



# ICMR BULLETIN

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## Draft

## National Health Research Policy

*Why has a need of a National Health Research Policy arisen now ?*

*Though history of health research in India goes beyond 1911, when the Indian Research Fund Association, the precursor of Indian Council of Medical Research (ICMR) was established, the country did not have a policy to guide research until the ICMR formulated its Health Research Policy in 2007.*

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

*In 2007 the Government of India created a new Department of Health Research within the Ministry of Health and Family Welfare. This was a clear signal that research would play a crucial role in shaping health policies and programmes in the country. Subsequently, a Committee of Experts reviewed the situation, and its Sub-Committee drafted this National Health Research Policy. It is hoped that the policy, which draws heavily from the Health Research Policy of the ICMR (2007), would facilitate the generation of evidence-base for health systems and services, so that they will be significant promoters of equity and contribute to national development. The policy will help to meet the multi-faceted challenges including those of creating and managing national health research system, capacity-building and networking, dissemination of results including their translation into action. In addition, this policy is expected to serve as a beacon to guide health research in India which should contribute towards attainment of better health for all Indians.*

*The draft is being widely circulated and open houses are being organized in major metros. It is available on the Council's website for a wider readership for comments and suggestions. The final version will be developed based on public opinion which will incorporate the comments and suggestions received. Send in your comments to Dr. Lalit Kant, Scientist-'G', ICMR Hqrs., New Delhi at [lalitkant@icmr.org.in](mailto:lalitkant@icmr.org.in)*

*This is an abridged version of the Policy. For a complete version please visit the ICMR's website ([www.icmr.nic.in](http://www.icmr.nic.in)).*

## Preamble

India is a significant contributor to knowledge on health, with research outputs ranging over the entire spectrum, from epidemiology and clinical care to biotechnology and genomics. A large number of government departments (Health, Science and Technology, Atomic Energy, Human Resource Development, Social Welfare, etc.) support health research.

Research is carried out in national institutes, autonomous research institutes, universities and other academic institutions and by a variety of private organisations, including the pharmaceutical industry. In addition, the Department of Science and Technology (DST), the Department of Biotechnology (DBT), the Council of Scientific and Industrial Research (CSIR), Defense Research and Development Organization (DRDO), Department of Agricultural Research and Education (DARE) and the University Grants Commission are some of the other major agencies financing health research. There are other Research Councils in the Ministry of Health and Family Welfare for Ayurveda and other Systems of Medicine. Research and development in private sector including the industry has also matured to play a significant role in health sector.

Health has been accepted as a fundamental right of all people by the Constitution of the World Health Organisation. The fundamental right to life enshrined in the Constitution of India, includes the fundamental role of health as an integral component. India is making significant investments in health and health research. The creation of Department of Health Research (DHR) is the testimony of recognition of importance of health research. 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 National Health Research Policy is formulated to channel efforts and funds in the right direction.

### **National Health Policy**

The first National Health Policy (NHP) of 1983 was a response to the commitment to the Alma Ata declaration to achieve "Health for All by 2000". It was revised in 2002.

The National Health Policy 2002 (NHP2002) reviewed the scenario and recognised that while there had been significant improvement in demographic trends, control of infectious diseases and growth of infrastructure between 1981 and 2000, health indicators were still far from optimal. Inequity in health care access was still continuing at a time when 'Health Tourism' was being promoted. During the 11<sup>th</sup> Plan about 3% of the health budget was earmarked exclusively for health research. The NHP 2002 envisaged that by 2010 the public investment in health would reach 2% of the GDP. But it has been below 0.4% during 2007-10.

It is, therefore, timely that a National Health Research Policy is enunciated to ensure that these goals are met.

### **Health, Health Research and Development**

Health is a key factor in national prosperity. Despite overall gains in health since Independence in 1947, in many instances, health inequities between rich and poor have widened. Newer and re-emerging diseases have undermined gains, and accidents, injuries, mental health problems as well as non-communicable diseases pose new and greater challenges even as we are trying to cope with the long standing challenges of maternal and infant mortality. Globalization, trade reforms and the focus on intellectual property rights are additional pressures for India to face. The rapid privatization of health care with the growth of for-profit corporate hospitals has led to a health tourism industry in India. The pressures for access to this high quality tertiary care has led to a wider use of state sponsored insurance for those below the poverty line e.g. in Tamil Nadu and the Bharat Nirman Programme. However, it is too early to assess the impact and changes this would bring about in the national health scene.

The scenario is rapidly evolving as the country enters the 12<sup>th</sup> Plan period with the restructuring of the health care system with the implementation of the National Rural Health Mission (NRHM) and the proposed National Urban Health Mission (NUHM), opening of a large number of medical colleges spread across the country providing the tertiary level health care, and the NGOs supplementing the Government's efforts. India is poised to take its rightful place in the global village that a policy spelling out the critical role of health research in the country's development is adopted.

### **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 programmes (for example Vitamin A Prophylaxis, National Vector Borne Diseases Control Programme, National Immunisation Days, use of bivalent vaccine for poliomyelitis eradication, DOTS regimen for treatment of tuberculosis in the Revised

National Tuberculosis Control Programme-RNTCP, new regimens for leprosy and kala azar likely to lead to elimination). The contributions made by these, essentially Indian discoveries to national welfare is unquestionable, but in some instances they had to be rediscovered by international agencies before they were nationally implemented. Further, the recognition that the continuous evaluation of the evidence bases for national health is a responsibility of the DHR is shown by the national subscription for the Cochrane data base, the first of its kind in the developing world.

### **International Initiatives Outlining Rationale and Need for Health Research Policy**

Giving an impetus to health research was the Commission on Health Research and Development, 1990 which proposed a set of strategies through which the potential of research could be harnessed to accelerate health improvements and to overcome health inequities throughout the world. Since then several global initiatives have been taken. In 2004, the WHO's World Report on Knowledge for Better Health, included a chapter linking research to action. In the same year, the Ministerial Summit on Health Research at Mexico City issued a statement on importance of research for better health and for strengthening health systems. In 2005, the 58th Session of the World Health Assembly passed a resolution acknowledging the Mexico statement and urged the member states "to establish or strengthen mechanism to transfer knowledge in support of evidence base public health, health care delivery system and evidence based health related policies. In the 60<sup>th</sup> World Health Assembly, 2007, one of the resolutions adopted was WHO's Role and Responsibilities in Health Research (WHA 62/12). It urges the member states to draw up or strengthen health research policies. At Bomako (2008) the statement issued by Ministers of Health, Ministers of Science and Technology, and Ministers of Education stressed the need to continue building on the progress made since Mexico.

A relatively recent development is the growth in the number, size and financial outlay of philanthropic foundations and international NGOs. While their stated aims and objectives cannot be faulted, in several instances there is cause for concern on their limited or narrow agenda, the likelihood of their diverting national focus or influencing the thrusts and directions. This could be detrimental to national

interests, thus reinforcing the need for national policies.

### **National Imperatives Necessitating a Health Research Policy**

The establishment of a Department of Health Research (DHR) in the Ministry of Health and Family Welfare is recognition by the Government of India of the key role that health research should play in shaping policies and programmes of the nation. This decision was preceded to the Report of India's National Commission on Macroeconomics and Health (NCMH) which builds a strong case for investing in indigenous research and encouraging Indian companies and universities in partnership to engage in R and 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.

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 300 medical colleges in the country are not contributing of their best to health research is highlighted by the fact that in 2007 96% of the research publications in India emanated from 9 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 and the proposed National Urban Health Mission 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.

This is the context in which the DHR has to define a National Health Research Policy. In India, while most of the agencies funding research have plans in general linked to the National 5 year plans, a coordinated National Health Research Policy which could guide the planning and implementation is not yet in place. The increasing international collaborative research in priority areas of national health also necessitates a clearly spelt out policy to ensure that the contributions of our international partners can enhance the ability of the partnership to improve national health. Some of the conflicts and failures of Indian health research can be attributed to the absence of such an overarching policy.

### Current Status of Health Research in India

#### Achievements of Health Research in India

There are several instances over the past sixty years that clearly indicate that, in spite of the handicaps and difficulties, contributions have been made in the health sector through research done in India by Indians, which have significantly changed the health scenario. Critics may say that none of the health research from India has merited consideration by the Nobel Committee. However, it must be emphasised that neglected diseases of poverty which have been primarily addressed by Indian health research should be judged not by its impact factor in a developed world oriented science but by the transformation of health. The measurable gains of tuberculosis control, polio eradication, and newer treatment of kala azar resulted from research done in India speaks for itself. These achievements are not the result of any single agency's efforts, although 60% of the research in neglected diseases is funded by the ICMR. 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 (Council of Scientific and Industrial Research, Department of Biotechnology, Department of Science and Technology, etc.), DRDO, 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. A key role that the DHR would play is in interpreting science of research for policy makers and responding to the demands from the health care system for critical answers.

#### Constraints and Concerns

There are constraints in health research that need to be identified and rectified by the DHR to maximize the benefits to the health system enabling it to be a vehicle for national development. Some of these constraints are:

- Policy makers do not readily recognise the developmental importance of national health research. In fact while the important current health programmes like the National Immunisation days and DOTS, arose from the results of Indian health research, they were implemented only when given the seal of international acceptance.
- National coordination of the considerable investment in research in the health sector is currently not done. There is no National Plan or consensus on priorities.
- A research culture and a climate that fosters health research are not present. In fact many scientists feel that they subserve a 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.
- Intersectoral linkages are weak and serve primarily for information and not for coordinated action.
- The tools of modern information technology and biotechnology are relatively inaccessible to the majority of health professionals and researchers.
- The links between health research and health services and programmes are weak and ill defined.

- Lack of enabling environment for translational research

### Challenges facing Health Research in India

Given the achievements made, the constraints faced and the concerns felt, the challenges before the country in health research are:

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

### The Health Research Policy Statement

**Policy Statement:** *Maximize the returns on investments in health research through creation of a health research system to prioritize, coordinate, facilitate the conduct of effective and ethical health research and its translation into products, policies and programmes aimed at improving health especially of the vulnerable populations.*

### Objectives of National Health Research Policy

- I. Identify priorities for effective and ethical health research to enable the achievement of the objectives of NHP 2002, NRHM, Bharat Nirman and National Food security Act as well as global commitments such as Millennium Development Goal (MDG) and IHR, ensuring that the results of health research are translated into action.
- II. Foster inter-sectoral coordination in health research including all departments within the government, private sector and the academia to promote effective translation to encourage/accelerate indigenous production of diagnostics, vaccines, therapeutics, medical devices, etc.
- III. Focus on the marginalized, the vulnerable and the disadvantaged sections of society.
- IV. Strengthen national networks between research institutes, academia and service institutes, and encourage Public Private Partnership (PPP).
- V. Put in place strategies and mechanisms for assessing the cost-effectiveness and cost benefits of interventions for health.

VI. Develop and manage human resources and infrastructure for health research and ensure that international collaborative research contributes to national health.

### Policy Prescriptions

The Policy prescribes creation of a National Health Research System which would be managed by a National Health Research Management Forum; and provides a 10-point action programme.

### National Health Research System

Health research in the country should be developed into a **National Health Research System (NHRS)** wherein all research agencies, cutting across ministries and sectors identify priority areas of research and coordinate with each other to avoid duplication, fragmentation, redundancy and gaps in knowledge, in order to enable the results of research to transform health as a major driving force for development.

### Goals of the NHRS

- To generate and communicate knowledge that helps to form the national Health Plan and guides its implementation, and thus contributes, directly or indirectly, to equitable health development in the country;
- To adapt and apply knowledge generated elsewhere to national health development; and
- To contribute to the global knowledge base on issues relevant to the country

### Underlying Values

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

### Operating Principles

#### National Health Research Plan

The DHR is responsible for the National Health Research Plan for a National Plan aligned with the Five Year Plans of GOI and its implementation and monitoring.

#### Priority setting

A priority research agenda will be developed in tune with the NRHM, proposed NUHM, national programmes, and relevant to national and local needs, based on the following principles.

- **Responsiveness**

Current and emerging issues such as demographic and epidemiologic transition, emerging scientific developments such as modern biotechnology (genomics, human genetics, new drug development, stem cell research), health system research, health economics, behavioural and social issues, emerging and re-emerging infections, etc. and the priorities of the National Health Plan will guide the research agenda.

- **Integration**

The integration of the National Research Plan with the priorities and aspiration of society is essential for the ready utilisation of the results of research. The linkages of the health system with communities, district and state governments and the central government is essential for developing the data bases necessary for research and service priority setting and decision making. The generation of this data shall be a priority.

- **Multidisciplinarity and linkages**

Health research, in addition to the field of health, intersectorally encompasses education, environment, ecology, social and behavioural sciences, population, agriculture, trade, commerce, in addition to the physical, chemical, biological and mathematical sciences. This multidisciplinarity will be reflected in the National Health Research Plan.

- **Social and behavioural sciences and health economics**

In order to make meaningful health policies, plans and programmes and to make medical technology useful and accessible to the community, it is essential to understand the community's perception of health problems, health services and health care providers. Social and behavioural sciences and health economics are integral to Health research and will be actively fostered.

- **Focus on vulnerable and disadvantaged populations**

Equity in services and development shall be the cardinal principle under riding the Health Research System. There shall be a special emphasis on vulnerable groups like scheduled castes, tribal populations, 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.

### **Private sector in health research**

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

### **International linkages**

In the current global scenario international collaborative efforts are recognised as one of the factors in successful research because of the complementarity of technology transfer, capacity building and access to diseased populations. There are a large number of potential partners and in the choice of partners the priorities of the National Health Research Plan and national interest shall be paramount. Linkages with international developmental partners and WHO and other UN agencies shall be further developed and strengthened to ensure that India plays a legitimate role as an emerging economy.

### **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 Drugs Controller General of India (DCGI).

### **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.

### **Monitoring and evaluation**

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

The National Health Research System would be managed by a National Health Research Management Forum.

### **National Health Research Management Forum**

The National Health Research Policy envisages a system wherein all present and prospective players have their own space. However, an overarching National Health Research Management Forum (NHRMF) is proposed, having representation of all key stakeholders, the DHR as its secretariat.

### **Terms of reference of NHRMF**

- i. advise on and evolve national health research policies and priorities and to evolve mechanisms and action plans for their implementation;
- ii. develop a 5 year projection of the plans for health research and to prepare an annual national health research plan;
- iii. do a mid-plan appraisal for course correction, as needed
- iv. promote the development of health research activities in the country;
- v. review biomedical and health research management, and suggest strategies to

overcome problems in implementation of policies;

- vi. suggest mechanisms to nurture a scientific environment to attract talent and to develop human resources for biomedical and health research; and
- vii. facilitate utilisation and dissemination of research results and advocacy for Health research

### **Structure**

The NHRMF will be chaired by the Minister of Health and Family Welfare and co-chaired by Minister of Science and Technology. The Minister(s) of State for Health would be the Vice-chairperson(s). The secretariat shall be in the DHR and its secretary shall be the Member-Secretary. All secretaries of various Departments in Science and Technology would be the members, The Director General of Health Services (DGHS) and 3-5 eminent scientists/public health experts would be the other members.

### **Stewardship**

This would encompass a range of activities for the national health system intended to ensure quality leadership, productivity, strategic direction and coherent action. Sub-functions would include strategic vision, policy formulation, priority setting, performance and impact assessment, promotion and advocacy, and the setting of norms, standards and frameworks for the sound practice of research.

### **Financing**

The essential functions of the system as regards finances would be to address issues related to resource generation, targeted allocation and judicious utilisation. On the basis of recommendations of the NHRMF, 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.

### **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.

### **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.

### **10- Point Action Programme**

In order that the Policy is able to achieve its objectives it recommends a 10-point action programme:

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



- iv. Encourage the development of fundamental research in areas relevant to health, such as physiology, biochemistry, pharmacology, microbiology, pathology, molecular sciences and cell sciences, to ensure that a national critical mass of scientists who can contribute the benefits of modern technology to health research is developed.
- v. Facilitate priority setting to guide the direction of health research and prepare rolling planning and strategy documents.
- vi. Build and integrate capacity for research in national health programmes, research institutions and in the private sector (profit and non-profit organisations) especially in rural and urban research centres utilising as far as possible areas of excellence already available in the country.
- vii. 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.
- viii. Manage global resources and transnational collaborations optimally to ensure that collaborative health research primarily facilitates the development of national health systems and services.
- ix. Ensure true intersectorality of health research and harness the resources in areas such as social sciences, economics and traditional systems of medicine.
- x. Optimum harmonisation of national policies in a variety of areas (education, social sciences, population, agriculture, nutrition, trade, commerce, etc.) is essential to facilitate intersectoral collaboration and partnership, so that maximum developmental returns can occur from health research.

## ABSTRACTS

### Some Research Projects Completed Recently

#### **Effect of age, gender, kidney size and pre nephrectomy glomerular filtration rate on renal function reserve in Indian kidney donors**

Renal function reserve is the ability of the kidney to increase its GFR when stressed. Donor nephrectomy has been shown to demonstrate renal function reserve in remaining kidney. After unilateral nephrectomy the remaining kidney increases its glomerular filtration rate (GFR) by 25% to 40% within four weeks. Factors affecting the renal function reserve of the remaining kidney include pre nephrectomy GFR, age, and gender. The study was undertaken to enumerate these factors in the Indian donors and compare it with western literature.

Kidney donors undergoing surgery in Army Hospital over a period of two years had their GFR estimated using DTPA scintigraphy at two times, pre nephrectomy and one month post nephrectomy. Data were analyzed to assess renal function reserve of the remaining kidneys and compare the increase in GFR with respect to age and gender.

The result indicated that GFR increased in 71 patients, remained same in 2 patients and decreased in 7 patients. One month post nephrectomy GFR of

the remaining kidney increased by 19.3%. GFR in male and female donors increased by 17.5% and 20.43% respectively. The GFR increased by 32.14 in 18-30 yrs., 15.8% in 31-40 yrs, 12% in 41-50 yrs, 20% in 50-60 yrs and by 13% in above 60 yrs group. The kidney size and renal volume of the remaining kidney continued to increase up to 1 year with maximal increase occurring within the first month. Similar increase was noted in males and females. Percentage increase in kidney size and renal volume was maximum for the younger group.

It was concluded that the renal function reserve in Indian donors is less than their western counterparts. Primary factor predictive of post nephrectomy GFR is the pre nephrectomy GFR; age and gender are other factors. Measurement of kidney size and renal volume pre and post nephrectomy is not an accurate indicator of the renal function reserve.

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**Dr. Tapan Sinha**

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### Evaluation of the DNA damage in the cultured peripheral blood lymphocytes of head and neck and oesophagus carcinomas as the predictor of response of to radiotherapy

The study was under taken on one hundred patients presenting with head and neck (74 patients) or oesophageal carcinoma (26 patients) to identify the correlation between the degree of DNA damage with treatment outcome with radiotherapy. Blood samples were collected before the start of treatment and after the delivery of 5,10, 15, 20, 25 and 30 fractions of radiotherapy. Patients also received concurrent chemotherapy with 100mg/m<sup>2</sup> Cisplatin on day 1, 22 and 43 of the treatment. The extent of DNA damage was evaluated by the frequency of micronuclei in cultured peripheral blood lymphocytes and by comet assay.

Pre-treatment samples showed micronuclei to be in the range of 23 to 46 per 1000 cells (mean=30.31). The frequency increased in a radiation dose dependent manner, and the highest micronuclei were observed after the delivery of 30<sup>th</sup> fraction of radiation (range = 111-160 MNBC/1000; mean = 140.14). The difference between the two means was significant (p=0.008). The initial micronuclei count was found not to correlate well with the outcome (p=0.432); however, higher frequencies at the completion of treatment suggested a significantly improved outcome compared to lower frequencies (p <0.001). Complete response was found in 55 patients and partial response in 45 patients. A partial clinical showing complete response had higher frequency of micronuclei. The study demonstrated that a non-invasive method such as analysis of micronuclei in peripheral blood can be used as a surrogate marker to predict the radiation response of the tumour in cancer patients.

**Dr. M. Vidyasagar**

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### Assessment of dynamic muscular stabilization in the non operative treatment of lumbar pain syndrome: A single blind control study

The low back pain (LBP) is a multifactorial and its treatment varies considerably. It includes meditation, physical therapy modalities and exercise therapy with each having several interventions. The present study was undertaken to determine the effect of

lumbar stabilization technique on pain, functional capacity, evaluate the pressure changes of back muscle (M) and abdominal muscle (T.A.), quality of life and recurrence rate.

A total of 141 patients (20-40 years of age), with sub-acute or chronic LBP included in the study were randomized in two groups and treated either by conventional treatment—a combination of two electro therapy (ultrasound and short wave diathermy) and one exercise therapy (lumbar strengthening exercises) and dynamic muscular stabilization techniques (DMST)—An active approach of stabilizing training. It was observed that pain, physical strength (BPC, APC) functional ability (walking, stairs climbing, stand-ups), quality of life and rate of recurrence improved significantly more in subjects treated with DMST than those treated with conventional method. The effect of DMST on pain severity, BPC, APC, walking, stairs climbing, stand-ups and quality of life was 27.5% (1.4 fold), 56.7% (2.3 fold), 48.6% (1.9 fold), 50.3% (2.0 fold), 50.7% (2.0 fold), 44.4% (1.8 fold) and 56.6% (2.3 fold) higher respectively than the conventional method. Similarly, the recurrence in subjects of DMST group lowered by 49.8% (0.5 fold) as compared to subjects of conventional method.

The study concluded that both treatments are effective in the management of LBP but recommends DMST intervention in their daily clinical practices. This reduces the pain significantly as well as enhances the average capacity of functional status to a greater extent and reduces recurrence rate.

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### Publications

1. Kumar, S., Negi, M.P.S. and Sharma V.P. Efficacy of dynamic muscular stabilization technique (DMST) over conventional technique in rehabilitation of chronic low back pain. *J Strength Cond Res* 23: 2651, 2009.
2. Kumar, S., Sharma, V.P., Tripathi, H.H., Negi, M.P.S. and Vendhan, V. Efficacy of dynamic muscular stabilization techniques (DMST) over conventional techniques in patients with chronic low back pain. *Indian J Physiother Occup The* 3:47, 2009.

3. Kumar, S., Sharma, V.P., Dev, R. and Negi, M.P.S. Diagnosis and prognosis by functional strength and ability in patients with low back pain. *Indian Physiother Occup Ther*. 3: 44, 2009.
4. Kumar, S., Negi, M.P.S., Sharma, V.P., Shukla, R., Dev, R. and Mishra, U.K. Efficacy of two multimodal treatments on physical strength of occupationally sub grouped male with low back pain. *Back Musculoskeletal Rehab* 22:179, 2009.
5. Kumar, S., Sharma, V.P., Negi, M.P.S., Shukla, R. and Dev, R. Comparative efficacy of two multimodal treatments on male and female sub group with pain. *Back Musculoskeletal Rehab*. 22:9, 2009.
6. Kumar, S., Sharma, V.P., Shukla, R., Ravi, D. and Negi, M.P.S. Back and abdominal pressure, Sexual frequency and quality of life in subject with and without low back pain", *Int J. Ther Rehab* 16:615, 2009.

#### Differential protein expression in plasma of subjects with acute coronary syndrome

Coronary heart disease is one of the most leading causes of morbidity and mortality worldwide. Detection and identification of novel plasma proteins by proteomic analysis tools provides an opportunity to gain disease state.

The study was carried out on patients with acute myocardial infarction-AMI (N=20), patients with unstable angina UA (N=20) and TMT or angiographically negative subjects (controls) (N=20) from medical emergency/CCU. A total of 10 ml blood was collected in EDTA vial from each patient at 6-12, 24, 48h and 6 weeks after the onset of chest pain. Plasma samples of each group were used to identify low-abundance proteins and serum was used for biochemical analysis. After depletion of highly abundant proteins by using proteo prep blue albumin kit, two dimensional gel electrophoresis (2DGE) was carried out with each sample, using narrow range of IEF IPG gel strips (pH 4-7 range; Bio-Rad).

Ten differentially expressed proteins were observed by 2DGE in AMI and UA samples as compared to controls. These proteins were identified by MALDI as: 7x-1-antitrypsin (AAT), Fibrinogen gamma chain (FGG), Apolipoprotein A-1 (Apo A-1), Immunoglobulin gamma heavy chain (IGG), Transthyretin (TTR), Alpha 2HS glycoprotein, Troponin I, Serpin, Transforming protein ra1B and an

unknown protein labeled as Q5JYW7. AAT, FCG, and Serpin showed approximately 2 fold increase in ACS and UA samples as compared to controls at 6-12h. Two fold increase in TTR was seen in AMI samples only; and a hitherto unknown protein Q5JYW7 showed nearly 40 fold increase in AMI and UA plasma at 24 h post chest pain. Apo A-1 and Alpha 2HS glycoprotein levels were decreased in AMI and UA Groups.

It was concluded that a number of proteins were identified that differ in abundance/expression in patients with ACS and those without coronary disease. These proteins comprise potential biomarker candidates for validation studies in individual patients and in larger clinical data sets to better define disease pathways and establish novel markers for disease. Further characterization of these proteins may provide new insight into their role in the pathophysiology of ACS.

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#### Daily corticosteroids to prevent infection associated relapses in patients with frequently relapsing nephrotic syndrome

Relapses of nephrotic syndrome often follow minor infections, commonly of the upper respiratory tract. Based on the assumption that corticosteroids inhibit cytokine production. A randomized control study was carried out in non blind parallel groups to examine whether daily administration of maintenance prednisolone during intercurrent infections, reduces relapse rates in children with frequently relapsing nephrotic syndrome. A total of 100 patients with idiopathic frequently relapsing nephrotic syndrome ( 2 relapses in 6 months) eligible for therapy with prolonged low dose alternate day prednisolone with or without levamisole were included in the study. During intercurrent infections, patients in the intervention group (50) received their usual dose of alternate day prednisolone everyday for 7 days where as patients in the control group (50) continued to receive alternate day prednisolone. Primary outcome was assessed by comparing the rates of infection associated relapses during one year follow up. To determine the frequency and type of

infections, and the cumulative amount of prednisolone received in both groups was the secondary outcome.

Patients in the intervention group showed significantly lower infection-associated and total relapse rates [rate difference 0.7 episodes/patient per year; 95% confidence interval (CI) 0.3, 1.1] and 0.9 episodes/patient per year (95% CI 0.4, 1.4) respectively, without increase in steroid toxicity. Poisson regression, adjusted for occurrence of infections showed that daily administration of prednisolone during infections independently

resulted in a 59% reduction in rate of relapses (rate ratio 0.41; 95% CI 0.3, 0.6). This intervention is likely to reduce the number of relapses to less than 3 in 12 months, for one out of six children treated. Hence it was concluded that the daily administration of maintenance doses of prednisolone, during intercurrent infections, significantly reduces relapse rates and the proportion of children with frequently relapsing nephrotic syndrome.

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## ICMR NEWS

The following meetings of various technical committees/groups of ICMR were held in April, 2010.

Meetings of Project Review Committees (PRCs)/and Other Meetings held at New Delhi:

Meetings to discuss the potential utility of technique for early detection of cancer development	April 1, 2010
Meeting of ICMR-HGF Joint Steering Committee	April 7, 2010
PRC on Ophthalmology	April 20, 2010
PRC on Neurology	April 23, 2010
Investigators Training Meeting of ICMR-UNFPA Study	April 26-27, 2010

### Participation of ICMR Scientists in Scientific Events

Dr. G.B. Nair, Director, National Institute of Cholera and Enteric Disease (NICED), Kolkata, participated in the XI Scientific Advisory Group Meeting at Seoul (April 12-13, 2010). He also participated in the Small and Focused Meeting to Address the Under Performance of Poliovirus, Rotavirus and Other Enteric Vaccines in the developing world at Seattle (April 19-20, 2010).

Dr. N. Selvakumar, Scientist F, Tuberculosis Research Centre (TRC), Chennai, participated in the Global Consultation on the TB Supernational Reference Laboratory Network at Geneva (April 14-15, 2010).

Dr. Dipika Sur, Scientist E, NICED, Kolkata, Participated in the Meetings of Board of Trustees of International Vaccine Institute at Seoul (April 15-16, 2010). She also participated in the Meeting of Multi-country Typhoid Fever Surveillance Programme in Sub-Saharan Africa, at Nairobi (April 27-29, 2010).

Dr. R.K. Sharma, Scientist C, Regional Medical Research Centre for Tribals, Jabalpur and Sh. B.K. Gulati, Scientist B, National Institute of Medical Statistics, New Delhi, participated in the Annual Meeting of Population Association of India, at Texas (April 15-18, 2010).

Dr. V. Kumaraswami, Scientist F and Director-in-charge, TRC, Chennai, participated in the VII Meeting of Regional Programme Review Group for Elimination of Lymphatic Filariasis in South-East Asia Region, at Jakarta (April 19-21, 2010).

Dr. S.L. Hoti, Scientist F, Vector Control Research Centre, Pondicherry, participated in the Peer Review Meeting on Comprehensive Guidelines on the Prevention and Control of DF/DHF at Bangkok (April 19-23, 2010).

Dr. V. Sudershan Rao, Scientist C, National Institute of Nutrition (NIN), Hyderabad, participated in the Annual Seminar of the Research Programme on Nutrition, Food and Health, at Helsinki (April 21, 2010).

Dr. B. Sesikaran, Director, NIN, Hyderabad, participated in the IV Session of the Codex Committee on Contaminants, at Izmir (April 26-30, 2010).