

**REPORT OF THE  
WORKING GROUP ON  
HEALTH RESEARCH  
FOR THE 12TH FIVE  
YEAR PLAN**

*WG-5:  
HEALTH  
RESEARCH*

**WG-5**

No. 2(6)2010-H&FW  
Government of India  
Planning Commission

Yojana Bhavan, Sansad Marg  
New Delhi – 110001

Dated 9<sup>th</sup> May 2011

**OFFICE MEMORANDUM**

**Subject: Constitution of working group on Health Research for the formulation of the Twelfth Five Year Plan (2012-2017)**

With a view to formulate the Twelfth Five Year Plan (2012-2017) for the Health Sector, it has been decided to constitute a Working Group on Health Research under the Chairmanship of **Dr. V.M. Katoch, Secretary, Department of Health Research, Ministry of Health & Family Welfare.**

The composition and the terms of reference of the Working group would be as follows:

1.	<b>Dr. V.M. Katoch, Secretary, Department of Health Research &amp; Director General, ICMR</b>	<b>Chairperson</b>
2.	Prof M S Valiathan, Director of the Sree Chitra Tirunal Institute of Medical Sciences (SCTIMS) , Thiruvananthapuram	Co Chairperson
3.	Joint Secretary (ME), MoHFW, Government of India	Member
4.	JS (Public Health), MoHFW, Government of India	Member
5.	Representative, Department of AYUSH, Government of India	Member
6.	Representative, Department of AIDS Control, Government of India	Member
7.	Representative, Department of Biotechnology, Government of India	Member
8.	Representative, Department of Science and Technology, Government of India	Member
9.	Representative, Department of Information Technology, Government of India	Member
10.	Representative, Defence Research and Development Organisation, Government of India	Member

11.	Representative Department of Agricultural Research and Education (DARE) & Director General, Indian Council of Agricultural Research (ICAR) , Government of India	Member
12.	Nominee of Secretary, Department of Scientific & Industrial Research (DSIR) & Director General, Council of Scientific and Industrial Research (CSIR)	Member
13.	Nominee of Chairman, Atomic Energy, Government of India	Member
14.	Representative, Department of Environment & Forests Government of India	Member
15.	Dr. Satish Chandra, Director, National Institute of Mental Health and Neurosciences (NIMHANS), Hosur Road, Bangalore	Member
16.	Dr. Syed E. Hasnain, Former Vice Chancellor, University of Hyderabad	Member
17.	Dr. K. Ramnarayan, Vice Chancellor, Manipal University, Manipal	Member
18.	Dr. G.K. Rath, Prof. & Head, Institute Rotary Cancer Hospital (IRCH), AIIMS, New Delhi	Member
19.	Dr. U.C. Sharma, Vice Chancellor, S.S. University of Health Sciences, Guwahati, Assam	Member
20.	Prof. K.K. Talwar, Director, Postgraduate Institute of Medical Education & Research (PGIMER), Chandigarh	Member
21.	Dr. Ab. Hameed Zargar, Director, Sher-I-Kashmir Institute of Medical Sciences, Srinagar	Member
22.	Sarojini NB, Sama, Resource Group for Women and Health, New Delhi	Member
23.	Dr. George Thomas, Chief Orthopaedic Surgeon, St. Isabel's Hospital, Chennai and Editor, Indian Journal of Medical Ethics	Member
24.	Prof Padmanabhan, Former Director, Institute of Science	Member
25.	Dr. Indira Nath, Pediatrician, Fellow, Indian Academy of Science, Formerly at AIIMS	Member
26.	Principal Secretary (H&FW), Government of Uttaranchal	Member
27.	Principal Secretary (H&FW), Government of Kerala	Member
28.	Principal Secretary (H&FW), Government of Sikkim	Member
29.	Mr. S. M. Mahajan, Adviser (Health), Planning Commission	Member
30.	<b>JS (DHR), Department of Health Research</b>	<b>Member Secretary</b>

## Terms of References

1. To identify major issues, areas for policy research in health sector for 12th Five Year Plan
2. To identify technology and operational gaps in health especially in the context of wide range of capabilities and infrastructural base in the country and build up coordination of basic, applied and clinical research in the Medical and Public health education.
3. To select technologies and approaches which are to be encouraged for development, implementation and evaluation in the public health programmes.
4. To identify and build up health research human resources and develop an interface between new technology developers (researchers in the Medical Institutions; State or Centre), health systems operators (Centre/State health services) and the beneficiaries (community).
5. To look into the research governance issues including ethical issues in medical and health research.
6. To explore the possibility of public-private partnership in medical, bio-medical and health research related areas.
7. The Chairman may constitute various specialists groups / Sub-groups/task forces etc. as considered necessary and co-opt other members to the Working Group for specific inputs.
8. Working Group will keep in focus the Approach paper to the 12th Five Year Plan as well as the identified goals, while making recommendations.
9. Efforts must be made to co-opt members from weaker sections especially SCs, Scheduled Tribes and minorities working at the field level.
10. The expenditure towards TA/DA in connection with the meetings of the Working group with respect to the official members will be borne by their respective Ministry / Department. The expenditure towards TA/DA of the non-official working group members would be met by the Planning Commission as admissible to the class 1 officers of the Government of India.
11. The Working group would submit its draft report by 31<sup>st</sup> July 2011 and final report by 31<sup>st</sup> August 2011.

**(Shashi Kiran Baijal)**  
**Director (Health)**

**Copy to:**

1. Chairman, all Members, Member Secretary of the Working Group
2. PS to Deputy Chairman, Planning Commission
3. PS to Minister of State (Planning)
4. PS to all Members, Planning Commission
5. PS to Member Secretary, Planning Commission
6. All Principal Advisers / Sr. Advisers / Advisers / HODs, Planning Commission
7. Director (PC), Planning Commission
8. Administration (General I) and (General II), Planning Commission
10. Accounts I Branch, Planning Commission
11. Information Officer, Planning Commission
12. Library, Planning Commission

**(Shashi Kiran Baijal)**  
**Director (Health)**

REPORT OF  
**THE WORKING GROUP ON HEALTH RESEARCH**  
**FOR**  
**XII PLAN**

**SEPTEMBER-2011**



DEPARTMENT OF HEALTH RESEARCH  
MINISTRY OF HEALTH & FAMILY WELFARE

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# **REPORT OF THE WORKING GROUP ON HEALTH RESEARCH FOR THE XII PLAN**

Health research is the key to a well functioning and effective health sector in the country. Major scientific breakthroughs hold the promise for more effective prevention, management and treatment for an array of critical health problems. The research to be undertaken should be on country specific health problems essential for the formulation of sound policies and plans for field action. But new interventions and development of new health products (drugs, diagnostics and vaccines) are possible only when there is well defined funding, infrastructure and priority for health research. Medical research in the country needs to be focused on new therapeutic drugs/vaccines for tropical diseases, normally neglected by multinational pharmaceutical companies on account of their limited profitability potential. In addition, India is also witnessing the 'dual disease burden' with the non-communicable diseases like cardiovascular diseases, diabetes, cancers etc. threatening to overtake infections. The thrust and focus of our medical research therefore needs to be on both the infections as also the newly emerging NCDs using cutting-edge science and technology based on genetics, molecular biology, genomics etc. It would be reasonable to infer that with the current low budget allocation to health research, it is difficult to make any dramatic break-through within the country, by way of new molecules and vaccines and other health products.

*The National Health Policy 2002 defined the goal for Health Research as follows:*

“Over the years, health research activity in the country has been very limited. In the Government sector, such research has been confined to the research institutions under the Indian Council of Medical Research, and other institutions funded by the Central/ State Governments. Research in the private sector has assumed some significance only in the last decade. In our country, where the aggregate annual health expenditure is of the order of Rs. 80,000 crores, the expenditure in 1998-99 on research, both public and private sectors, was only of the order of Rs. 1150 crores. It would be reasonable to infer that with such low research expenditure, it is virtually impossible to make any dramatic break-through within the country, by way of new molecules and vaccines; also, without a minimal back-up of applied and operational research, it would be difficult to assess whether the health expenditure in the country is being incurred through optimal applications and appropriate public health strategies. Medical Research in the country needs to be focused on therapeutic drugs/vaccines for tropical diseases, which are normally neglected by international pharmaceutical companies on account of their limited profitability potential. The thrust will need to be in the newly-emerging frontier areas of research based on genetics, genome-based drugs and therapies, vaccine development and molecular biology etc. “

Since its establishment, the ICMR has been making concerted efforts to address the health needs of the nation. Given its limited resources – human, financial and infrastructural the Council has





discharged its national obligations through its network of 31 national institutes including 6 regional medical research centres, over 100 field stations and a strong and vibrant extramural research in medical colleges and other institutes. The rapidly growing economy with an average annual growth rate of almost 9.0% has thrown up new challenges in the health sector: a population that is divided into an increasing number of middle and upper middle class and the marginalized segment of society. The health challenges continue to be huge, and complex. We have at the same time serious problems of malnutrition, both under-nutrition among children and growing problem of obesity in school going and adolescents, continued infectious disease burden among the poor to rising cardiovascular disease and diabetes disease load among the rich. What is more, 'development' – rapid industrialization of India, use of pesticides and fertilizers for improving crop yields are rapidly degrading the environment, causing air and water pollution resulting in several health problems from chemicals in breast milk to increasing cancers in different communities.

Due to improved health care, there is a growing and greying middle class adding to older citizens which is demanding specialized geriatric care. To address these unique 'double burden', the national research agenda needs to be constantly updated to cope with these new challenges. Finally, the global trade and new intellectual property rights regimes have added another dimension of the rise in cost of medicines and the limited possibility of producing affordable generics in the future. We need to create our own products and processes, if we have to ensure affordable health care for our population; even to address the infections like TB, malaria, HIV/AIDS etc. that largely come under the public health system.

Clearly, Medical Research in the country needs to be focused on creating our own therapeutic drugs/vaccines and other interventions especially for tropical diseases for which there have been few inventions in the last decades. However, the development of new health products (diagnostics, drugs and vaccines) is a long and complex process and we need to have systems in place to encourage innovation and appropriate ethical and regulatory frame-work for pre-clinical work and clinical trials for bringing our health products to market.

The thrust and focus therefore needs to be to create new directed knowledge generated in frontier areas of research based on genetics, molecular biology, etc. and conventional means to develop affordable genome-based drugs and vaccines, which is the strength of the resurgent India. Over the years, the Council has been doing its best in all these areas, despite limited resources.



## New Scenario

During the last 10 years, the overall situation has somewhat changed with more resources being provided for biomedical research to and through the ICMR, and to other science agencies. But unlike biomedical research, health research is much more encompassing covering a wider horizon for the creation of new knowledge and tools for application in human populations. To address this challenging task and to give a greater thrust and focus to Health Research, a new Department of Health Research (DHR) under the Ministry of Health & Family Welfare was created on the 17<sup>th</sup> September, 2007. The Department was formally launched on 5<sup>th</sup> October, 2007.

The mandate of DHR is as follows:

1. Promotion and co-ordination of basic, applied and clinical research including clinical trials and operational research in areas related to medical, health, biomedical and medical profession and education through development of infrastructure, manpower and skills in cutting edge areas and management of related information thereto.
2. Promote and provide guidance on research governance issues, including ethical issues in medical and health research.
3. Inter-sectoral coordination and promotion of public-private partnership in medical, biomedical and health research related areas.
4. Advanced training in research areas concerning medicine and health including grant of fellowships for such training in India and abroad.
5. International cooperation in medical and health research including work related to international conferences in related areas in India and abroad.
6. Technical support for dealing with epidemics and natural calamities.
7. Investigation of outbreaks due to new and exotic agents and development of tools for prevention.
8. Matters relating to scientific societies and associations, charitable and religious endowments in medicine and health research areas.
9. Coordination between organizations and institutes under the Central and State Governments in areas related to the subjects entrusted to the Department and for the promotion of special studies in medicine and health.
10. Administering and monitoring of Indian Council of Medical Research.

With the creation of Department of Health Research, a paradigm shift in pursuing the national health research agenda is expected. Since independence, India has spent most of its resources and energy on the development and deployment of new knowledge about various diseases (especially infectious diseases which account for most deaths) in a concerted attempt to control, treat or eradicate them. While tools used were mostly global, the strategies developed were local. The new disease control/treatment regimens and methods of their usage in public health were the original concepts from India, especially for diseases like tuberculosis and leprosy. These strategies have been widely acclaimed and recognized and have found their way into international programmes operated through agencies like the WHO. India has thus spent considerable efforts in successfully putting



various ideas into action. As a result, we have achieved great successes in the area of infectious diseases like elimination of guinea worm disease, eradication of smallpox, elimination of leprosy and polio as public health problems. During the recent times, the country showed remarkable and globally acclaimed successes in controlling the speed of spread of H1N1 epidemic. In addition, there have been emerging and re-emerging infections like H1N1, exotic viral infections that have been continuously challenging the health system. As the infectious diseases have no respect for borders, we may well have prevented a disaster of spread of these epidemics in the Indian sub-continent. While we count these successes with legitimate pride, there have been failures in some sectors. We have also not been able to successfully address issues like the huge maternal and child mortality and have been way behind in the achievement of MDGs 4 and 5. We have also not been very successful in providing access to even minimal health care to our large tribal and marginalized communities. All these remind us of the need for constant vigilance and a nation-wide targeted, concerted and committed time-bound action plan. Such efforts need to be on a mission-mode with defined deliverables keeping in mind available human resources, infrastructure, and unique socio-economic as well as geographical realities while setting achievable and realistic targets for the XII Plan.

### **The XII Plan approach paper for S&T lays emphasis on**

- (a) An in depth review of our existing institutions, structures and mechanisms so that the much needed resources, financial and human, are deployed in an optimal fashion. There is no alternative but to focus on innovations to develop and deploy affordable tools for the management of various diseases guided by equity as the core value.
- (b) Building of alliances and partnership as another key element for a vibrant innovation ecosystem for translating research outputs to measurable social and national outcomes.

This is especially important as in the post-TRIPS era, there is little chance of using products and processes developed outside for use in India in view of protection of intellectual property rights. Discovery and development of indigenous health products is imperative to achieve equity with access to our large populations. India has often been found wanting on converting ideas and leads into products and processes for various reasons. Building of alliances and partnership for a vibrant innovation ecosystem for translating research outputs to measurable social and national outcomes therefore has been emphasised as one of the key elements in the approach paper of the XII Five Year plan.

Considering that health is a major driver of economic development and social contentment in any country, India has unique challenges due to its large population and demographic transition. We have the largest young population and a significant spurt of the people who are living longer and need specialized geriatric health care. To address these existing and new challenges, Department of Health Research has been assigned 10 business of which 9 are new and their evolution is vital for developing the health research agenda of the country for achieving the targets in a time bound manner.



The only ongoing activity of Department of Health Research pertains to administering and monitoring Indian Council of Medical Research (ICMR) which is in its 100<sup>th</sup> year of existence. Today, the ICMR stands out as a formidable and strong structure having 31 national and regional institutes and more than 100 field stations under its fold. More significantly, the Council has been able successfully access the strong medical college system across the country and support/collaborate with other national research institutions. It is, therefore, imperative that ICMR be further strengthened by continuous modernization of its own institutions as well as by opening of new centres focussed on the new emerging communicable and non-communicable diseases, cutting-edge basic science like transplant immunology, genomics, proteomics *etc.*, strengthen infrastructure for animal experiments, clinical pharmacology, critical health policy issues, health systems research, socio-behavioural science research *etc.* The human resource within the ICMR is very small in terms of the numbers with many institutes/centres functioning with sub-critical scientific pool. **It is absolutely essential to enhance the number of researchers and supportive workforce in the ICMR. There is no gain saying the fact that ICMR will continue to be the fulcrum of the new Department of Health Research, dedicated to taking the modern health technology to the people.**

The DHR has already embarked upon path of improving research governance by developing appropriate policies; establishing authorities to implement the policies; initiating the process of creation of suitable infrastructure in a medical colleges and other institutions; developing a special scheme to strengthen human resources in medical colleges and state structures; initiating the establishment of an extensive infrastructure encompassing all regions of the country to carry out research on various infectious diseases aimed at containing all future outbreaks or epidemics. Lastly, DHR has also planned a major initiative in respect of establishing a vibrant and effective inter-sectoral co-ordination amongst science agencies in the country having the strength and mission of developing new products and processes or have overlapping areas of activity. These include agencies of Government of India involved in basic science and/or innovation on one hand (DST/DBT/CSIR/DSIR/DRDO *etc.*), or with a major emphasis on epidemiology and public health (ICMR/DHR/ICAR/DARE), agencies like DIT, DAE having a strong technology platform, Rural Development & Water Supply, Alternate Energy Sources, Women & Child Development, Environment and Forests, having complimentary areas of activity. Towards this end DHR plans to establish during the XII Plan well defined mechanisms to create synergies, structures for technology generation and its introduction, and implementation of the knowledge locally or internationally which suits our needs.

Before undertaking an assessment of the current situation it is necessary to recap the vision and tasks identified for the new department, after wide consultations with the stakeholders, at the time of its creation in 2007. These have been further fine tuned during the process of preparation of Results Framework Document (RFD). Most of these, as pointed out at the beginning were completely new areas of activity.

The Department has a vision “To bring modern health technology to the people through innovations related to diagnostic, treatment methods and vaccines for prevention; to translate them into



products and processes and, in synergy with concerned organizations, introduce these innovations into public health systems”.

## **OBJECTIVES**

1. To provide research leadership for resolving existing and emerging health challenges by promotion, co-ordination & development of basic, applied, clinical and operational research.
2. To address matters related to major health problems pertaining to epidemics, natural calamities and other emerging causes of morbidity and mortality.
3. To improve research governance.
4. To accelerate translational programmes specially by facilitating joint projects with other stake holders like DSIR, DARE, DRDO., DBT, DAE.
5. To promote public-private partnership for translating research leads into development of affordable diagnostic technologies and pharma products including vaccines to achieve broader objectives of providing better healthcare for the people.
6. To accelerate international co-operation in medical and health research.



## Assessment of Current situation

The Department has analyzed the current situation so as to prepare a strategy for future. The important points emerging from this analysis are described below –

- a) **Strengths-** Currently health research in the country is primarily being supported by 31 ICMR institutions and nearly 100 Field Stations/Units funded by ICMR. In addition, other science agencies like DBT, DST, DRDO, Department of Information Technology, DARE, DSIR/CSIR, Department of Environment and Forests, Department of Atomic Energy, Ministry of Women and Child Development, *etc.* are funding certain sectors of health research mostly through extramural funding and to some extent through their specialized institutions.
- b) **Challenges –** Notwithstanding many strengths enumerated above, the health research in India faces several challenges/hurdles which include emerging and newly emerging infectious diseases; increasing burden of chronic non-communicable diseases; decline in mortality and fertility rates; ageing population ; lack of adequate infrastructure and human resources; poor funding and priority setting in comparison with developed nations; inadequate regulatory structure for such governance; health inequities between rich and the poor, including marginalized community/sections *etc.* Lack of coordination and translation mechanism in terms of testing institutions and ill-defined regulatory pathways, is another pressing challenge. Collectively, all of these have retarded the pace of progress in health research field as also translation and implementation.

The XI Five Year Plan of the ICMR had identified certain challenges based on the report of National Commission on Macro Economics and Health. The challenges identified included demographic changes, disease burden due to communicable diseases (HIV, TB, Malaria and emerging and re-emerging infections); non-communicable diseases (cardio-vascular diseases, diabetes, cancer, mental health, chronic and pulmonary diseases, asthma, accidents and injuries, oral health, suicides and stroke and neurological disorders; urban health; nutritional problems; reproductive & child health; quality of drugs and devices; narrow research base; limited human resource and neglect of translational research. The XI Plan had also mentioned of a shift from medical to health research and the need for strengthening the governance structure for medical research. Creation of a dedicated Department of Health Research is a step in that direction. Significantly, even at the beginning of XI Plan, the challenges were mostly the same. Yet, despite the earlier disadvantages, there has been significant progress during the last 5 years. **(Annexure I)**. The ICMR launched several research initiatives for containing the transmission of HIV, treatment of the drug resistant TB and malaria as well as other emerging and re-emerging infections. New programmes have also been launched to carry out research on various non-communicable diseases in a much more focused and accelerated way than before. Nevertheless, several new challenges have emerged during this period that include:

- i) increase in the drug resistance among various infectious agents due to misuse of drugs as well as laxity in the safety precautions in the hospitals;



- ii) genetic disorders, that are becoming more evident due to availability of new diagnostic tools but are largely preventable due to improvement in the technology;
- iii) increase in injuries due to accidents/trauma due to high urbanization;
- iv) significant neonatal mortality despite increase in the hospital deliveries;
- v) deaths due to childhood pneumonia, diarrhoea ;
- vi) morbidity and mortality due to pyrexia of unknown origin;
- vii) lack of adequate progress on gender related issues in health care;
- viii) inadequate delivery of adequate healthcare to marginalized sections including tribes;
- ix) increase in the diseases due to unsafe water (communicable as well as non-communicable);
- x) slow progress in the developing of the areas like disease burden studies specially vaccine preventable diseases; and
- xi) health systems research, health economics and socio-behavioural aspects.
- xii) sub-critical qualified/trained human resource despite reasonably high inputs into various aspects of the health research by nearly ten departments of Govt. of India. Some of the major challenges are elaborated below :

**Epidemiological and demographic transition:** India continues to grow both in terms of young population as well as increasing proportion of elderly population. The health services thus need to be geared to face the burden of all the chronic diseases faced by this growing elderly population. Thus, the research efforts need to be geared towards identifying the health problems in the context of changing social norms and the care of elderly population.

**Emerging and re-emerging infectious diseases:** Due to the vastness of our country, the assessment of prevailing diseases is very challenging. Further, new diseases are emerging and old and extinct diseases are re-emerging. Pandemic H1N1, first time reports of human cases of Crimean Congo hemorrhagic fever and a major proportion of encephalitis-like disease with the causative agent as yet unidentified underscore the enormity of challenge of new and emerging diseases. The distribution and epidemiological significance of several drug resistant organisms also remains inadequately understood. Further, the cause of death due to fevers (acute as well as chronic) also remains undetermined in a significant proportion of these cases. Newer vaccines are being developed and a major decision would need to be made as to whether they should be introduced into the immunization programme. Such decisions require research on the cost effectiveness of vaccines versus the current methods of sanitation, mosquito control, clean water *etc.* There is as yet no concerted effort to study these aspects specially in case of available/ likely to be available vaccines against rota virus, influenza, papilloma virus *etc.* Research is needed on policy issues as how such interventions could be introduced vis-a-vis their acceptability by people, cost-benefit analysis *etc.*



**Reproductive and child health:** During the XI Five year plan, there has been gradual improvement in the percentage of under 5 mortality rates, maternal mortality rates as well as birth rate. However, the progress has not been as targeted and intense operational research is required to accelerate the pace for achieving the desired results. Low birth babies are a major public health issue which need social as well as health interventions.

**Nutritional problems:** The problems of under nutrition and increasing childhood obesity continue to be worrying. Micronutrient deficiencies, toxicity due to arsenic and fluoride, pesticides and other harmful materials (additives) other important problems which need to be addressed.

**Urban Health:** Urban health has emerged as a major health issue in the recent times, especially migration from rural and tribal areas is on the rise. Accidents and injuries now constitute a major cause of concern as over 2.0 lakh people die in India due to accidents. This 'triple burden' of communicable, non-communicable and injuries need to be considered for both research and health care. Most rural folk are forced to come to cities for treatment where they find difficult to get admission/ stay . It is predicted by the Mckinsey Global Institute that in the next 20 years, India will have 68 cities with more than one million population. Currently, we have 42 such cities. Thus by 2030 India would have twice as many cities as the whole of Europe. Urban population would increase from 340 to 590 million which means that 10% of the India's population will reside in cities. We need to start planning for urban health now. If urban health care system is improved, the rural population would also benefit by the improved health infrastructure and manpower. But this requires multi level and multi-sectoral planning. Fresh thinking on research approaches for policy making would be required rather than the current vertical decision making. A trans-disciplinary approaches involving not merely medical personnel but also engineers, economists, social scientists and the civil society would be needed. The experience of developed countries like Japan and Korea where overcrowding has broken up extended families putting pressure on the nuclear family with resultant is but a pointer to the impending mental health challenges in our country. Rising suicides amongst children and lack of care for aged have become worrisome.

**Non-communicable diseases:** With increasing life span, the number of ageing population is on the rise with resultant rise in non-communicable diseases like cardiovascular and neurological problems are becoming more and more pronounced. The recent study conducted by ICMR has shown the prevalence of diabetes ranging from 2.5% in Jharkhand to 10% in Chandigarh and other urban areas of the country. While the percentage of population having cancers has remained static, the profiles are changing and burden due to absolute numbers is showing a marked increase.

**Trauma:** The number of injury cases mainly due to road side accidents has been rapidly increasing in India. The nature of services to cope with such emergencies is grossly inadequate. Intense research efforts are required to understand the profile of these injuries for their





appropriate management strategies which include preventive, curative and rehabilitation services.

**Drugs and devices:** Adequate availability of drugs as well as devices at affordable prices has been the cause of concern. Despite the stated goals of tackling this problem, the progress remains to be slow and the impact is not visible.

**Increasing health inequities:** During the XI Plan, health care facilities in urban areas have undergone major changes. While the number of specialized/super speciality hospitals in the private sector has seen a rapid increase which have also been reflected by medical tourism, this has also led to a greater divide in the capability of all Indians getting appropriate medical care in a cost effective way. The gap between rich and poor specially marginalized communities/sections has shown an increase resulting in heavy economic burden on populations pushing them down the economic ladder.

**Inadequate infrastructure and human resources:** At macro level, the facilities for different disease investigations and patient management continue to be grossly inadequate despite attempts of the government to open AIIMS-like institutions and granting permission to open a large number of medical colleges, the number of health personnel remains far below the norms and is also not equitably distributed. These personnel are either not adequately trained in research methodology or have poor motivation due to various reasons in most parts of the country. Though a lot of initiatives have been taken to improve the situation, it will take quite some time to reach desirable standards.



## Creating a Promotive Environment for Health Research

Several changes in the national and international health research environment during XI Plan period can be used as strong positive inputs to drive the new health research.

1. The Prime Minister of India has declared innovation as the main pathway for development of the country. The Hon'ble Prime Minister has also expressed the commitment of the government to double the spending on Research and Development sector.
2. The DBT has created a translational health research institute and similar infrastructure.
3. The ICMR has created a dedicated structure for translational research.
4. There is a felt need and initiative for the indigenous production of medical devices and health equipments for affordable health care.
5. India continues to be a globally accepted leader in the production of high quality low-priced pharmaceuticals and vaccines.
6. Indian industry is investing more in R&D aimed to create new IPR and is partnering with Indian institutions to produce globally competitive products.
7. A large number of leads potentially useful for development of diagnostics, therapeutics and vaccines are available from the publicly funded Indian institutions.
8. Ten science and other departments of the Govt. of India are contributing towards the development of better/improved diagnostics/therapeutics and vaccines and also contributing to implementation research.
9. Translational research, implementation research, health systems research, policy research, health economics and other vital areas important for harnessing the fruit of advances in the knowledge have made their presence felt in the Indian scenario.
10. Non-governmental agencies like the Public Health Foundation of India are partnering with the governmental institutions to strengthen public health research in India.
11. The regulatory mechanisms are rapidly improving and becoming more user- friendly which is conducive to the growth of thinking and innovative environment in the academic institutions as well as the industry.
12. A massive national effort is underway for the development of human resources at all levels – school, college, university and new schemes to retain and attract the right kind of qualified scientists and physicians from overseas.
13. There is positive resonance to the initiatives to enlarge the health research base of the country by increasing funding to medical colleges and institutions in the periphery, strengthening the infrastructure base in the medical colleges and intersectoral coordination by creating synergy amongst science and user departments.



During the XII Plan period, the strategy of Department of Health Research would be:

- Nation-wide strengthening of infrastructure and developing human resource to ensure availability of geographically equitable resources and environment for enabling health research.
- Strengthening human resources and creating enabling environment for the pursuit of health research.
- Establishment of surveillance and diagnostic facilities for service and research on infectious diseases.
- Inter-sectoral coordination for ensuring optimization of resources.

### **To sum up**

The DHR aims at bringing modern health technology to community by:

- Encouraging innovations related to diagnostics, vaccines and treatment methods .
- Translating the innovations into products/ processes by facilitating evaluation/ testing in synergy with other Departments like MOH&FW and other science departments and introducing these innovations into the public health system through health systems research as the main pathway to achieve the goals.
- Strengthening the ICMR so that it serves as fulcrum of this Department in generating scientific knowledge for translation and implementation through DHR mechanisms and in partnerships with other science and health departments.



## Broad Frame work of activities of DHR

In the current scenario, the ICMR **focuses on active research programmes for generation of new knowledge** whereas DHR concentrates on

- Governance
- Development of infrastructure and manpower in medical colleges, state health systems, universities *etc*;
- Promoting the translation and implementation research through Central & State Govt Institutions through optimum use of knowledge management & NKN and by partnering with professional bodies, NGOs/ private sector and other stake holders
- Strengthen and augment international collaborations in health and
- Creation of mechanisms for management of epidemics/ pandemics *etc*.

**The above-mentioned strategy proposed for the XII Plan was discussed by the experts of the Working Group on Health Research set up for this purpose. (Annexure II) The individual proposals and the observations of the Working Group in respect of each are discussed below:**

### **Special support to medical colleges:**

India has currently nearly 300 medical colleges, about 150 in the government sector. Various medical institutions have served well and continue to contribute in terms of specialized health care, education and to some extent research. While research should have been an integral activity, it has not happened in that way and the research activity has been mostly confined to about 20-25 medical colleges who garner most of funding for biomedical and health research. This has created a heavy responsibility and work load on these national institutions which is affecting the growth of quality health care, health education and health research in the country. The DHR has plans for establishing multi-disciplinary research units (around 250 units) at least in all the government medical colleges. These units will provide the modern technology infrastructure which will improve the quality of the specialized care, training of doctors and other health care professionals and then research as per the needs of the population.

**Experts of Working Group on XII Plan have emphasized that the DHR should focus on schemes aimed at modernizing the infrastructure for research in medical colleges and consider working with MCI and NAMS to find ways to improve the environment / facilities for research in medical colleges. Strengthening should be for research laboratories as well as auxiliary support systems like bioinformatics/biostatistics/nation-wide e-library network *etc*. A FIST-like programme of the Department of Science & Technology can be used as a model by the DHR to augment and complement facilities and infrastructure provided to medical colleges.**



*This special programme for medical colleges which is not so far in mainstream of healthcare and academic system, is expected to bring a qualitative change in the working of these colleges especially those in the public sector. The outcome of the support system in these medical colleges will be reflected by quality medical education which would lead to more patients being provided with advanced medical care across the country, larger number of researchers generating good quality research projects in the areas of national priority and thus contributing to a strong knowledge base of the country.*

### **Establishment of model rural health research units:**

There is a wide gap between the available specialized health care technology and the technology being developed vis-a-vis their utilization in the State health systems. This is particularly true for rural health settings. It is generally felt that technology application needs specialized infra-structure and can be done only in urban settings. In order to develop models for transfer of such technology to the end care users, the Department has planned to establish model rural health research units in all the States (about 50); more than one in larger states) where technology transfer and the research targeting health interventions will be done in partnership with the States.

**During the consultations, experts have suggested that public-private partnership (PPP) model may be pursued by DHR for laboratory strengthening at the village / district levels through a system of empanelment.**

*This special programme for rural areas will lead to continuous transfer of technology for handling infectious and non-infectious diseases by the state health services resulting in reduction in morbidity and mortality. This will also be measurable by active joint projects by Unit, local medical colleges and state health services addressing local problems. These changes will be continuously monitored to ensure sustenance.*

#### **i) Establishment of a National Network for Viral Diagnostic/Infectious Disease Laboratories**

India continues to have outbreaks/ epidemics due to various infectious pathogens. Currently national apex institutes like NCDC, New Delhi and NIV, Pune are mandated to undertake the investigations that results in heavy burden affecting their real referral role. The resultant delay in diagnosis/detection and adequate/incomplete data about these outbreaks significantly impact the response time for interventions. Significantly, avoidable delays in both short and long terms strategies for prevention, treatment through vaccine production/introduction and up-gradation of infra-structure etc. The Department is planning to establish about 250 laboratories of three grades on infectious pathogens which will work under the overall guidance of apex institutions like NIV, NCDC through appropriate linkages and networking.

**As suggested by Experts a separate dedicated centre for Influenza research is being proposed in the schemes of DHR for prompt investigation of epidemics/ outbreaks.**



*Impact of this major empowerment will be visible by prompt and accurate diagnosis and management of various infections; identification of causative agents for the outbreaks/ epidemics and smooth data flow from across the sites of epidemics by efficient knowledge management using NKN for policy interventions like quick deployment of resources and measures like introduction of preventive strategies like new vaccines etc.*

**ii) Establishment of other specialized research units including labs**

As an emerging developing country, India has plans and ambitions to be in the fore front in the creation of new knowledge/technology and making the technology available to our population through appropriate interventions. For this purpose, modern clinical / public health oriented set-ups are needed to work on cutting edge science like stem cells, molecular medicine, nano medicine etc., and specialized centres/Institutes for mental health, oral health, health systems, health economics, policy related to research on implementation, molecular & transplant immunology etc. The Department plans to establish/ develop such centres for service, education and research.

**During the consultations, experts also emphasized that the DHR should have a well developed Division/ Centre(s) on Food & Nutrition to study the potential harmful effects of additives present in food as well as other safety issues (imported/ local). Health effects of pesticides and other environmental factors may be given special attention. The DHR should help in the development of 4-6 apex laboratories and empanelment of specialized labs/ set ups in the country for testing of pharmaceutical/biological products which is vital for the growth of pharmaceutical/biotech industry: Establishment of a Special division/ centre on research on “Disaster management and Bioterrorism” should be explored. The DHR should have a dedicated cells/ divisions/ units for studying critical aspects related to National Programmes; responses required to deal with health issues gaining importance in media etc.; There should be a cell/ centre within the DHR to advise on various aspects of newly developed / introduced vaccines or any other intervention.**

As suggested by experts, all of these specialized laboratories, cells/ divisions have been proposed in the XII Plan.

*Impact of these initiatives will be reflected by increase in number of research studies in cutting edge areas, development of more affordable reagents/ technologies/ tools for public health use and also global leadership in diagnostics and pharmaceutical products. This will also result in affordable advanced health care thus saving costs on public health expenditure.*

**iii) Human Resources Development for Health Research**

A major constraint in the current scenario is the lack of adequate and properly trained human resources for the health research. As a result, the output does not match the input



we make as the investment is concentrated in few places only. The Department plans to strengthen human resource base of the country by organizing focused training programs within and outside India, for mid-career professionals in medical colleges and other academic establishments. Over 3000 personnel are proposed to be covered in various programmes mentioned below. Improving the career path for young researchers, expanding the number of specialized researchers and then providing good initial support in the form of start up grants are planned as a part of this programme. Activities proposed in this regard are:-

- (a) Fellowships for training: Researchers in identified advanced fields
- (b) Scholarships at PG level: Support for producing human resources in newer areas
- (c) Young researcher program: To encourage young students for research
- (d) Special training programs: In specified areas, this also includes support to selected institutions for training
- (e) Mid-career research fellowships: Faculty development for medical colleges

**During the consultations, experts emphasized on the need for a strong career development & advancement schemes for research students, medical faculty and other researchers, creation of a dedicated Research Cadre, innovative fellowship systems trainings (that address issues as not losing seniority in the Govt system), schemes for women scientists (who leave research on domestic and other grounds) to rejoin research career with other career incentives and establishment of Research Chairs/ special research positions in medical colleges in partnership with State/ Central Govt. Building of a strong and vibrant partnership with academic bodies, Health Universities as well as other universities were also emphasized.**

All these have been included in the proposed activities of XII Plan.

*All these activities will create a strong human resource development mechanism for providing mentorship and creating conducive environment for needs of different categories of aspiring researchers. Outcome will be measurable by the numbers of persons trained; projects generated by them and development and/or introduction of new technologies into the health care system at all levels.*

**iv) Inter-sectoral coordination & national and/ international collaboration**

While several science departments are significantly contributing to innovation related to different aspects of biomedical research, it is felt that translation process and further implementation research is not as strong as is needed. In order to strengthen research effort in which the partnership of different government agencies, NGOs and Industry is required, the Department has planned to provide support in the form of grant-in-aid to selected projects; create awards, dedicated funding for translation of innovations and their implementation and support to professional associations etc. for developing guidelines and



priority setting. Thus there will be special focus on encouraging innovation, their translation and implementation by collaboration and cooperation with other agencies by laying special stress on implementation research so that there is a better utilization of available knowledge. In the XII Plan it is proposed to focus on such areas and fund projects where synergy is expected to bring better results.

It is proposed that an Inter-departmental mission of biomedical and health research may be launched around medical / health priorities such as:

- i) Tuberculosis.
- ii) Viral infections with potential for outbreaks.
- iii) Zoonotic diseases.
- iv) Maternal and Child health including gender issues in health.
- v) Nutrition and Food safety.
- vi) Diseases preventable through measures like vaccines, environmental interventions, public health education *etc.*
- vii) Diabetes, cardiovascular, mental and chronic neurological disorders.
- viii) Affordable health care technologies (diagnostics, therapeutics, devices *etc.*).
- ix) Innovation in health care delivery.
- x) Rural healthcare.

**While endorsing the above areas experts emphasized that priority be given to emerging infections; mental health and ageing-related diseases such as dementia, Parkinson's Disease, *etc.*; Urban health; especially the emerging triple disease burden due to communicable and non-communicable diseases and trauma; mechanisms to provide information / guidance on healthy life style; Gender issues in the provision of health services, setting up of district research stations, *etc.***

All of these suggestions have been incorporated in XII Plan

As discussed above, it is of paramount importance to create synergy among various science agencies/ departments – those mainly involved in basic science and or innovation on one hand (*e.g.*, DST, DBT, CSIR/DSIR, DRDO *etc.*) to those with major application on epidemiology, public health (*e.g.*, ICMR). Thus, the effort should be on i) establishing mechanisms to evaluate technologies for improving health care at individual & public health level; ii) fostering academia-Industry link: creating processes and cell to link developers with industry for translation of leads into products/processes; and iii) establishment of a rapid clearing house mechanism for evaluation of health research technologies including the commercial applications. In addition agencies/ departmental having with complementary activities with DHR such as, DIT, ICAR/ DARE, Social Justice,





Environment and Forests, Women and Children; Water resources; other user departments of MOH&FW etc are proposed to be engaged in the process. Strengthening of international collaborations of scientific and strategic mutual interest will be a priority.

During the consultations it was emphasized that DHR should focus on development of mechanisms (regulatory/promotional) to accelerate the indigenous production of instruments/ medical devices that are vital for affordable health care; DHR should focus on schemes aimed at making health care affordable for the poor / marginalized groups/ communities; The DHR should set up Technology Assessment Board/ Department consisting of economists, social scientists, public health professionals and other specialists (similar to the Offices of Technology Assessment in some countries) whereby new technologies can be scientifically assessed for promotion and also before introduction / procurement. Schemes to promote development of indigenous products by the Indian pharma industry should be established on the lines of DST/CSIR model. With over US \$85 billion of pharma products going to be off patent during the coming 5 years, the domestic industry would have a good opportunity for growth. But there is also need to set up strict regulatory mechanisms systems and mechanisms for quality control of drugs and other health products. To address this need, the DHR should set up apex drug testing laboratories and related regulatory infrastructure in every state in synergy/ coordination with DCGI and other appropriate mechanisms. The expert group also suggested setting of a Medical Technology Development Board to promote development of indigenous medical technologies.

All of these suggestions have been included in XII Plan.

*These new initiatives will help in the creation of an efficient, promotive and regulatory structure involving different agencies in the Govt as well as outside to develop integrated solutions for the promotion of health. Outcome of these initiatives will be reflected in the generation of joint inter-departmental/ inter-agency projects on health problems ( some already identified above); more affordable technologies for public health use; lesser dependence and expenditure of imports/ technologies for advanced health care and stronger indigenous health care globally competitive industry.*

**v) Establishment of regulatory framework for research governance**

Research governance is one of the major tasks allocated to the Department. During the last two years, the Department has already developed a National Health Research Policy, Knowledge Management Policy and also prepared a draft Bill on Ethical Issues pertaining to Biomedical Research. Department is also perusing Assisted Reproductive Technology Bill as well as a Bill on Alternate System of Medicine. During the XII Plan, all these policies are to be implemented. Department proposes to establish an authority (ies), systems and extracting evidence generation through model projects for improving the research



governance in health in India. Further mechanisms are being built to create systems/ administrative structures for recognition of health research institutions and for identification & promotion of affordable technologies for improved diagnosis, treatment and prevention of various relevant diseases.

To summarize, DHR plans to improve governance by -

- a) Putting in place appropriate Guidelines, Acts, through appropriate regulatory authorities and structures to evaluate and recommend technologies, programmes, studies etc. for introduction into the public health system
- b) Enactment of an Ethics Bill and the establishment of the National Bioethics Authority.
- c) Creation of National Health Research Forum for implementing National Health Research Policy.
- d) Establishment of mechanisms for mapping, accreditation/ recognition etc. of health research institutions.
- e) Research for establishment of mechanisms for knowledge management for better service, education and research.

**Development of robust ethical systems to promote ethical animal and human research programmes and its implementation was considered as a top priority by Experts. Existing regulatory and related loopholes emerging from the current experience should be plugged and used to develop regulatory framework.**

*Outcome of the establishment of above systems and regulation will be reflected in improved ethical standards in biomedical research; proper allocation and utilization of resources for health research; better environment for product development for domestic and international purposes and optimum usage of infrastructure as well as human resources for health care, medical/ biomedical education, training and research.*

**vi) Strengthening and expansion of programmes of ICMR**

The Indian Council of Medical Research (ICMR) continues to provide critical support to various national programmes by generating new knowledge about the diseases, developing and evaluating tools for diagnosis and treatment and provide help in the framing of its policies for guiding research and providing feedback to the governments:

- i) During the XI Plan the ICMR has created a dedicated system of **translational research** in which the leads obtained by its scientists as well as other researchers in the country are being explored for their application in the health care system.
- ii) The ICMR continues to synergize/ harmonize its agenda with national health programmes. Over the years, ICMR has established **a large number of Institutions** (31



- of which two - the National Institute for Research in Environmental Health (NIREH), Bhopal and National centre for Disease Informatics (NCDI), Bangalore were established during current plan), field centres and has created networks of Institutes/ centres/ units on diseases ranging from vector borne diseases, viral infections, tuberculosis, leprosy, kala-azar to nutrition, cancer, genetics, blood disorders and reproduction as well as traditional medicine and herbal remedies.
- iii) Establishment of a **Tribal Health Research Forum** for promotion of health of marginalized communities and creation of a **Vector Science Forum** are recent landmarks. A major initiative on Health Systems Research and initiation of programmes on newer areas like nano medicine were other important developments.
  - iv) While the Council has maintained its focus on diseases of poverty, several other initiatives have been launched such as special drive to develop projects in medical colleges in the periphery, strengthening the fellowship programmes, further strengthening international partnerships, increasing attention on maternal and child health, mental health and through DHR mechanism is working towards **better synergy with other science departments and user departments** in MOHFW to ensure faster transfer of technology to end users. All the above programmes need to be further strengthened and consolidated during XII Five Year Plan.
  - v) During XII Plan, it is proposed to further **expand and strengthen its extramural research** programme with focus on medical and other institutions, programmes on mental health, social and behavioural research, health system research, climate change and health, gender issues, complementary aspects of traditional and modern medicine, trauma and other non-communicable diseases while continuing its emphasis on infectious diseases.
  - vi) **Strengthening of the human resource base** (number of scientific, technical and managerial/ administrative) of ICMR is further proposed to be strengthened by restructuring and creation of new positions. New positions are proposed to be created for long term programmes that are currently run as extramural yet will always be important. New schemes for development of dedicated Research Cadre in medical colleges will be initiated by the DHR/ ICMR.
  - vii) **Opening of new centres on Primate research, other animal models** (National Animal Resources), Policy Research, Zoonotic diseases, Drug resistance, NCDs, Health Systems Research, Health Economics, Clinical pharmacology, Genetics, Transplantation Immunology, Clinical research, oral health, social and behavioural research *etc* is being targeted as future priorities.
  - viii) **Encourage schemes to develop health research in a holistic approach** (integration of different systems/guidelines for better service and to provide support to investigate on reportedly useful treatment methods not covered by any other medical system) will be explored.



While all the above aspects for areas need to be strengthened to fulfil the aspirations and needs of different stakeholders, ICMR proposes to give special emphasis to the following areas:

1. **Extramural research programmes:** Though the ICMR is proposing to expand and strengthen its own institutions, this will only partially meet the needs of the Country. Further empowerment of medical college system across the country is expected to provide greater capacity for not only research but service and good education as all three are interlinked. Keeping this in view, it has been decided that the ICMR Institutions/Centres will focus only on selected areas and strengthen the research in the country by expanding the extramural research programme with a special emphasis on public health aspect and implementation research through medical and other institutions in the periphery. Further, the ICMR plans to continue its focus on communicable diseases, vector borne diseases, mental health, social and behavioural research, health systems research, gender issues, climate change and health, complementary aspects of traditional/ alternative systems and modern medicine, oral health, trauma and other non communicable diseases. The extramural research programme of the ICMR which has expanded several fold during recent years will be further expanded in the XII Plan.
2. **Specialized Centres:** During the XI Plan, ICMR had proposed to open several centres mainly on non-communicable diseases. Due to various constraints, only the National Centre on Disease Informatics, Bangalore and National Institute for Research in Environmental Health, Bhopal could be established. During the XII Five Year Plan, it is proposed to establish the centres for which action has already been initiated. In addition, it has been planned to open centres on policy research, drug resistance, health systems research, health economics, clinical pharmacology, clinical research, social and behavioural research, transplant immunology and other cutting edge/ relevant areas. Wherever, permanent institutions take long time to establish, as an interim measure it proposed to set up centres of advanced research/Centres of excellence in extramural mode.
3. **Application of e-governance/ management in health research:** Department of Health Research has already decided to go for e- governance by creating IT-enabled systems for public, project review process and analysis. The IT component is being proposed in the DHR budget for efficient e-management for not only governance but also as a research tool for operational research to implement knowledge management policy developed by the department during the XI Plan utilizing NKN. All model projects, appropriate administrative systems are proposed to be established during the XII Plan.

vii) **Use of Information Technology:** During the consultations, experts have made several general recommendations which cut across specific areas/ aspects mentioned above :



- The DHR should have IT-enabled systems for dealing with public and a paper-less project management system.
- DHR/ ICMR should have an user-friendly electronic system for the applicants to know the real-time status of their proposals.
- A IT-component should be included in the DHR budget for e-management.
- A system of research audit should be established by the DHR.

viii) **Strengthen synergy and co-ordination:** Experts emphasized that appropriate mechanisms may be considered to strengthen the synergy/ coordination between the DHR, DCGI and FSAI which have common objectives and mandate towards ensuring safe food to Indian people.

*Expansion and strengthening of the ICMR will be reflected by the overall improvement in quality and quantity of health research by medical colleges, universities, other academic institutions as well as ICMR network. Output of these research will also be measurable by the research leads translating into products/ processes and interventions introduced into the programmes and practices. These will also be in the form of ICMR' inputs into policy change for disease prevention and management at patient and public health level. Number of publications and patents; persons trained through capacity building; contributions to disaster management as well as new leads/ knowledge generated will also be measurable outcome.*



## Priority areas – The 10 Point agenda:

While all the areas listed above are important and strongly recommended by their champions, after discussions on draft paper department has proposed the following areas to be of top priority agenda for the DHR for the XII Plan:

1. **Strengthening of research infrastructure:** Establishment of multi-disciplinary research units in medical colleges, model rural health research units in the states; creating a network of laboratories for infectious diseases; non-communicable diseases and specialized areas is considered as one of main priorities.
2. **Strengthening of human resource and creating enabling environment for research** in medical colleges, universities and health research institutions and to consider pathways for developing a good environment to promote health research.
3. **Efficient research governance and regulatory frame work** on core areas pertaining to ethics, clinical trials on new drugs/ devices; ensuring well defined mechanisms for approvals and passage as well as implementation of bills / policies developed is considered as among high priorities.
4. **Development of centres on policy related areas** such as vaccine preventable and other chronic diseases, health economics and health systems research, social and behavioural sciences are proposed to be major thrust areas for XII Plan.
5. **Translational and implementation research** is proposed to be given special emphasis. Besides specific programmes in governmental and academic institutions promotion of public-private partnership will be given special attention for translating research leads into development of affordable diagnostic technologies and pharma products including vaccines to achieve broader objectives of providing better affordable healthcare for the people.
6. **Establishment of efficient mechanisms for the selection, promotion, development, assessment and evaluation of affordable technologies** and their judicious application has been identified as priority. For this purpose structures like Technology Development Board/ Technology Assessment Boards etc have been envisaged.
7. **Creation of efficient mechanisms for inter-sectoral coordination and national/ international collaboration** is among the high focus action areas in XII Plan. This would include development of mutually acceptable systems/mechanisms for collaborative action among departments, institutions and other stake holders in the country and other countries.
8. **Strengthening of ICMR institutions,** establishment of new specialized centres within and outside the ICMR and expansion of existing extramural programmes of the Council.



9. **Optimum use of Information Technology using the National Knowledge Network** as backbone for health research aimed at service, education and research and research management.
10. **Research priorities will be guided and focused on problems of tribal and other marginalized communities** and addressing gaps in the knowledge in diseases affecting these populations.



## BUDGET

During the XI Plan, Rs.4496.08 crores outlay was approved for the ICMR. The DHR was created during the middle of the XI Plan and no separate budget was sanctioned for this Department.

For the XII Plan, an outlay of **Rs.15,000 crores** is proposed. Main budgetary items are:

### **DHR other than ICMR: (Rs 6500 crores)**

- **Infrastructure development** ( Rs.3000 crores; 250 multidisciplinary units in medical colleges; 50 MRHRU units; specialized centres/ units)
- **Human Resource Development** (Rs 1000 crores; 1000 midcareer and 2500 young investigators; 2/3 from medical colleges )
- **Laboratory network for research on viral and other infectious diseases (Rs 900 crores; 6 regional BSL III; 50 cat. I state level labs and 200 Cat. II district level labs in medical colleges)**
- **Grant in Aid scheme for projects requiring inter-sectoral coordination, translation specially in PPP mode and IT enabled governance as well as implementation research ( Rs 1500 crores)**
- **Governance and departmental expenses** (Rs 100 crores)

### **ICMR: (Rs 8500.00 crores)**

- **Funding of extramural projects ( Rs 2500 crores including the ongoing projects);**
- **Funding of intramural programmes through ICMR Institutes/ Centres ( Rs 2500 crores including the ongoing studies)**
- **New Institutes/ Centres/ upgradation of existing ones (Rs 3150 Crores – Non communicable diseases - Cardiovascular, neurological, mental, ageing ; Primates and other animal models; Health Systems Research, Health Economics, Policy Research on Drug resistance, Vaccine Preventable Diseases, Clinical Pharmacology, Molecular and Transplant Immunology etc.)**
- **Outbreak /Disaster Response Fund- Rs 50 crores**
- **New positions – (Rs 300 crores) – Mostly scientific for creating essential structure in DHR, its outreach units/ labs; ICMR Institutes/ Centres in deficient areas as well as new Institute and Hospital at Bhopal.**





## ANNEXURE II

### Achievements of DHR/ICMR during the XI Five year Plan

Department of Health Research (DHR) was created in 2007 and started functioning on a regular basis around end of 2008 when new Secretary who is also the Director-General of Indian Council of Medical Research (ICMR) joined. DHR has been assigned ten business of which nine are new and administering and monitoring the ICMR was the only ongoing activity.

During the XI Plan period the Department of Health Research took a number of initiatives to implement the nine new business besides the strengthening of ICMR. Four schemes have been prepared after wide consultations which will serve as Phase I of new department. These schemes pertain to infrastructure development for research in medical colleges and rural areas in state services; human resource development; network of laboratories and mechanisms to deal with outbreaks/ epidemics/ pandemics and other disasters and grant-in –aid to projects which require inter-sectoral coordination to develop affordable technology/ knowledge to address public health issues. All the schemes have been approved in principle by the Planning Commission and other procedures are being completed to launch within XI Plan. Further, in order to improve the research governance, various policies like Health Research Policy, Knowledge Management Policy, policy to map and recognize health institutions as well Bills for Assisted Reproductive Technologies; revised Bill on Ethics – The Biomedical and Health Research involving human participation Regulation Bill, 2011 have been developed.

In the meantime, the DHR through its century old organization ICMR has made many important scientific contributions to face the challenges of national crises like H1N1 pandemic, previously not reported infections such as Crimean Congo fever and also contributed to new knowledge towards development of technologies that have/ will have potential application in our national programmes on communicable as well as non-communicable diseases.

Two new institutes - the National Institute for Research in Environmental Health (NIREH), Bhopal and National Centre for Disease Informatics and Research (NCDIR), Bangalore were established during the XI Plan period.

#### **Some significant achievements are listed below.**

- Four flagship programmes of the Department of Health Research viz., Tribal Health Research Forum, Vector Science Forum, Special support to medical colleges and Translational Research have been initiated through ICMR mechanism during this plan.
- During 2007-11, 15 Centres for Advanced Research were established in addition to funding 283 multi-centre Task force studies and 623 ad-hoc research projects.
- About 1200 projects are ongoing in the areas of epidemiology and communicable diseases, reproductive, maternal & child health and Nutrition, non-communicable diseases, basic medical sciences, health systems and socio-behavioral aspects.



- Tribal Health Research Forum has been established to synergize and intensify the research efforts of seven ICMR Institutes engaged in the area of tribal health research and work towards translating the identified leads to public health benefit .
- Vector Science Forum, created to promote focused co-ordinated research on vector-borne diseases meets regularly to review progress, identifies new areas that need focused and which could be introduced into our national programme.
- Special support to medical colleges on a mission mode has been initiated as part of the DHR/ICMR's outreach programme; this programme has identified several medical colleges, especially those located in North, North-east parts of India where the outreach was minimal, for intensive training of the faculty on research methodology, study design etc and has started providing seed grants.
- Translational Research that envisages harvesting the innovations/leads identified into products/processes/methodologies with a portfolio of over 100 potential leads for a wide spectrum of disease conditions and for varied applications such as diagnostics, methods that have application in disease control programmes, has about 50 leads in advanced stage of validation and refinement for converting them to products, processes and methods for public good.
- The flagship journal of the Council, The *Indian Journal of Medical Research* continued to be the top medical journal in India with highest impact factor. The Journal is now available full text free-to-access since inception (1913) and has totally web-based editorial management.
- During the period, about 50 patents (both in India and abroad) were filed and several technologies are in advanced stage of commercialization.

### Creation of New Infrastructure

- Some major institutions set up include the School of Public Health at NIE, Chennai in July 2008.
- New field stations of RMRC Port Blair at Car Nicobar, Narcowry; NIV Pune at Gorakhpur, UP, Alappuzha, Kerala were established. The NIMR shifted to its own campus at Dwarka, New Delhi and is fully functional. The Institute has also been identified as Centre of Excellence (COE) in malaria research by the NIH, USA.
- All ICMR institutes have further strengthened their linkages with State Governments in local health related issues for technical and operational support
- Model Rural Health Research Unit at Ghatampur was strengthened so as to develop it as a model of partnership with states for transfer of technology to end users.
- The National Clinical Trials Registry in India, an online system for registration of all clinical trials ([www.ctri.nic.in](http://www.ctri.nic.in)) in India was established
- A Network of Viral/ Infectious Disease diagnostic laboratories set up in the country to build capacity for handling outbreaks of all emerging-re-emerging and common viral diseases all across the country and to carryout research. Three different levels of laboratories are being



- set up. Sixteen new ( 14 BSL II and two BSL III) laboratories have been established within ICMR and also other institutions so far during XI Plan to deal with these pathogens; one BSL IV plus a few other category of such laboratories are scheduled to be commissioned soon. Eventually this programme will merge and synergize with DHR.
- A network of laboratories for diagnosis and characterization of H1N1 influenza virus was established with NIV, Pune as coordinating Institutions during the crisis of the 2009-2010 pandemic. NIV has earlier been identified as a WHO referral center and reference center with eight other regional centers.
- Malaria Parasite bank (*Plasmodium falciparum*, *P. vivax* and *P. malariae*) with over 1075 isolates serves as a national resource/facility for Plasmodium isolates in the country. Other repositories on mycobacteria, HIV and leishmania also continued to function during this period.
- National Tumor Tissue Repository (NTTR) at Tata Memorial Center, Mumbai with about 15000 normal and tumour tissues from various anatomic sites for research.

### Human Resources Development

- A total of 45 medical doctors joined the MD-Ph.D. Programme of ICMR during XI Plan whereas 250 have availed of the scheme that offers financial assistance for MD/MS/MCH/ DM thesis.
- Over 500 Senior/Junior Research fellowships and more than 3500 Short Term Studentship programmes to undergraduate medical students were sanctioned during the Plan period.
- A new Centenary Post-doctoral Fellowship scheme was launched, 33 fellowships have been awarded so far.
- International Fellowship scheme launched to provided support to Junior (12) and senior level (6) biomedical researchers.
- Newly created fellowships (6) under German Science Centre for Infectious Diseases (IGSCIDI)

### Technology Development and Translation Research

- A real time RT-PCR useful for early diagnosis was developed for detection of dengue viral RNA.
- A kit for JE developed and supplied for national programme.
- DNA chips developed for studying the molecular mechanism(s) of survival of TB and Lepra bacilli in host and several useful candidates for translation identified.
- New rapid molecular methods for detection of rifampicin, isoniazid and ethambutol resistance in TB developed.
- Developed a new DNA fingerprinting method useful for diagnosis of TB and other mycobacterial infections.



- Luciferase reporter phage assay developed using recombinant mycobacteriophages for both rapid diagnosis and drug susceptibility testing.
- Study of genomic diversity of leprosy bacillus and expression of its genes in human host has led to identification of genetic markers with potential to elicit diversity among *M. leprae* strains.
- Developed an immune-chromatographic dipstick kit for the rapid diagnosis of cholera with sensitivity and specificity of 92% and 73% respectively.
- Monoclonal antibody based indigenous diagnostic assay developed for diagnosing patients with *Chlamydia trachomatis* infection.
- Rapid IgM ELISA and Latex Agglutination Tests for Leptospirosis developed.
- Technology developed for the production of mosquito larvicide, *Bacillus thuringiensis* var. *israelensis* was transferred to industry.
- Multiplex PCR for detection of *An. annularis* species complex and their vectorial attributes developed.
- Bivalent rapid diagnostic malaria kits tested, approved and successfully inducted into the National programme.
- Real-time PCR assay developed to diagnose and simultaneously estimate parasite load in clinical samples of Visceral Leishmaniasis (VL) and Post Kala-azar Dermal Leishmaniasis (PKDL).
- Developed a ELISA kit for identification of Paragonimiasis (lung fluke) after characterization of Paragonimus species in NE India.
- Non - invasive prenatal diagnostic technique developed for hemoglobinopathy shown to be suitable detection in the 10 to 15 week pregnancy.
- Simple and inexpensive screening test for Fragile X syndrome, a common cause of mental retardation in males, developed.
- Established an inexpensive, fast and accurate flow cytometric technique for evaluation of osmotic fragility in hemolytic anemias.
- Technology for estimation of Vitamin A in blood samples using Dried Blood Spot (DBS) developed.
- Technologies of double fortified salt (DFS) and fortification of wheat *atta* with iron and other essential nutrients transferred to the industry.

### **Clinical Trials for National Health Programmes**

- The current dosing schedule leads to adequate plasma levels of nevirapine in HIV- infected children receiving antiretroviral therapy with fixed dose combinations.



- A bivalent whole cell killed oral cholera vaccine ( developed by International Vaccine Institute) in a Phase III randomized control trial in Kolkata showed protective efficacy of 67% in all age groups at the end of two years and 65% at the end of three years post vaccination.
- Developed and proved the concept of common regimen for treatment of leprosy, now adopted as Uniform Multidrug Therapy Regimen (UMDT) by WHO.
- Co-administration of albendazole with DEC is operationally feasible, safe for community use and has an edge over DEC alone for the Lymphatic Filariasis (LF) elimination programme and has been accepted and implemented by the National Programme.
- Established that the combination therapy of DEC and albendazole for filariasis resulted in enhanced efficacy against geohelminths.
- Demonstrated better efficacy of reduced osmolarity ORS in young children and adults in dehydrating diarrhoea compared to that of standard ORS.
- Phase-III Clinical Trial with an intravascular injectable male contraceptive RISUG<sup>®</sup> did not indicate any side effects after two years of intervention.
- Long-term retrospective follow up study (after 9-10 years) of RISUG injected subjects showed no serious adverse clinical symptoms suggesting its safety and efficacy as a long term male contraceptive.
- Phase – 3 clinical trial with subdermal contraceptive single rod implant Implanon indicated its efficacy and acceptability to women as a contraceptive.
- Low dose magnesium sulphate was as good as standard dose for management of eclampsia.
- A combination of metformin and life style modification could help women with Polycystic Ovarian Syndrome (PCOS), improve ovulation, pregnancy outcome, self-esteem and endocrine parameters.
- DEC fortified salt has been demonstrated to be a potential supplementary strategy to MDA of annual single dose DEC.

### **Epidemiological/Operational research**

- Key results on the Home based management of young infants are: In the *Shishu Rakshak* arm there was 21% decline in early neonatal mortality rate compared to control arm. Decline in IMR (29%), young infant mortality rate (25%) post-neonatal mortality rate (42%) was observed in *Shishu Rakshak* arm compared to control arm. In the *Angan Wadi Worker* arm also 13% decline in IMR was observed compared to control population but it was statistically not significant. The impact on NMR, post-neonatal mortality rate and young infant mortality rate in the AWW arm was less remarkable and / or statistically insignificant.
- ‘Developed a Mental Health Needs Scale’ of the mental health needs of the people living with HIV-AIDS (PLHAs) which is now being used by National AIDS Control Organization (NACO).



- Mathematical models for HIV/AIDS epidemic developed to study the transmission dynamics of HIV/AIDS in the population.
- Epidemiological studies at Ghatampur (UP) have showed a steep decline in prevalence of disease indicating the endemicity to be due to back-log of cases and that *M. leprae* persists in environment.
- Use of Remote Sensing (RS) and Geographical Information system (GIS) established for assessing the density of malaria vectors.
- A filariasis transmission risk map for India was created using a GIS based geo-environmental risk model.
- Control of *Aedes* spp. successfully demonstrated using temephos and environmental management in a peri-urban area through involvement of community volunteers.
- Allowing of paramedics to provide emergency contraceptive pill/services would enhance its accessibility manifold.
- The Pune low birth weight (LBW) study - birth to adulthood showed that all LBW children showed poor speed on differential aptitude test with lower IQs.
- The National Level Expert Group recommended a maximum residue level of one part per billion (ppb) for an individual pesticide for carbonated water based on the ICMR data.
- Revision of nutrient requirements and recommended dietary allowances for Indians carried out.
- Based on the findings on ICMR-ICAR data, on analysis of aflatoxin levels government recommended PAU-201 rice variety samples collected from Punjab to be safe for human consumption and showed that black spots are not indicative of fungus.
- Data on the safety of consumption of *lauki* juice recommended that *lauki* should be tasted before extracting juice that it is not bitter and guidelines for clinicians formulated.
- An intervention model to manage the effects of fluorosis was prepared through the combination of *Safe drinking water and supplementation* mainly with calcium, vitamin C, iron and vitamin D<sub>3</sub>. led to complete reversal of bone deformities caused due to fluorosis both in mild and moderate cases and partial reversal in severe cases.
- *Jaivigyan* Mission Mode Project on Rheumatic Fever and Rheumatic Heart Diseases revealed the prevalence of beta haemolytic streptococci (BHS) in 26.5% and 8.8% respectively, whereas, that of Group A streptococcus was 11.1% and 2.5% in throat samples respectively in Chandigarh and Vellore. A significant development of the project has been up-scaling of this project to Punjab Rheumatic and Congenital heart disease Programme by Chandigarh nodal centre. The programme has also been initiated in four districts of Himachal Pradesh.
- Database on national prevalence data on diabetes for different time periods.
- Published Cancer Atlas that helped map patterns of cancer.



- Developed a magnifying device (Magnivisualizer) for cancer screening in the field.
- National Cancer Registry Programme (NCRP) provided information about patterns of cancer patient care and survival through Cancer Registries.
- Genetic polymorphism established in relation to hypertension in North East.

**Guidelines :**

- National Guidelines developed for the Prevention, Management and control of Reproductive Tract Infections including Sexually Transmitted Infections (RTIs/STIs).
- Guidelines for Management of Diabetes
- Guidelines for management of three type of cancers (oral, buccal and stomach) developed.