:

(i) Establishment of Network of Research Laboratories for Managing Epidemics and National Calamities (VRDL).
(ii) Establishment of Multi-Disciplinary Research Units (MRUs) in Government Medical Colleges/Research Institutes
(iii) Establishment of Model Rural Health Research Units (MRHRUs) in States
(iv) Human Resource Development (HRD) for Health Research.
(v) Grant-in-Aid (GIA) Scheme for inter-sectoral Convergence & Promotion and Guidance on Health Research.
(vi) Health Technology Assessment in India (HTAIn).
(vii) International Cooperation.
(viii) Development of Tools/support to prevent outbreaks of epidemics.

The weakness of the publicly funded health structures and the research infrastructure is a key limiting factor in realizing the full benefits of this commitment to research. The fact that the almost 281 Government medical colleges and 261 private Medical Colleges in the country are not contributing of their best to health research is highlighted by the fact that in 2018, 89% of the research publications in India emanated from top 15 medical colleges. Much of this published research is not on priority health concerns and the translation of key research findings into policy which could improve the health of the people is very limited and needs to be enhanced. Epidemiological know-how, surveillance technology and diagnostic services which are essential for determining health priorities are very poorly developed. With the launch of the National Rural Health Mission (NRHM) and the National Urban Health Mission (NUHM), the enhancement of the above described infrastructure to provide the evidence base for policy and programme becomes a critical issue. 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 evaluation of diagnostics and trials of drugs, devices of both modern and traditional systems of medicine.

Health is also now recognised as a fundamental issue in National Development and a factor that promotes equity. A clearly defined Health Research Policy with well defined vision, mission, strategy and deliverables therefore is the basis for maximising the return on investment in health research. It is expected that such a policy will give special attention to the health problems of socially underprivileged groups (tribes, women, other marginalized groups) and difficult/inaccessible areas.

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, inspite of the handicaps and difficulties, contributions have been made in the health sector through research done in India which have significantly changed the health scenario. Some examples of such contributions would include:

- the identification of emerging or remerging infections (Kyasanur Forest Disease, *Vibrio cholera* 0139, resurgence of leptospirosis, adult variants of measles, HEV, Dengue, Chikungunya);
- development of diagnostics (Japanese encephalitis, Dengue, Hepatitis A, Group A Rotavirus, Malaria, Kala Azar, 0139 cholera, Hepatitis *C, Chikungunya,* TB diagnostics development like GeneXpert*);*
- development of vaccines (COVID-19, 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, rotavirus);
- development and operationalisation of treatment regimens (short course chemotherapy for TB, multi-drug therapy for leprosy)
- 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 for contraception, dysfunctional uterine bleeding, breast and ovarian cancer; Artether for treating malaria);
- 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 anti retroviral therapy for HIV;
- developing the Ethical Guidelines for Biomedical research on Human Subjects in India(2016);
- Development of Clinical Trial registry in India;
- Establishment of screening programs for cancer, Dialysis program, neonatal programs, Mental health programs and geriatric care programs
- Establishment of National Data Quality Forum (NDQF): It is a multi-stakeholder collaborative platform for a sustained dialogue among the producers and consumers of demographic and health data in India on issues related to data quality and potential solutions, and for supporting institutionalization of promising solutions.

The contributions of the pharmaceutical industry including vaccine manufacturers and biotechnology companies (for Covid vaccines, Rotavirus vaccines, Bio-similars) in making available at affordable cost almost all drugs/vaccines and medical devices/equipments 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 coordinated efforts of a number of agencies of the Government, especially in the Ministry of Health and Family Welfare, Indian Council of Medical Research, the Ministry of Science and Technology, Department of Biotechnology, Department of Science and Technology, 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. Some of the identified constraints are:

- 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.
- Medical colleges have very few physician-scientists, who have high quality original research programs. It follows that medical students do not have adequate role models or mentors to prepare them for a research-centric career. This track is different from that of an academic clinician, whose primary role is patient care, with research as an additional output. The difference is subtle but critical in terms of the type of research undertaken at even the apex medical institutions and leaves even the best trained graduates unprepared for genuinely research-focused careers. Major structural changes within the system will be needed to develop and promote such physician-scientists. This is difficult but necessary if transformative changes are desired. Else, any change will be incremental and a health research ecosystem that produces high-value discoveries will remain as unlikely as before.
- National coordination of the considerable investment in research in the health sector is currently not done.
- A 'research culture' and a ‘climate’ that fosters health research are not present. In fact many scientists feel that they sub-serve a bureaucratic 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.
- Inter-sectoral 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.
- The duplicacy of research work is another concern.

3. Vision of National Health Research Policy

The Vision of National Health Research Policy is to maximize the returns on investments in health research through creation of a health research system to prioritize, coordinate, facilitate conduct of effective and ethical health research and its translation into products, policies and programs aimed at improving health especially of the vulnerable populations.

4. Objectives of National Health Research Policy

A well designed health policy framework is an enabler and a driver for the national health research effort that has a positive impact on national development - whether in terms of health of our people, performance of healthcare services delivery, health equity or for more general social and economic development. Infact, National Health Research Policy needs to be founded on principles which ensure that the research that is conducted:

(i) Identifies priorities for effective and ethical health research to enable the achievement of the objectives of National Health Policy, NRHM, Bharat Nirman and National Food security Act as well as global commitments such as Millennium Development Goals (MDG) and International Health Regulations (IHR), ensuring that the results of health research are translated into action;

(ii) Is of high scientific quality and is conducted in an ethical manner which meets international scrutiny;

(iii) Is sustainable and results from strengthening of local institutional and individual capacity as well as on judicious use of resources;

(iv) Is collaborative between different disciplines, sectors and among internal and external stakeholders and partners and also encourages public private partnership;

(v) Occurs in an enabling environment that incentivises and encourages research and researchers;

(vi) Is used for decision making by Government and other stakeholders and is translational;

(vii) Is oriented to individual, public/community good with special focus on the marginalized, the vulnerable and the disadvantaged sections of society;

(viii) Puts in place strategies and mechanisms for assessing the cost-effectiveness and cost benefits of interventions for health;

(ix) Develops and manages human resources and infrastructure for health research and ensures that international collaborative research contributes to national health and is in tune with contemporary global health research.

5. National Health Research System (NHRS)

In order to achieve inter-sectoral coordination and to make national priorities for health research, a new architecture of national health research system is envisaged. Health research system is a concept that integrates and coordinates the objectives, structures, stakeholders, processes, cultures and outcomes of health research towards development of equity in health and in national health system. It is a system for planning, coordinating, monitoring and managing health research resources and activities, and for promoting research for effective and equitable national health development.

Health Research in the country would 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.

5.1 NHRS shall:

- Generate and communicate knowledge that helps to form the national health plan and guides its implementation, and thus contribute, directly or indirectly, to equitable health development in the country;
- Adapt and apply knowledge generated elsewhere to national health development; and
- Contribute to the global knowledge base on issues relevant to the country.

5.2 Underlying values of NHRS

The NHRS can only be viable if there are strong underlying values which recognize that health research is an investment which is equitable, based on ethics, owned by the people and leads to development of the Nation. Some of these values are:

- **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.

- **Originality** : Focus will be on original thinking so as to become a society of original thinkers and innovators. This will both ensure affordable tools/ products for our population as well as globally competitive and respect in the international arena.

- **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.

5.3 Functions of NHRS

The National Health Research System would be responsible for:

(i) Developing National Health Research Plan
The DHR is responsible for the National Health Research Plan aligned with the National Health Plan and its implementation and monitoring.

(ii) Set priorities
A Priority Research Agenda will be developed in tune with the National Programmes, and relevant to national and local needs, based on the following principles:

a. **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.

b. **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.

c. **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.

d. **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.

e. **Focus on vulnerable and disadvantaged population:** Equity in services and development shall be the cardinal principle under riding the Health Research System. There shall be a special emphasis on vulnerable groups like scheduled castes, particular vulnerable tribal groups (PVTGs), unorganized labour, women, children, adolescents, North East 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.

(iii) Engage with Private Sector

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 stake holders in Health care research and delivery. The National Health Research System would recognise their important role in health research and shall foster their participation in the system as partners. These engagements have to be concurrent and intense rather than linear and loose.

(iv) Strengthen International Linkages

In the current global scenario International collaborative efforts are recognised as one of the factors in successful research because of the complimentarity 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 to ensure that India plays a legitimate role as an emerging economy.

(v) Ensure Ethical Research

The Bill on Research on Human Subjects and establishment of the National Biomedical Research Authority therein along with the guidelines developed by other agencies shall regulate all research. The Health Research System shall review these Guidelines from time to time, and harmonise them with International Guidelines. Facilitation of training in ethical research shall be the responsibility of the DHR. A major achievement has been the establishment of a National Clinical Trial Registry and all clinical trials are mandated to be registered by the DCGI.

(vi) Ensure 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. The NHRS would track the resources available and spent on research in the country and monitor its impact on health. Though a minimum of 2% of health expenditure has been achieved, 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.

(vii) Monitor and Evaluate impact of health research

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. Set mechanisms to ensure that best practices are encouraged, and practices are evidence based.

(viii) Partnership with State health system.

Encourage health research within States. Help set state level health research system by strengthening partnership between central and state systems.

(ix) Assess Health Research System

The health research system would need to be assessed periodically to provide evidence that it is functioning optimally. A suggestive strategy for the assessment of the health research system is given below:

5.4 Strategy for Assessment of the National 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.

The NHRS shall be managed by a **National Health Research Management Board (NHRMB).**

6. National Health Research Management Board (NHRMB)

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 Board is proposed, having representation of all key stakeholders, the DHR 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 an annual National health research plan;
(iii) To do a mid-Plan appraisal for course correction, as needed
(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 and dissemination of research results and advocacy for Health research.

6.1 Composition of NHRMB shall be as under:

Sl. No.	Designation	Position in NHRMB
1	Health & Family Welfare Minister	Chairperson
2	Minister(s) of State for Health & Family Welfare	Vice-chairperson(s)
3	Secretary, Department of Health Research	Member
4	Secretary, Department of Science & Technology	Member
5	Secretary, Department of Biotechnology	Member
6	Director General of Health Services (DGHS)	Member
7	8-10 eminent scientists/ public health experts (number flexible)	Members
8	Selected representatives from State Governments	Members
9	Joint Secretary, Department of Health Research	Member Secretary

NHRMB can also co-opt officials and experts as per the requirement of the research proposal.

These experts would also be the Chairmen of the various working groups which would be constituted to address the following areas:

(i) Development and evaluation of interventions for promotion, restoration, maintenance and protection of health.
(ii) Human resource management and infrastructure development.
(iii) Knowledge management.

(iv) Encouragement to translational research and originality in basic science research, and innovations.
(v) Optimizing intra- and inter-sectoral networks, coordination and collaboration especially with private sector and industry.
(vi) Track current resource flow and future requirements to address priority areas of health research.
(vii) Establishment of priorities for health research.
(viii) Implementation of health research policy, planning, monitoring and evaluation.

6.2 Responsibilities of NHRMB

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, the setting of norms, standards and frameworks for the sound practice of research and providing best practices for research management.

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 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. Ensure that funds are spent objectively.. 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, communities, and media. 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. A synergy with Knowledge Management Policy would be made.

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 including medical colleges and rural health research centres. A situation analysis done periodically would ensure a phased and realistic plan for constructive and sustained capacity development. Thus, both the 'Supply' and 'Demand' sides of the research system needs will be addressed.

Harmonise optimally National policies in a variety of areas (education, social sciences, population, agriculture, nutrition, science, etc) 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.

Ensure true inter-sectorality 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.

Facilitate priority setting to guide the direction of health research and prepare Five-year Plan and strategy documents. Priority determination in health research is an on-going process and has to be done at regular intervals. Groups of experts would be convened in individual areas (example communicable diseases, non-communicable diseases, maternal and child health) and also multidisciplinary expert groups including social sciences, health economics etc. These groups would identify priorities linked to setting goals to be achieved in a time bound fashion.

Encourage the development of fundamental and basic 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 created. A critical mass of health researchers can only be built up by developing a research culture in the educational institutions. Health research would be incentivised. Originality and innovation would be encouraged. This would require strong links between medical colleges, industry and research institutions and close supervision by the National Health Research System. Mechanisms favouring seamless movement of personnel between teaching, research and industry. Schemes to train, maintain and retain skilled human resource would be developed and implemented.

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 including improving access to tools. This would require a diversity of expertise in addition to basic science such as epidemiology and clinical research.

Establish linkages between health research and national health programmes to identify key operational issues and facilitate the operationalisation of evidence based programmes and to obtain feedback for the optimisation of health research. The evidence available for health strategies would be operationalised. Links between the research community and the service components would be strengthened. The operational research necessary for this, based on a full understanding of National Programs, is one of the responsibilities of the researchers.

Build and integrate capacity for research in National Health Programs, research institutions and in the private sector (profit and non-profit organisations) both in rural and urban research settings utilising as far as possible areas of excellence already available in the country. The technological, information and research excellence already in the country would be recognised and 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 would be judicially used for capacity building.

Ensure that the global knowledge base is available for national programmes, 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 is essential for this. A beginning has been made by the National subscription to the Cochrane Review and the access to consortium of e-libraries.

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 as well as the ethics of international collaborative research is ensured.

Generate the evidence-base for health systems and services, to be significant promoters of equity and contribute to national development so that health research becomes a poverty reduction tool. 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.

7. Prioritisation criteria for Health Research

7.1 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. 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 are side nt 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.

In addition NHRP is also to consider the benefits of collaborative research between MoHFW and Census division. This will enable to analyze the health conditions of different geographical areas and to achieve population based health outcomes. Inequalities in healthcare service delivery can also be addressed through this fruitful collaboration.

Disease Burden

(i) Communicable Disease

a. ***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. 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.

b. 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.

c. ***Malaria:*** In1998, Malaria, dengue and some other conditions falling in the category of 'malaria and vector-borne diseases' 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.

d. ***Emerging and 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 diseases surveillance is cornerstone 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.

e. ***Diarrheal diseases in children:*** It is the third most common cause for under five mortality. As per the National Family Health Survey, the prevalence of childhood diarrhoea has increased from 9% to 9.2% from 2016 to 2020 in India. A study shows that under-five mortality and infant mortality (IMR) has been reduced to 50% and 41% in 2016 from 74% and 57% in 2005. Another study revealed that there have been more childhood diarrheal deaths in the states of Uttar Pradesh and Assam than rest of the states of India.

f. **Acute respiratory tract infections:** As per the 2019 report of the National Health Portal of India, 41,996,260 cases and 3,740 deaths from respiratory infections were recorded across India in 2018. India contributes to 18% of the global population, with severe acute respiratory infection (SARI) as one of the prominent causes of mortality in children >5 years of age. Measures in terms of the diagnosis and surveillance of respiratory infections are taken up globally to discover their circulating types, detect outbreaks, and estimate the disease burden. The associated pathogens comprise respiratory syncytial virus (RSV), rhinovirus, influenza virus, parainfluenza virus, adenovirus, etc. Identification of these respiratory viruses was not given high priority until now, but the pandemic of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has sensitized our system to be alert about the burden of existing infections and to have proper checks for emerging ones.

(ii) Non-communicable Diseases

a. ***Cardio-vascular Diseases:*** Starting from a level of about 38 million cases in the year 2005 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. The prevalence rates among younger adults and women (in the age group of 40 years and above) are also likely to increase.

b. ***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 and particularly concentrated in the urban population.

c. ***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.

d. 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.

g. ***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 including 'severe' cases, some of which may require greater levels of care, including hospitalization.

h. ***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 died 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. The toll is expected to rise to 1.1million 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.

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

j. ***Suicide:*** Suicide is a 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 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.

k. ***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.

l. **Degenerative diseases:** These are the result of a continuous process based on degenerative cell changes, affecting tissues or organs, which increasingly deteriorate over time. Neurodegenerative disorders are the most common. The burden of neurodegenerative disorders such as Alzheimer's disease and other dementias and Parkinson's disease has been increasing and is expected to rise further with increases in the proportion of older age groups in India.

(iii) Problems of Urban Health

India's urban population is 481 million which amounts to nearly 35% 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%. 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 healthcare. 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 healthcare for the urban poor a matter of priority. It may be necessary to create a separate unit with multi-discipline expertise to address this .issue.

(iv) Nutritional Problems

The incidence of nutritionally poor population, particularly the rural poor, is quite high in Orissa, Bihar, Madhya Pradesh, Uttar Pradesh and Andhra Pradesh. Another related issue is the problem of *hidden hunger* - as the problem of micronutrient deficiency. While estimates suggest that 800 million people are undernourished, the number of people suffering from micronutrient deficiency is as high as 3.5 billion globally; a very high percentage of these are in India. In India, the magnitude of iron deficiency is perhaps the greatest. Thus, for example, 70% of pregnant women in India suffer from iron deficiency anaemia (IDA) ; and the figure for young children is also high. Between 10 and 20 million children in India suffer from vitamin A deficiency (VAD) and 60,000 annually go blind because of VAD. The consequences of these deficiencies, in terms of impaired physical and cognitive development, disability and mortality are correspondingly staggering. There is a need to develop appropriate vehicles for these micronutrients. With the increase in the availability of processed food and development to 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

According to the National Rural Health Mission, maternal, pre-natal 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 in1998-99(NFHS-II).

Significant improvement has taken place in reproductive health of the population. The couple protection rate has increased from 1.4% in 1970-71to 50-52% in 2002-03 and total fertility rate has declined 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 in justice, 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 healthcare.

7.2 Other Challenges

Technological areas in medicine

Additionally, priority should be given to frontier technological areas such as artificial intelligence, genome editing, gene therapy that will have broad-based implications across multiple diseases and may drive the fast-growing economic sectors within medicine.

Digital Health and Telemedicine

Promotion of research and innovation in the area of Digital Health and Telemedicine is the need of hour. This aspect of health research should also be incorporated for better and inclusive health services in the country. Separate research funds should be allocated to the medical colleges, universities and health institutions for the promotion of digital health research among the medical community.

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 Humans 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 devicesarecurrentlyflowingintoandfloatingaroundthecountry.Thereissevere shortage of technical experts for repairing medical equipment.

Narrow Research Base

Presently 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. 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 of 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 to 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. Diseases are persisting, and/or emerging because of sociological changes, life-style changes, and social disruptions (riots, violence etc.). Diseases are not solely rooted in biological causes, but are multi factorial. 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

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 arise. 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.

Clinical Trials

Clinical trials are a type of research that studies new tests and treatments and evaluates their effects on human health outcomes. People volunteer to take part in clinical trials to test medical interventions including drugs, cells and other biological products, surgical procedures, radiological procedures, devices, behavioural treatments and preventive care.

In India, we can build a network capable of generating high quality evidence of global standards regarding regional and local diseases of public health importance. This would provide evidence-based, cost effective, scientifically proven and culturally appropriate answers to clinical questions with regard to diseases and problems of public health importance. To achieve this, firstly the priority health research areas which will favourably affect the country's health needs are to be identified. Priority areas may be identified by literature review, systematic reviews, review of burden of disease data to ascertain the research gaps.

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 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; healthcare in disaster situation;

gender and health; studies on the use and misuse of medical technologies*:* While more and more healthcare technologies are being introduced in healthcare 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.

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 are as 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 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 changesatmolecularlevelspeciallyingeneticcompositionoftheorganisms.
- *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, their comparative advantages, strength of their 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 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 into 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 databases 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 challenges of globalisation.

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 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 world wide 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 world bring about a significantly larger gain for the poor than would an acceleration of comparable magnitude achieved against non- communicable conditions. The additional 4.1 years of life expectancy that faster progress against communicable ailments would generate (compared to the base- line scenario) is almost 3 times as great as 1.4 year increase that faster decline in non-communicable diseases would produce.

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.

8. Engaging with private sector

Private healthcare sector in India has grown rapidly over last two decades with little policy to guide its growth. It has emerged as major stakeholder in delivery of healthcare delivery services in the country. Private sector has immense capacity to substantially invest in health research but their role can only be realized until investment is accompanied by strong economic returns. Therefore, it is pertinent to realize their role and engage private sector in health research. Engaging private sector would be based on principles of ethics, shared responsibility and mutual benefit and respect.

Strategies for engagement of private sector include:

(i) Mapping of private organizations with high quality research capacity and linking with other research institutes.
(ii) Incentivizing private sector for participation in health research: Government may provide some incentives (exclusive fellowships, grants for project implementation, recognition, felicitation etc.) for encouraging participation of private sector in health research in areas of national and regional priorities. The incentive mechanism should have transparent and efficient governance to ensure easy access to private sector.
(iii) Fostering partnerships between public and private health sector for sharing resources and capacities in health research, particularly in advanced basic research procedures like genomics and transcriptomics. This would also aid in addressing gaps in the areas of health research in rural areas and among vulnerable populations.
(iv) Encouraging investment of private sector in health research: Corporate Social Responsibility (CSR) should be leveraged for filling health research infrastructure across the country. They may also be able to have return on investment by developing health research infrastructure and utilizing it for provision of services for patient care.
(v) Development of hybrid models of funding research by private sector.
(vi) Capacity building of private practitioners and faculty, students working in private hospitals in health research methodology.
(vii) Use of financial and economic modeling to identify new ways to encourage private sector engagement in research and development. For example policy changes, new opportunities for investment etc.

The multi-pronged approach would enable private sector to transition from passive role of commissioning and applying health research to complementary role of funding, developing, promoting, monitoring and evaluation of health research.

9. Strengthening International Linkages

Research has been identified as one of the propelling forces for global health and development. Even though there has been a shift in concept of health research paradigm, from 'being mandated and enacted from health sector' in 1970's to 'improving health and health equity through inclusive research processes requiring multiple sectors and disciplines' today, there has been a huge inequity in distribution of health research globally. A comparison of health and health research expenditure in United States (US), United Kingdom (UK) and India clearly show the wide disparity (Table 1).

Table 1: Expenditures on health and health research in US, UK & India

Expenditures	US	UK	India
Health Expenditure per capita (in US$)[1]	10,246.14	3858.67	69.29
Health Expenditure (as % Gross Domestic Product(GDP)[2]	17.9	10	3.6
Health Research Expenditure (as % of GDP)[3]	0.65	0.44	0.12

[1]Source: The World Bank Data. Current Health Expenditure [Internet] 2017 [Accessed on 26.11.2020]. Available from: https://data.worldbank.org/indicator/SH.XPD.CHEX.PC.CD

[2]Source: OECD Data. Health Spending [Internet] 2019 [Accessed on 26.11.2020]. Available from: https://data.oecd.org/healthres/health-spending.htm

[3]Source: Røttingen JA, Regmi S, Eide M, et al. Mapping of available health research and development data: what's there, what's missing, and what role is there for a global observatory?Lancet 2013;382:1286-307.

Collaboration for research on global threats has become a necessity. COVID-19 pandemic has made it all the more evident that health research in India needs to be strengthened by establishment of global partnerships and up-scaling of international collaboration. Further, it needs to be realized that knowledge or evidence generation is universal process and India should emerge as hub for it in coming years. However, international linkages should be based upon principles of solidarity, ethics, equality, mutual respect and benefit, shared responsibility and respect for national sovereignty.

Strategies for strengthening International linkages:

(i) Proactive role in global health research governance, including priority identification and agenda setting for health research: This includes identifying health issues which are of global priority and participating with international bodies such as World Health Organization (WHO), world bank etc. for international projects.

(ii) Bilateral, Multilateral and Regional collaborative framework for facilitating and strengthening interactions among governments, academia, institutions and industries on topics of mutual interest. This will include joint implementation of biomedical research projects, exchange of evidence and

scientific information, training of scientists, faculty and others through exchange programs and joint organization of scientific meetings, workshops and conferences etc.

(iii) Funding for health research: According to recommendations of the Commission on Health Research & Development, Mexico Ministerial level summit in 2004 and Bamako Mali Ministerial Summit in 2008, 2% of national health sector budget and 5% of the external development partners' (EDPs) health sector contribution should be on health research and capacity building for health research of any country. This should be implemented gradually through annual health budgets. Also transparent monitoring evaluation framework should be established for access and utilization of such funds.

(iv) Development of policies and protocols for transfer of biological materials and data taking into consideration privacy, ethics, ownership and most importantly national security.

(v) Development of collaborative health research networks where in common methods can be utilized to study problems and data can be pooled between collaborators to provide comparisons between countries and regions.

(vi) Incentivising research on conditions and issues that are relevant to community with global context in perspective, by providing financial support towards guidance and training.

(vii) These linkages would aid in working collaboratively on access to medicines, vaccines and medical equipments through implementation of flexible regulatory mechanisms under Intellectual Property Rights (IPR).

10. Monitoring and Evaluation of impact of Health Research

Monitoring and Evaluation (M & E) of health research is important for tracking progress towards its intended goals and timely course correction. This is pertinent in context of resource limited settings where allocated resources are to be used efficiently and maximizing research benefit is envisaged. The M & E framework should be able to assess the impact in following domains:

(i) Research related impact: generation of new knowledge, knowledge dissemination, capacity building, training, leadership, academic collaborations, research networks and data sharing.
(ii) Influence on policy making: This domain encompassed type, level as well as nature of policy network.
(iii) Health and health systems impact on service delivery, health information system, resource allocation, cost and human resource.
(iv) Societal impact: evaluation of public engagement with research, equity, inclusion and human rights.
(v) Broader economic impact: amount of funding for research and development (R&D) awarded by funding health research organizations, medical charities, and overseas companies, income from intellectual property, patents granted, licences awarded and brought to the market, research contracts, and income from industry.

The M & E framework should be based upon logic model with common components including goals, inputs, activities, audience, outputs, outcomes and impact.

Similarly, following indicators could be developed for monitoring the implementation of NHRP:

Objectives	**Implementation departments**	**Indicators**
Setting prioritized agenda for health research	Department of Health Research (DHR), Indian Council of Medical Research (ICMR)	Development of National Health Research Priority Agenda through consultative process.
Ethics and Research oversight	ICMR, Institutional Ethics Committees (IECs)	Availability of National Ethics Guidelines Number (proportion) of registered IECs Number of people trained in ethics guidelines Number of research misconduct reported

Resource generation for health research	DHR, ICMR and other allied funding ministries such as Department of Biotechnology (DBT), Department of Science Technology (DST)	Amount and proportion of fund allocated for health research Amount and proportion of fund spent on health research Guidelines for international funding in health research developed Amount and proportion of international funding received for health research
Research output	DHR, ICMR, academic and research institutions	Number (proportion) of human resource trained in health research Total number of publications Number (proportion) of international collaborations
Linking evidence to policy	Ministry of Health & Family Welfare (MoHFW)	Standard treatment protocols developed in National Health Programs

The list of indicators should be dynamic and reviewed periodically. This would aid in measuring the relevance, efficiency, effectiveness, outcomes and impact of investments on health research. Further, the policy should also entail guidelines for frequency of monitoring and evaluation of research activities.

NHRP should include a plan for accountability and evaluation for increasing the productivity of health research institutes. The evaluation process should be based on indicators and feedback should be given to the institutions for improvement.

11. Storage of data/data repository

The health research in India is being conducted in fragmented manner. Large volume of data is being generated but due to lack of standardization and linkages between different stakeholders, the data remains unutilized by government for informed decision making. Further, this practice not only entails duplication of efforts but also contributes in waste of resources and inability for researchers, policymakers and academicians to make meaningful use of the information/evidence so generated. Therefore, there is an urgent need to design, document, and retrieve health research data in a centralized, yet secure way, without compromising on the data integrity, confidentiality, and regulatory requirements. The principles of data sharing openness, accessibility, transparency, legal conformity, protection of intellectual property, ownership, professionalism, quality, efficiency, accountability, sustainability and privacy should be maintained. There is multitude of evidence to suggest that centralized data system contributes in improving efficiency of any health systems, aims in better care coordination and governance.

COVID-19 pandemic has highlighted the role of data in ensuring timely policy initiatives (e.g. Arogyasetu, COWIN app, etc.). Therefore, National Health Research Portal should be created to allow centralized flow of information. Centralized data system allows information to exist inside one mainframe but remain accessible from numerous points. The National Health Research Portal would serve as data bank where results of various forms of health research undertaken by different stakeholders (public sector, private sector, DST, DBT, etc.) could be shared. The National Health Research Portal would be developed and maintained by Department of Health Research (DHR) under Ministry of Health & Family Welfare. Also, the National Health Research Portal would sync with directives under National Data Sharing and Accessibility Policy of 2012

All the publicly funded health research should be deposited in this centralized system by the individuals, academic and research organizations, civil society and non-governmental organizations. The access to data would depend upon its sensitivity. Three types of access to health research data will be available as follows:

(i) Open access: Data that will be available without any registration or authorization.
(ii) Registered access: Data will be accessible through prescribed process of registration.
(iii) Restricted access: Data usually restricted in nature, as prescribed by Government policies, would be accessible to authorized departments or ministries under government.

The National Health Research Portal would be linked with data portal of allied departments such as DBT, DST and other open data sources (both national and international).