



INDIAN COUNCIL OF
MEDICAL RESEARCH

भारतीय आयुर्विज्ञान अनुसंधान परिषद
INDIAN COUNCIL OF MEDICAL RESEARCH
अनुसंधान परिषद

TENTH PLAN
DOCUMENT
2002-2007

1 Prologue

“To accomplish great things we must not only act, but also dream. Not only plan, but believe”

- Antole France

The Indian Council of Medical Research (ICMR) is going through a change. The demands on ICMR have necessitated the change. The role of research and modern science in fighting diseases and improving health is being increasingly re-emphasized. Links between research and disease control programmes are being better appreciated. The Council has shifted gears to move from a pure biomedical research organization to one that has health research at its core around which its future research agenda is woven. Its mandate covers the whole spectrum of research from biological to social, laboratory to field, and from idea to use. The Council commits itself to take its research agenda forward, and to strive to get research results translated into efficient control and prevention strategies.

A major thrust is being given to capacity building, including training and institutional strengthening. Infrastructure and skills are being brought to bear not only against a range of diseases, but also span across areas such as health research policy, burden of disease estimation and priority setting. This is critical for achieving self-reliance to assess the country's health problems and determine their solutions, drawing on internal resources and identifying other resources as required from outside.

As we near the end of the 9th Plan, it is appropriate to re-examine and re-evaluate the nature of health challenges we face. Spectacular advances in modern biology have opened the doors to promising areas of investigations. Adequate resources are needed to meet these evolving research opportunities. Recognizing the need for a closely defined and focused research strategy to meet challenges in infectious diseases, non-communicable diseases, nutrition, reproductive health, basic medical sciences, the ICMR has closely looked at emerging technologies and identified promising research opportunities and has woven its 10th Plan proposals around them.

This document gives thumbnail sketch of the achievements during the 9th Plan and proposals for the 10th Plan. The details are annexed.

2

Health Development and Planning

Human development and improvement in quality of life are the ultimate objectives of all planning activities. This is to be achieved through policies and programmes aimed at promotion of both equity and excellence. Social sector planning tries to ensure that appropriate policy and programme initiatives are taken and adequate investments are provided to social sector. Health & Family Welfare are important areas in social sector.

It is being increasingly realized that a healthy population is an essential pre-requisite for all development. Steps taken during the last five decades have resulted in decline in death rate and rise in life expectancy. The major areas of current focus include continued high morbidity due to communicable diseases, rising disease burden due to non-communicable diseases and nutritional problems. Large size of the population in the age-group 15-50 (about 60%), unmet need for contraception and high unwanted fertility are the other areas of major concern.

India is passing through an epidemiological, health and demographic transition. While increased life expectancy has brought in its wake an increase in chronic degenerative diseases, infectious diseases are still dominant and remain as major issues for health sector development in the years to come. Further, population growth, urbanization, increase in economic activities, threatened ecology, environmental degradation and privatization of health care are some of the issues attracting attention for assessment of their impact on health and human development. Health problems related to ageing and lifestyles have also come to the fore demanding research to be addressed to these areas as well.

ICMR, therefore, is readying itself to confront the research needs of disease burden—a mixed load of past, present, and future, as it steps into the 10th Plan period. Communicable and noncommunicable diseases and their impact on the socio-economic development process are receiving priority attention. The strategy is to strike a balance between upstream research, which is basic and mission-oriented, and downstream research which is applied and operational for the successful application of research. Both are necessary for health development. Downstream research requires the identification of well-tested knowledge in relevant areas of health and the processes to facilitate the application of that knowledge for adoption in health sector policy development. Applied research needs to address adequately the issues related to sectoral convergence by partnership development between the community, health service providers and other ministries. Research areas pertaining to the control of micronutrient malnutrition, the problem of low birth weight and its effect on human health on a long-term basis are major priority areas.

Research related to stresses on the health programmes due to environmental and ecological degradation is also being addressed. The Council has accorded high priority to research in this area with particular reference to air and water pollution, microbial and chemical pollution and waste disposal. The emphasis of research is on objective measurement of the levels of pollutants and their effect on ecology, on helping policy agenda generation in this area and on assisting in monitoring and implementation of regulations.

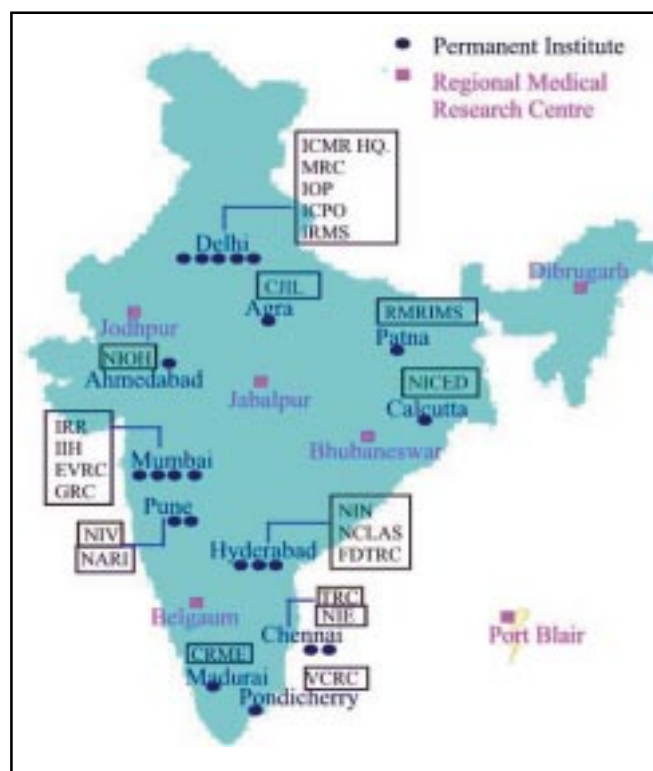
▲ Looking back at 9th Plan

Thrust Areas, new initiatives and achievements

ICMR's performance

Founded in 1911 as Indian Research Fund Association, it was re-christened as Indian Council of Medical Research in 1949. It is the apex organization to formulate, conduct, coordinate and promote biomedical research in India. Research is conducted in its 26 Institutes/Centres.

In addition there are more than one hundred field stations scattered in various parts of the country.



The Council also supports biomedical research in various Universities, Medical Colleges and other Institutes by providing research grants as part of its extramural research programme.

Human Resource

The Council has strength of nearly 4,900 personnel of which only 12 percent are scientific, about 56 % are

technical and the rest 32% belong to the administrative cadre.

The scientific staff is not only woefully inadequate, but also ageing. Over half are more than 50 years of age. The table below gives the ratio of auxiliary and administrative staff to a unit of scientific personnel for various S & T agencies. The ICMR has a larger proportion of administrative and auxiliary staff as compared to other agencies. One of the reasons for higher ratio of auxiliary staff is the large number of personnel for field activities.

Number of supporting personnel/ R&D personnel		
Agency	Auxiliary	Administrative
DRDO	0.39	0.22
CSIR	0.54	0.37
ICAR	1.72	1.05
ICMR (1996)	3.14	1.60
ICMR (2000)*	4.60	2.60

(Source: Research and Development Statistics, 1996-97, Ministry of Science & Technology, June 1999) *Internal analysis

The only new blood that has been inducted has been against vacant posts. The ban on creation of new posts has hamstrung ICMR's progress. Rapid progress is being made in bio-medical sciences. Fresh technologies have opened new vistas. But the Council is unable to exploit them to the full in the absence of adequate human resources. Cutting-edge areas in science are being neglected.

The Council plans to give Health Research Manpower Development a major thrust in the 10th Plan period and attempt to correct the imbalance.

Fiscal Review

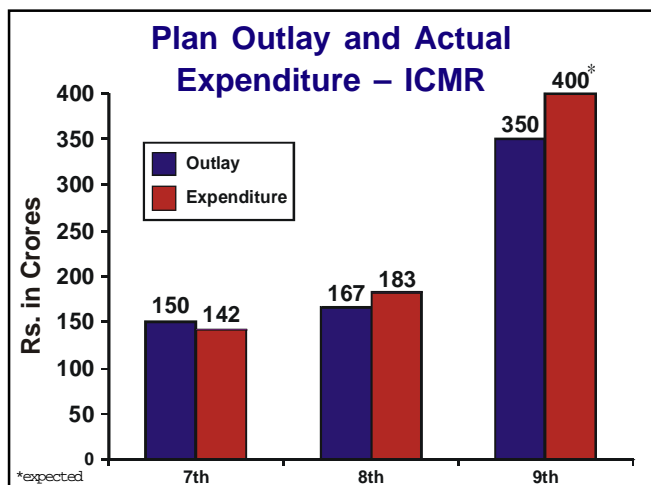
Since the Sixth Plan there has been a progressive growth in funding for Science & Technology, spanning a wide range of disciplines. Later a similar thrust was given to Agriculture Research, which ushered in an era of Green Revolution. But bio-medical research has failed to attract such an attention.

There has been an increase in outlays in the 8th Plan by a factor of 3 for ICAR, for 2 for DBT and 1.7 for CSIR, but for the ICMR the increase was notional (by 1.1 times only). For the 9th Plan the outlays were increased by 2-2.5 times for all agencies.

Plan outlays of Science & Technology agencies (Rs in crores)			
Agency	7th Plan	8th Plan	9th Plan
ICMR	150	167	350.0
ICAR	425	1300	2635.0
CSIR	370	655	1327.5
DBT	132	265	675.0

(Source: Research and Development Statistics, 1996-97, Ministry of Science & Technology, June 1999)

A glance at the Plan outlays for ICMR and actual expenditure would show a trend of enhanced capacity for utilizing the funds. In the eighth plan, the annual allocations were increased, hence the Plan expenditure was in excess of the Plan outlay. The same trend continued in the 9th Plan.



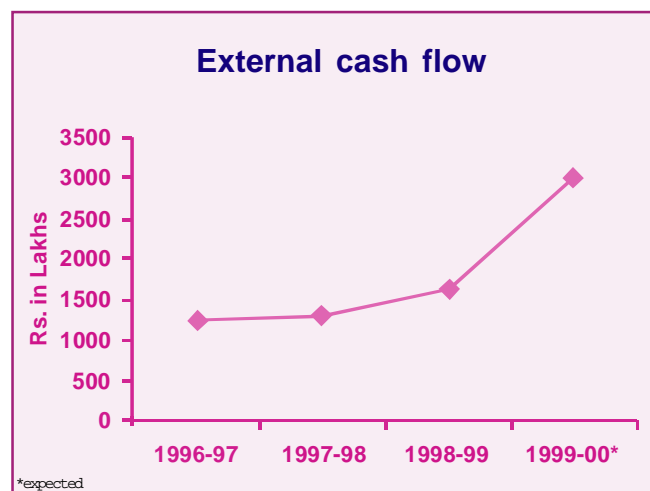
In the Ninth Plan the outlay for 'Health' was Rs. 350 crores. The actual expenditure is expected to be Rs.400 crores.

Year	Allocation (Rs in crores)	Actual expenditure (Rs in crores)
1997-98	45.52	45.10
1998-99	65.0	61.0
1999-00	71.5	70.25
2000-01	101	101
2001-02	120	185*

*expected

Grants received from External agencies

There has been a gradual increase in the quantum of external cash flow to the ICMR over the years. This

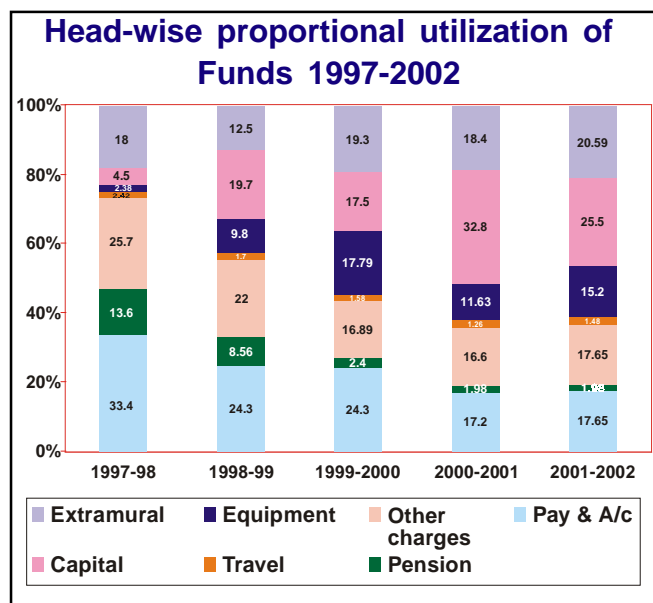


includes projects funded by other national and international agencies, earning through consultancies and contract research and royalties. A fillip has been given over last couple of years for generation of external resources. Scientists are encouraged to apply for external funding.

How was the money spent?

It has been possible to transfer a substantial amount of expenditure on 'pay and allowances' and 'pensions' from 'Plan' to 'non-Plan'. The 'Plan' component has reduced from 33.4% in 1997-98 to 17.65% in 2001-02. A major portion of funds was utilized for infrastructure development. The proportion for capital

works increased from 4.5% in 1997-98 to 25.5% in 2001-02, and for 'equipment' from 2.4 to 15.2% in the same period. The funding for extramural projects also increased from 12.5% in 1998-99 to 20.6% in 2001-02. The proportional funding under the heads 'other charges' and 'travel' has, however, remained almost same over the last couple of years.



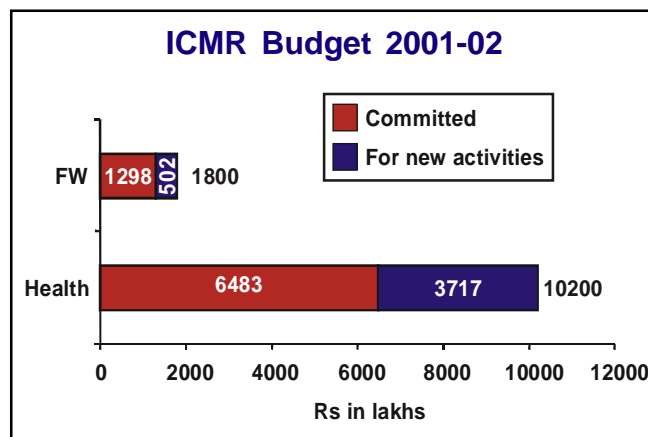
The average quantum of funding for biomedical research as part of extramural programme by different scientific agencies is shown below. It reflects poorly the relevance of ICMR as a funding agency.

Year	DBT	DST	ICAR	ICMR
1994-95	25.5	9.95	6.2	4.0
1995-96	38.6	9.10	8.02	4.9
1996-97	24.0	14.5	10.9	5.9
Average	29.4	11.2	8.4	4.9

(Source: Research and Development Statistics, 1996-97, Ministry of Science & Technology, June 1999)

For the last year of the 9th Plan, the budget under head 'Plan' is Rs.120 crore (Rs.102 crore in 'Health'

and Rs.18 crore in 'Family Welfare'). Of this Rs.77.8 crores is committed for the on-going activities, Rs.42.2 crores is available for new activities. During 2000-01 several new initiatives were approved, but could not be funded. In order to initiate these in 2001-02, the Council needed additional Rs.64.6 crores, which again did not come.



Research Publications

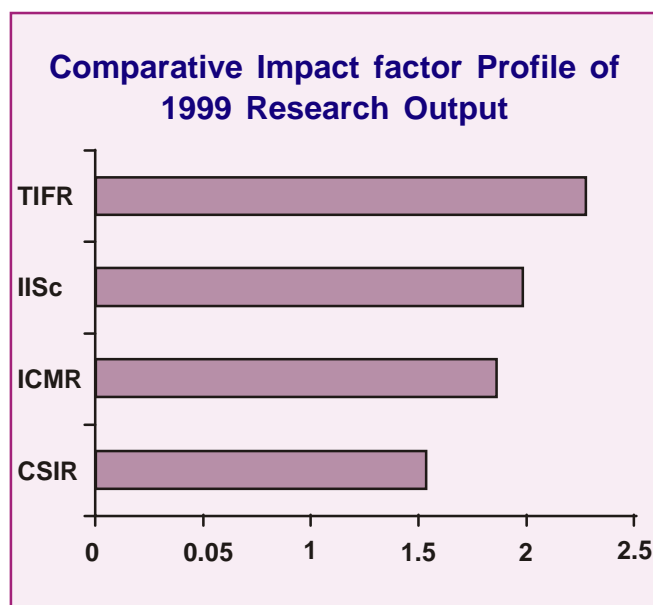
A review of SCI/JCR-based research output of ICMR Institutes during the first four years of the 9th Plan period shows that on an average about 335 papers have been published each year. The average impact factor has shown an encouraging upward trend.

During 1999, 317 papers were published with an average of 13 papers per Institute/Centre. The average Impact factor is 1.86.

Name of Institute	Total SCI papers	Total IF	IF / Paper
ICPO	9	47.00	5.22
CJIL	4	11.23	2.81
NICED	25	59.54	2.38
NIV	14	31.01	2.22
RMRC, Bhub.	9	19.89	2.21

A comparison of impact factor profile for 1999 research output of other Science and Technology Organization/ Institutes shows that impact factor per paper of ICMR

was 1.859 as compared to 1.538 of CSIR, 1.977 of IISc and 2.271 of TIFR.



(Source : CSIR Research, Output, 1999-an analysis. Indian National Scientific Documentation Centre, New Delhi, April 2000)

Awards and Honours

Scientists at the ICMR have won some of the most prestigious awards in biomedical sciences. During 1999-2000 and 2000-2001, itself, 24 coveted awards were bagged which includes. Dr. Yellapragada Subba Row Memorial Lecture Award, B.C. Guha Memorial Lecture Award, Glaxo Oration Award, Shanti Swarup Bhatnagar Prize, and Dr. B.C. Roy National Award.

Major initiatives taken

During the 9th Plan some important initiatives with far reaching implications were undertaken. Some of the major ones include:

1. Formulation of draft Health Research Policy
2. Estimation of disease burden in the country
3. Setting priorities in health research
4. Forming health research information system
5. Development of Human Resource
6. Boosting research on health and environment
7. Enhancing support of medical research during natural disasters

8. Maximizing benefits through upgradation, modernization and replacements
9. Establishing chain of microbial containment facilities
10. Funding Pre-clinical Toxicology units, Clinical Pharmacology Units.
11. Centres for Primate Research
12. Vaccines Development especially for HIV/AIDS.

Details of these initiatives may be seen in Chapter 6, where 10th Plan proposals are described.

Modernization

To compete globally in the fast pace of medical research, the ICMR needs an infusion of substantial financial inputs for overhauling its aging infrastructure and refurbishing its laboratories with modern scientific equipment. The scientists also need to be trained to use this modern technology. There is an imperative need for the application of modern research concepts such as state-of-art or current approaches, equipment and above all information sciences that can dispel the dangers of instant obsolescence. Only when such facilities are within its reach can the ICMR contribute its share to medical sciences in solving some of pressing health problems facing the country. During the latter part of the 9th Plan period there was a concerted effort to modernize the laboratories of the ICMR. Funds were utilized to replace some of the obsolete equipments, install a few new ones, and increase funds for consumables. Equipments which were non-functional for want of repairs were brought under maintenance cover. Some of the buildings which could not be repaired earlier were taken care of. Some new capital works were also started. In short, the last couple of years was a phase of infrastructure strengthening which would continue in the early part of the 10th Plan Period and lead to a phase of consolidation.

New Institutes/Units established

- * National Institute of Epidemiology, Chennai

- * Intellectual Property Rights Unit (ICMR Hqrs)
- * Medicinal Plants Unit (ICMR Hqrs)
- * Filariasis Elimination Cell (VCRC, Pondicherry)

Summary of Thrust Areas of Planning Commission in Bio-Medical and Health Services Research in 9th Plan

Addressing the issue of Biomedical and Health Services Research, the Planning Commission has suggested that during the 9th Plan period optimal co-ordination of the basic and applied research should be attempted by networking and if needed by multi-agency funding of important projects.

The thrust areas identified in the various sub-heads are :

Health

Basic Research

- * Immunodiagnostic tests for common infections
- * Development of newer drugs for treatment of common infections in view of the increasing resistance to antibiotics
- * Development of resistance modulating agents to combat the increasing bacterial resistance to antibiotics
- * Development, testing and quality control of newer drugs in the modern system of medicine and ISM&H
- * Newer drug delivery system for better targeting of drugs and reduction in side-effects
- * Development of therapeutic and prophylactic vaccines for infections utilizing newer biotechnological tools so that they are thermostable, have long shelf life, free from side effects and are affordable
- * Development of newer vector control measures including testing of bio-pesticides like neem

Applied & Operational Research

- * Development and testing of alternative strategies for control of communicable and non communicable diseases

- * Improving programme implementation
- * For efficient implementation of on-going health programmes
- * Horizontal integration of the vertical programmes for health and family welfare at the primary health care level.

Family Welfare

Basic and Clinical research

- * Drug delivery systems for the delivery of contraceptive steroids
- * Vas-occlusive methods
- * Spermicides based on plant products such as neem oil and saponins
- * Vaginal contraceptives including those using plant based substances
- * Testing contraceptives, which are considered to be effective in Indian Systems of Medicine and/or used among tribals
- * Research on methods for male fertility regulation including long-acting androgens
- * Clinical trials on newer non-surgical methods of MTP
- * Post-marketing surveillance for *Centchroman*

Operational Research

- * Studies on demographic transition and its consequences
- * Studies on continuation rates and use-effectiveness of contraceptives
- * Operationalizing integrated delivery of RCH services, nutrition, education, women and child development, rural development and family welfare services at village level, utilizing the available infrastructure under various programmes

Nutrition

- * Research studies on major micronutrient deficiencies with special emphasis on prevention, speedy control, and effective management
- * Changing nutrition-fertility and nutrition-infection interactions and their implications to health and nutritional problems; evolving and testing appropriate intervention strategies

- * Changing dietary habit and lifestyle and their impact on nutritional status especially obesity and micronutrient deficiencies
- * Increasing longevity and changing lifestyles their impact on nutrition and risk of non-communicable diseases
- * Nutritional interactions and their health implications
- * Improvement in the methods of assessment of nutritional status of the individual and the community
- * Studies on determinants of nutritional status under varying conditions and effective modifications of the adverse influences
- * Operational and socio-behavioral research to improve performance of the ongoing interventions

Indian Systems of Medicine

- * Medico-botanical surveys
- * Cultivation of medicinal plants
- * Pharmacognostical studies
- * Develop new drug formulations
- * Testing of indigenous drugs for safety and efficacy
- * Undertake clinical trials on formulations traditionally used in tribal societies and reported as being effective
- * Investigation of prevention and curative role of Yoga and Naturopathy in life-style diseases.

(Extracts from "Thematic issues and sectoral programmes" Biomedical & Health research , 9th Plan, Planning Commission, New Delhi)

SNIPPETS OF ACHIEVEMENTS

COMMUNICABLE DISEASES

Tuberculosis

Tests for rapid diagnosis of rifampicin resistant *M.tuberculosis* by molecular methods were developed. Luciferase reporter assay for rapid diagnosis of tuberculosis with sensitive and drug resistant organisms was developed. Clinical trials with regimens to shorten the duration of treatment; and non-rifampicin regimen in continuation phase were undertaken. A model DOTS center was established. Surveillance for MDR-

TB showed that its prevalence is below 3%. DNA finger printing pattern was used to monitor spread of strains, and understand transmission dynamics. Endogenous reactivation was found to be commoner than exogenous re-infection in patients with relapse. HLA antigen profile of patients showed increase of HLA-DR2. Non-HLA gene polymorphism showed that functional mutant homozygotes of mannose building protein gene are associated with susceptibility to TB. Natural killer cells in TB patients were as efficient in recognizing their target cells as normal NK cells but have defective killing properties.

Leprosy

Transmission of *M.leprae* through breast milk, genital and oral mucosa and nasal breath has been studied. A high prevalence of cardiovascular and central nervous system involvement has been found in lepromatous leprosy cases. Clinical trials with different drug combinations have been undertaken to reduce the duration of treatment and rate of relapse, late reaction, and persistent activity. Deformities of hands and feet are being corrected using improved surgical procedures. A serum antibody competition test (SACT) has been developed and evaluated for monitoring trends. Ribosomal RNA targeting probes, RT-PCR and ATP bioluminescence assay for detection and viability determination have been developed. A controlled 5-arm double blind randomized prophylactic anti-leprosy vaccine trial showed ICRC and BCG+killed *M.leprae* vaccine provided 64-66% protection. Studies on population genetics indicate that the presence of 9 alleles of chromosome 10p13 increases the susceptibility to leprosy. PCR-ribotyping has been used to demonstrate strain difference in *M.leprae*.

Diarrhoeal Diseases

Surveillance for *V.cholerae* has shown an increase in non-01, non-0139 *V.cholerae* in and around Kolkata. A new phage typing scheme for *V.cholerae* 0139 has been developed. *V. parahaemolyticus* strains 03:K6, 04:K68 and 01:K25 have been detected. *E. coli* 0157:H7 has been shown to be present in animal

food stuffs and food handlers. A new recombinant oral cholera vaccine is ready for phase II clinical trials. Significant progress has been made in molecular probes for *E.histolytica* and *G.lamblia*. Group B rotaviruses causing diarrhoea has been detected. An ELISA test for diagnosis of rota viruses has been developed.

Malaria

Distribution and bionomics of members of the species complexes of major Anopheline vector species has been studied, and transmission potentials determined. Rapid antigen capture dipstick tests for *P. falciparum* and *P. vivax* were evaluated and found to be satisfactory. Polymorphic nature of *P. falciparum* and *P. vivax* have been studied with a view to understand response to drugs and to correlate genetic variations with epidemiology and immune profile in an area. b-Arteether, 80/53 and Ayush-64 were clinically tried and recommendations given to the programme. Remote sensing and GIS were used to stratify the country requiring different control measures. Efficacy of impregnated mosquito nets was demonstrated in different geo-ecological sites. Feasibility of using biological control measures was shown. Health impact assessment of new developmental projects with focus on vector borne diseases has been undertaken. Action plans for malaria control in urban areas and developmental project sites have been prepared.

Lymphatic filariasis

Applying GIS software and using available reports, a filariasis map of India showing prevalence and distribution of infection and disease has been prepared. Rapid assessment procedures, mathematical models, costing models have been developed and used as tools for decision making in selective intervention strategy. Relative advantages of selective chemotherapy, mass chemotherapy and mass medicated salt as control strategies have been studied. A synthetic vaccine has been developed for experimental filariasis. Various strategies for morbidity management have been worked out. Immunodiagnostic tests (ICT,Og4C3) have been evaluated and found to have acceptable

sensitivity and specificity. A cell to provide technical inputs for elimination of filariasis has been established.

Visceral leishmaniasis

The degree, spread and reasons for unresponsiveness to sodium antimony gluconate in kala-azar patients are being studied. Clinical trials of newer drugs (e.g. Meltofocin) and drug combinations (e.g. pentamidine and allopurinol) in management of visceral leishmaniasis and Post Kalazar Dermal Leishmaniasis (PKDL) have been started. Validation of DAT is underway. Immunohistochemical straining techniques for diagnosis of PKDL has been standardized. Persistent presence of a 600 bp band in DNA isolated from PKDL skin lesions was demonstrated. Its potential for use as a diagnostic test is being explored. A species specific PCR assay for detection of *L. donovani* has been developed and is being evaluated. A nucleic acid probe for diagnosis, detection and epidemiology of kala-azar is being developed. A leishmaniasis parasite bank has been established.

Viral diseases

HIV/AIDS : A cohort of persons practicing high risk behaviour, but HIV-ve is being followed. Sero-incidence and relative importance of various risk factors have been studied. Sentinel surveillance for HIV among TB patients has shown the prevalence to increase from 10% in 1995 to 30% in 2000. A HIV bank has been established. Genotype C3 of subtype C is commonest in India. A recombinant between subtype C and A has also been detected. Shedding of HIV in genital ulcer diseases has been studied. Average values for lymphocyte populations in normal adults in India have been established. ELISPOT assay for measuring CTL responses has been standardised. Spectrum of opportunistic infections and drug sensitivity pattern have been studied. Studies on youth sexuality and socio-behavioural aspects are also being undertaken. Efforts towards development of HIV/AIDS vaccine have been initiated.

Poliomyelitis : All polio isolates from India have been characterised. Facilities and expertise for virus genome analysis have been established. Molecular biology tools are used to track wild polio reservoirs, transmission from one region to another, and biodiversity of virus. Environmental sampling for polio virus has been started. Vaccine derived poliovirus isolates from AFP cases have been characterised to study the genetic changes. The WHO up-graded the status of the Enterovirus Research Centre from a Regional Reference Laboratory to Global Specialized Laboratory for Polio.

Japanese encephalitis : JE virus strains isolated from various parts of the country have been genotyped. Strain differences have been shown to affect cross protection with other JE strains. Efforts are being made to develop a DNA-based and a peptide based vaccine. An early warning system to predict an outbreak has been developed and is being tested. Tests for detection of JE virus in desiccated mosquitoes has been standardized. An IgM ELISA based test kit has been developed, and an agreement for transfer of technology to industry has been signed.

Dengue : An ELISA test system has been developed for diagnosis of recent dengue infection. Trans-ovarian transmission of dengue virus has been established.

Hepatitis B : HbsAg and anti-HBs ELISA tests have been developed.

Hepatitis A : Technology for development of vaccine against Hepatitis-A has been transferred to industry.

Hepatitis E : ELISA test for diagnosis of HEV has been standardized. Phylogenetic analysis of Indian HEV strains shows that they are related to those of neighbouring countries. Virus attenuation studies indicated that a high level of chlorination of drinking water (about 1.5ppm) is essential to prevent water borne Hepatitis E infection.

Measles : A variant strain of measles virus was isolated and found to be responsible for unusual presentation and high mortality in outbreaks among children and

adults in various parts of the country. An ELISA test to detect IgM antibodies from serum and CSF has been developed.

Leptospirosis

The mysterious Andaman Haemorrhagic fever was determined to be due to leptospirae. High seroprevalence of leptospirosis was detected in different population groups of Andaman & Nicobar Islands. Risk factors associated with the infection were identified. Studies on clinical spectrum led to the recognition that pulmonary involvement is an important clinical variant. Evaluation of the available diagnostic kits indicated that MCAT, lepto-Dipstick and Lepto-lateral Flow have acceptable sensitivity and specificity. The method of characterization of strains was standardized. Several post-flood outbreaks of jaundice in India were detected to be due to leptospirosis.

Miscellaneous infections

Chlamydia: A PCR has been standardized, and role of cytokines in pathogenesis of *C.trachomatis* infection in infertile patients is being studied. Genotyping of isolates showed predominance of D serovar. An EIA test kit for detection of chlamydia infection in eyes, and SDA slide culture technique for fungus have been developed.

Trematode infection: Schistosomal dermatitis has been studied in Assam and its epidemiology, pathogenicity and pathology has been worked out. An animal model has been developed, and a new focus of food borne trematode infection has been identified.

Epidemiology

A National Institute of Epidemiology has been established at Chennai. Short and long term Field Epidemiology Training Programmes have been started.

Tribal Health

Baseline surveys for health, nutrition, morbidity and mortality profile have been undertaken in various tribes with special focus on primitive tribes of Madhya

Pradesh and Andaman & Nicobar Islands. A focus of endemic fluorosis was detected in Mandla district. Prevalence of genu valgum was 51% and of dental fluorosis was 74%. High prevalence of Hep B was detected among tribes of Andaman & Nicobar islands. An intervention study for its prevention and control has been started. Genetic diversity among the tribes is also being studied. Prevalence of various types of haemoglobinopathies is being studied and operational research for instituting prevention and control strategies is being undertaken.

NON-COMMUNICABLE DISEASES

Cancer

The National Cancer Registry Programme has generated vital data regarding magnitude and common sites of cancers in India. The tobacco related cancer sites, like lung, oral cavity, pharynx, are common among men all over the country. Cancer of stomach is common in registries in southern part of the country. Cancers of uterine cervix and breast are the two most common sites among women in all the registry areas. Studies on association of viruses and pre-cancerous and cancerous lesions of cervix revealed important role of HPV in development of cervical cancer. Prospective multidisciplinary studies on natural history of uterine cervical dysplasia revealed a number of behavioural risk factors such as early age at consummation of marriage before 18 years, sexual promiscuity of either partners, smoking habits, deliveries conducted by untrained persons, unsafe sexual habits, unhygienic menstrual practice as associated with development of cervical dysplasia and/or carcinoma-in-situ. Alternative strategies for early detection of cervical cancer like, visual inspection of cervix by paramedical personnel, visual inspection by locally developed magnification instrument, have been developed. The operational research projects for testing implementation of control of cervical cancer programme within the existing health care system provided useful information.

Studies on occupation associated cancers addressed areas like, carcinogenicity of DDT and HCH, studies

on workers exposed to benzidine dyes, carcinogenic potential of HCH in animals exposed to aflatoxin, presence of green symptoms in agriculture tobacco workers, role of black tea extract on carcinogenesis in animals, development of microbial systems for assessing the genotoxicity, genotoxic potential of air samples from high air pollution areas, and chemical analysis of pan masala. Nutrition related studies included, presence of experimental iron deficiency and gastrointestinal tract tumours, screening for protective factors in foods and biomarkers of genotoxicity, determination of levels of nitrosamines in certain food groups and measurement of the quantity of volatile nitrosamines formed from foods under stimulated gastric conditions, study of micronucleated cells and DNA adducts in peripheral blood lymphocytes of patients suffering from precancers and cancers due to pan masala habit, development of oral sub-mucous fibrosis among pan masala users.

Breast cancer: Human mammary epithelial cell line has been established. Initial cultures produced growth stimulatory factors while later cultures produce growth inhibitory substances. Cases with p53 and negative ER showed a poor prognosis

Prostate cancer : Immunochemical staining for oncogenes in prostate malignancies was extended to a larger group and results compared with histological grading.

Urinary bladder cancer : Immunobiology studies initiated and correlated with results of treatment.

Experimental melanomas : Melanoma cell culture has been established and different doses of melatonin screened for antitumour activity. Results showed that melatonin has both oncocidal and oncostimulatory actions depending on dosage administered.

P53 mutation in lymphomas : Immuno-chemical stains were standardised. P53 gene polymorphisms were identified in 4 and mutations in 1 out of 58 cases studied.

Neuroembryonal tumors: Immuno-chemistry showed correlation of differentiation antigens with expression of adhesion molecules.

Cardiovascular diseases

An epidemiological study to assess the prevalence of Coronary Heart Disease (CHD) showed a lower prevalence rate of CHD amongst the rural population and an increasing gradient of prevalence of CHD from rural to urban areas and smaller town to bigger cities. A multicentric case-control study on acute-myocardial infarction in Indians was initiated to identify and quantify the association of known risk factors for acute myocardial infarction. A *Jai Vigyan* Project on control of Rheumatic Fever/Rheumatic Heart diseases has been launched, with the aim to identify rheumatogenic strains and markers for vaccine development for Indian population.

Mental Health

Psychiatric consequences of earthquake which struck Maharashtra in 1993-94 have been studied. Studies have been initiated now in Gujarat following the earthquake in early 2001. In another study, childhood and adolescent psychiatric disorders were found to be around 10-14%. Simple measurement tools have been developed to assess quality of life including psychosocial stress. New studies to be taken up in remaining part of 9th Plan include: identification of factors and processes contributing to suicidal tendencies; public attitude of stigma against mental disorders, mental health of special groups such as women.

Gastroenteric diseases

Studies on mechanism for non-response to interferon therapy in patients with chronic hepatitis-C showed that aminoacids in NS5A region of HCV genome determine the response to this therapy. Use of parenteral glycyrrhizin in treatment of subacute hepatic failure showed better response.

Geriatric health issues

Prevalence of functional impairment of common physical parameters among the elderly has been ascertained. The quality of life of elderly and its possible correlates have been assessed. A baseline

study to know the awareness of their own health and disease profile and needs for health care has provided valuable inputs for developing health care services for the elderly.

Occupational Injuries and diseases

Data-bases on occupational diseases (e.g. silicosis, agate industry, quartz grinding etc.) have been generated wherein 34-40% of agate workers have silicosis and 51% have depressed pulmonary functions. Noise pollution and health effects, occupational exposure to heavy metals and organochlorine pesticides, agricultural ergonomics, and safety aspects and health of women in industry have also been studied and for the first time it was reported that HCH causes ECG abnormalities including WPW and RBB in the exposed workers. In addition, data on environmental health problems, level of pesticide residues in human beings, and exposure to heavy metals, air pollution and its health impact have been produced and critically examined. This has revealed a level of 11.04 and 3.49 ppm for DDT and BHC respectively. Links between various occupational/environmental exposures and health effects have been documented. Experimental studies on carcinogenicity of various chemicals like DDT, Lindane, methyl isocyanate have been conducted. Strategies for prevention and control of occupational diseases have been evaluated and validated which include exhaust system for agate grinding and use of gloves for preventing green tobacco sickness.

REPRODUCTIVE HEALTH

Studies have focused to develop male and female methods of fertility regulation as well as to increase the contraceptive usage of available methods. Significant advances have been made in development of improved and new methods of fertility regulation and also in understanding basic mechanisms underlying reproductive physiology, assessment of safety and efficacy of existing methods of fertility regulation, and identification of the constraints in utilization of available contraceptives. Human sperm antigen 80kDa has been identified to be developed as anti-fertility vaccine.

Clinical trials and pre-programme introduction studies were carried out to evaluate newer contraceptives. A low cost pregnancy detection test has been developed. Immunodiagnostic kits for estimation of various fertility related hormones have been developed and evaluated. Cost effective methods were developed for termination of early pregnancy (RU-486 and PGE-2 vaginal gel). Guidelines for Assisted Reproductive Technology have been drafted. *In-vitro* fertilization procedure has been successfully used. A base-line information on reproductive health awareness and sexual behaviour among adolescents has been conducted to launch future interventions.

Role of estrogen receptors in male infertility: immunohistochemical studies indicated presence of estrogen receptors (ER) in human and monkey testis. Administration of tamoxifen in male mice indicated possible interference of male fertility. The studies confirmed the presence of ER in spermatogonia, spermatid as well as in the basement membrane of seminiferous tubules. The studies confirmed the occurrence of infertility in males treated with 200 mg/day of tamoxifen in mice.

NUTRITION

Relationship between low birth weight babies and CEF, adolescent pregnancies, micronutrient deficiencies, maternal infections have been studied. Micronutrient deficiencies of Vit.A, Iron, Zinc, Folic acid, riboflavin etc. in children were investigated and various corrective measures were suggested. Association between diet and disease conditions like cancer, cataract, hypertension etc. has been explored. National Nutrition Monitoring Bureau provided baseline information on morbidity and community perception on health and nutrition; and effect of natural disasters. Food toxicology and safety, and guidelines for recommended dietary intakes are other important areas on which work was undertaken.

BASIC MEDICAL SCIENCES

Pharmacology : A multicentric study was carried out at 12 centres at different parts of the country to study the nature and frequency of Adverse Drug Reactions

(ADRs) in chosen hospitals. The data analysis is under progress. It is also proposed to disseminate information of ADRs to medical professionals, alert Drugs Controller General of India in appropriate cases and to develop and establish a viable and self-sustained programme and network for ADR monitoring at national level. Clinical trials on *Vijaysar* (anti-diabetic) have been initiated.

Haemoglobinopathies: A *Jai Vigyan* Project on community control of Thalassemia syndrome has started. Prenatal diagnosis of haematological disorders i.e. G-6PD deficiency, thalassaemia, von Wille-Brand disease has been established.

Genomic research: Studies related to gene identification in areas of communicable diseases, non-communicable and genetic diseases are being conducted in diagnostics, drug and vaccine development. A clinico-genetic study on Handigodu disease has been undertaken. A major extramural programme for supporting initiatives in genome research has been launched.

Ethical Guidelines : Guidelines have been revised and released for use in research on human subjects.

Miscellaneous : Samples of placental tissue analysed for elements like cadmium, zinc and copper showed that placental tissue could be used as a model for elemental analysis.

Studies on ICC: Possibility of liver damage when combination of herbal drugs are given over a prolonged period of time is being investigated in mice.

Ultrastructural study on placenta: Studies amongst cases of pregnancy induced hypertension revealed reduction in density of phagosyncytial membranes and increase in number of syncytial knots.

Pigment cell biology: Whole skin organ culture with serotonin showed that increase in pigment production on UV exposure is related to the combined effect of serotonin and melatonin. Similar studies with tryptamine showed that melanocyte cell cycle can be altered by dark and light phase in the presence of tryptamine.

PUBLICATION, INFORMATION AND COMMUNICATION

The Council and its Institutes/Centres undertook various activities relating to publication, information and communication for the benefit of the scientific community and the lay public.

Publications : The Indian Journal of Medical Research (IJMR) brought out three special issues. Several important non-periodical publications were brought out by Council's Institutes/Centres.

Biomedical Information : Setting up of the ICMR-NIC Centre for Biomedical Information, and the Bio-informatics Centre at ICMR Headquarters. Major achievements were provision of information services from MEDLARS databases continued to be supplemented by factual information from other biomedical databases.

IndMed, a new Internet-based abstracting/indexing service with inclusion of 77 Indian journals was developed.

Scientometric Studies : Updated the Directory of Journals Publishing papers from ICMR Institutes with additional value added inputs.

Management Information System : The ICMR Homepage was developed.

INTELLECTUAL PROPERTY RIGHTS

In order to create a state of preparedness in the senior scientists of ICMR in the area of intellectual property rights workshops on Intellectual Property Rights were organised by the Council in collaboration with relevant agencies.

TRADITIONAL MEDICINE RESEARCH

A multicentric flexible dose double blind randomised clinical trials on an Ayurvedic drug in diabetes mellitus was initiated. National Training Programme-cum-Workshop on Quality Control & Standardisation of Traditional Remedies was organized. A joint publication with CSIR on over 200 commonly used herbal drugs/medicinal plants was brought out. Multicentric clinical trials on an ayurvedic drug treatment of bronchial

asthma were completed. Training Programme-cum-Workshop on role and use of biostatistical techniques in planning, conducting, methodology & evaluation of controlled clinical trials on traditional remedies. A Medicinal Plant Unit has been set up at ICMR Hqrs.

INTERNATIONAL COLLABORATIONS

- * Under country budget of WHO for biennium 1998-99 activities were finalized. Funds were utilized for research capacity strengthening through training programmes and workshops.
- * Indo-Vietnam Joint Commission on Science & Technology included Medical Science as a priority area for cooperation
- * Indo-Italian Joint Committee on Science & Technology discussions were held for collaborative research in biomedical sciences.

FRANCE

- * ICMR-INSERM collaboration revived and modalities of cooperation and further areas of mutual interest finalized

USA

- * Indo-US Joint statement on HIV/AIDS signed
- * Indo-US Joint Statement on Maternal and Child Health and Human Development & Research signed
- * ICMR-NIH Policy Forum on Biomedical Research established

GERMANY

- * GSF special Agreement for Cooperation in Biomedical Sciences revitalized

RUSSIA

- * Indo-Russia Joint Working Group on Science & Technology a sub Working Group on Medical Sciences set up

IAVI

- ICMR-IAVI : Joint Statement signed for development of HIV vaccines.

▲ Approach to the 10th Plan

The overall mandate of the ICMR would continue to guide the approach for the 10th Plan. The Council would undertake and support basic, epidemiologic, applied and operational research in the areas of national public health importance using conventional approaches as well as tools of modern biology.

The ICMR's Vision 2020 would however provide the strategies and the road-map to work towards the mandate:

- * provide leadership to revitalize health research, develop health research policy, ensure its translation into a national plan and priorities.
- * Facilitate development of a research culture, capacity strengthening and research environment in medical schools and health research institutes through re-organization and re-structuring.
- * Step up research in fundamental and strategic research aimed at development and field evaluation of low-cost and effective interventions in modern and indigenous medicine in health concerns of public health importance.
- * Form strategic international networks, partnership and alliances in areas of health research for development.
- * Create more opportunities for South-South interaction in health research.

Within these parameters, proposals for the Tenth Plan have been developed. There are general developmental plans in addition to the health problem-specific, institution based activities. While doing so the Government's directive to projectise all activities/ programme and projects by adopting the zero-based Budget approach has been kept in mind. The details

of the 9th Plan activities which would be continued in the 10th Plan are given in the relevant sections, Here only the new activities have been summarized.

In the 10th Plan period, it is hoped to sustain the 'build-up' and continue the new initiatives started in the 9th Plan, and the seize the opportunity provided by emerging technologies to address the issues of public health importance.

Ten-Step Strategy

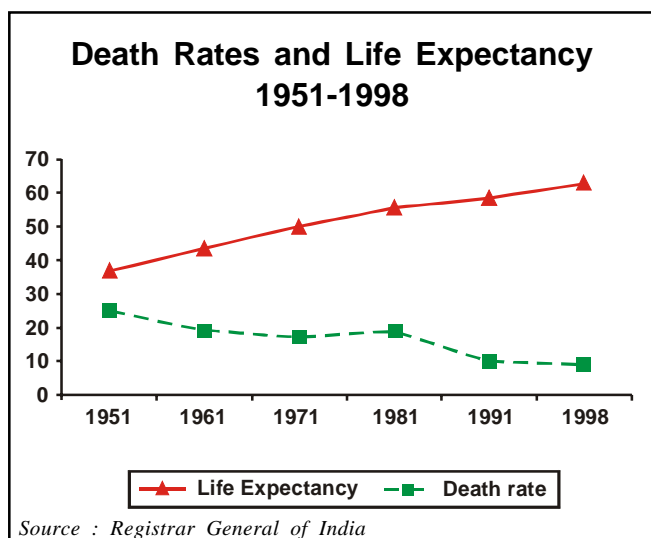
1. Enunciate a Health Research Policy.
2. Develop Health Research Manpower Policy and Plan.
3. Mount a programme for Health Research Capacity Strengthening.
4. Harness and use new and emerging technologies to find solutions to health issues.
5. Move towards equity in health through research.
6. Generate knowledge about biologic, socio-economic, environmental, behavioural and other determinants of disease conditions for developing effective, affordable, acceptable and accessible intervention strategies for their control.
7. Develop and validate intervention strategies at community levels.
8. Develop new and improved tools for prevention, diagnosis, treatment and control of diseases.
9. Develop and strengthen mechanisms for implementation of research findings.
10. Strengthen management capabilities to improve efficiency in administration, financial and project management skills.

5 Looking ahead

Health Trends

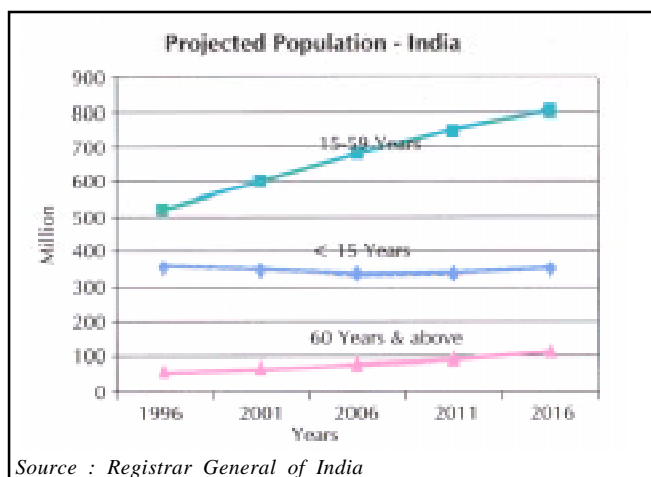
Future health trends

Two cardinal factors which are likely to influence health trends in India in the next decade are demographic transition and estimated burden of diseases.

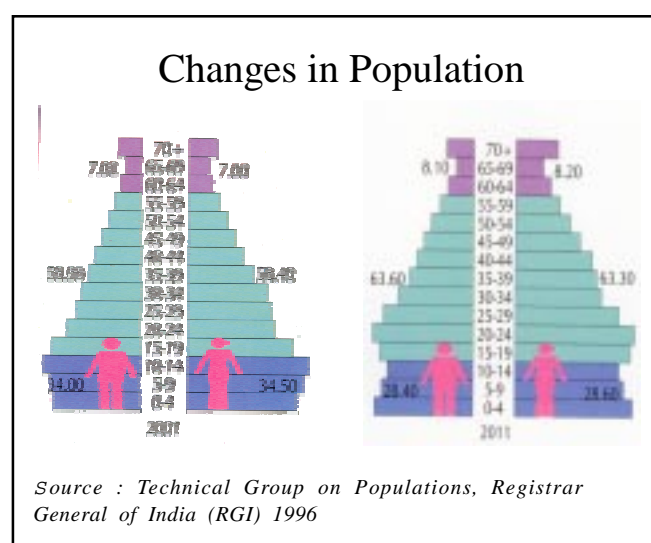


Demographic transition

Indian population is likely to touch 1100-1160 million by 2010. The life expectancy at birth almost doubled from 32 years in 1941-51 to about 63 years; and death rate which was 27.4/1000 in 1951 has declined to 9.0 in 1998.



Changes in population pyramid (1996-2016) are expected to result in an increase in the age-group 15-59 years from 519 to 800 million, in below 15 years a decline from 353 to 350 million but the age group over 60 years will almost double with increase from 62.3 to 112.9 million. The largest age group to increase is between 15 and 59 years.

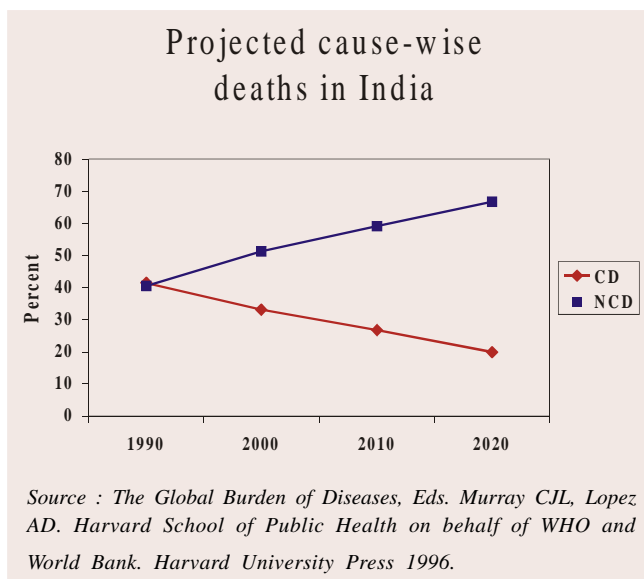
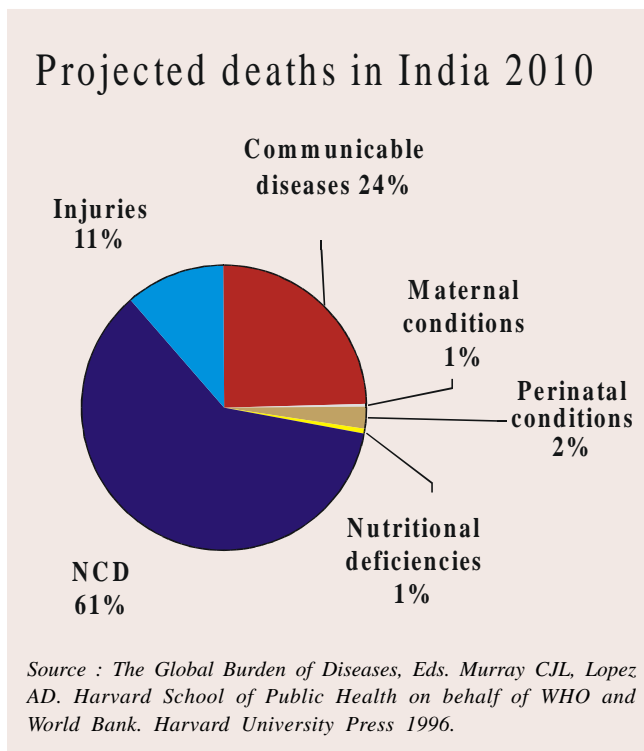
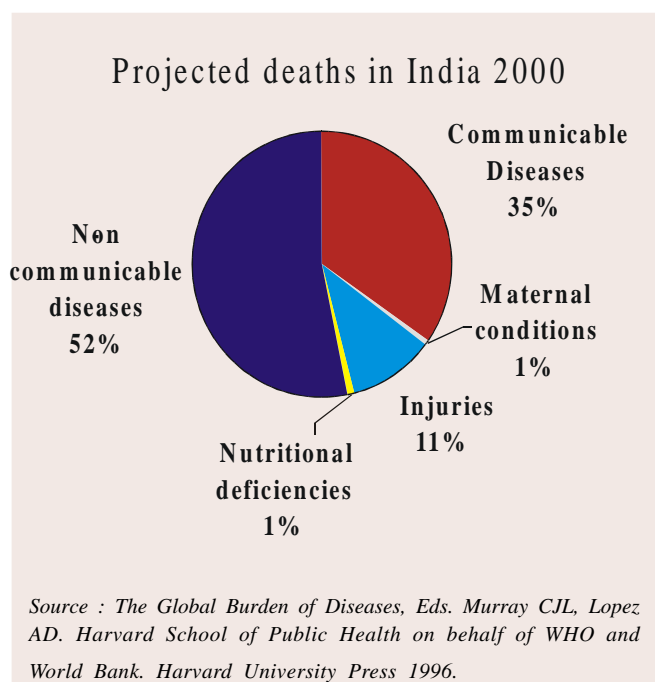


This provides a window of opportunity to achieve rapid population stabilization, if their felt needs are met through effective implementation of family welfare programme. At the same time it would be a challenge to meet the rising number of life style related diseases. India is currently in the phase of demographic transition. The challenge for the health sector is to promote healthy life styles, improve access to and utilization of health care so that the country can achieve substantial reduction in mortality and morbidity. Occupational health and environmental health programme need be augmented to ensure that working population remain healthy and productive. If these challenges are fully met, it is possible to accelerate reduction in morbidity and mortality rates in this age group and improve health indices of the country. Similarly increase in the number of persons beyond 60 years would pose

challenge of adding life to years by improving their quality of life. With growing number of senior citizens there may be substantial increase in health care needs especially for management of non-communicable diseases. Increasing availability and awareness about technological advances for better understanding of these problems raise the expectations of the population for an acceptable, affordable and sustainable interventions. Health research will have to gear up to make available necessary preventive, promotive, curative and rehabilitative strategies for growing population of senior citizens.

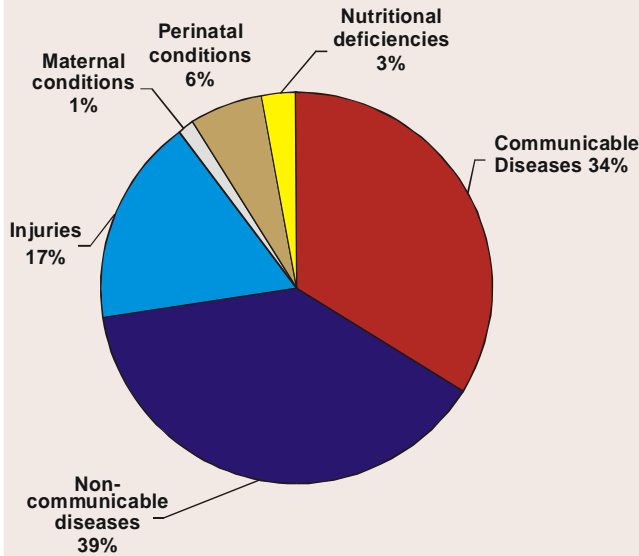
Estimates of Disease Burden

The only estimates for burden of disease for the country as a whole are available from the data of the Global Burden of Disease study undertaken by Harvard School of Public Health. Though the data may have drawbacks, it does give a trend over the years. It indicates that the deaths due to communicable diseases are likely to decrease from 46% in 1990 to 25% in 2010, while those from non-communicable diseases would climb from 43% in 1990 to 61% in 2010. Deaths due to injuries are also expected to increase. Mortality from maternal and perinatal conditions along with nutritional deficiency are likely to decrease further.



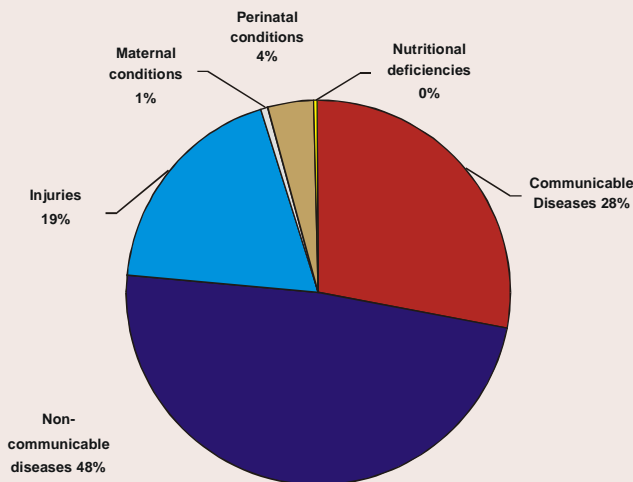
The report had also used Disability Adjusted Life Years (DALY) as an indicator for burden of disease. The estimated burden from communicable diseases is expected to decline from 41% in 1990 to 28% in 2010, while the burden due to non-communicable diseases is likely to rise from 29% in 1990 to 48% in 2010. The increase is also expected in injuries, which may show a jump from 14.6% in 1990 to 18.4% by 2010. Morbidity due to perinatal and maternal conditions and nutritional deficiencies would continue to decline.

**Projected burden of diseases - India
DALYs lost, 2000**



Source : *The Global Burden of Diseases*, Eds. Murray CJL, Lopez AD. Harvard School of Public Health on behalf of WHO and World Bank. Harvard University Press 1996.

**Projected burden of disease - India
DALYs lost, 2010**



Source : *The Global Burden of Diseases*, Eds. Murray CJL, Lopez AD. Harvard School of Public Health on behalf of WHO and World Bank. Harvard University Press 1996.

A careful re-analysis of the base line scenario for India in 2000 in Global Burden of diseases study shows that the proportion of communicable diseases of the total burden may start to show a decline, but

in absolute numbers the burden of some of the infectious diseases is likely to occupy the top positions.

Clearly more than 60 % of these diseases are infectious, about quarter (25.2%) are life stylediseases and one relates to perinatal conditions (13.5%). It would be these diseases along with trauma care that should receive top priority in the 10th Plan.

**The base line scenario of DALYs by
cause for year 2000, India**

Category	Total in '000	% of Total
Infectious and parasitic diseases	84665	33.8
Maternal conditions	3370	1.3
Perinatal conditions	15231	6.1
Nutritional deficiencies	7229	2.9
Non-communicable disease	96757	38.7
Injuries	42905	19.2
Total	250158	

Source : *The Global Burden of Diseases*, Eds. Murray CJL, Lopez AD. Harvard School of Public Health on behalf of WHO and World Bank. Harvard University Press 1996.

Cause specific DALYs

Causes	Total in `000	%
Lower respiratory tract infections	19354	17
Tuberculosis	16901	15
Diarrhoeal disease	16860	15
Perinatal conditions	15231	13.5
Ischaemic heart disease	13223	11.7
Unipolar major depression	10064	8.8
HIV	8362	7.4
Cerebrovascular diseases	5223	4.6
Measles	4001	3.5
Tetanus	3783	3.3
Total	113002	

Source : *The Global Burden of Diseases*, Eds. Murray CJL, Lopez AD. Harvard School of Public Health on behalf of WHO and World Bank. Harvard University Press 1996.

Looking at the age-specific death rates it is seen that about 35 % of the deaths take place in those under 15 years of age, while 23 % are in the age group of over 70 years.

Computation of age-specific DALYs of these ten causes from the Global Burden of Disease study indicates that 88% of lower respiratory tract infections, 93% of diarrhoeal diseases, 88% of tetanus, and all the cases of measles and morbidity due to perinatal conditions take place in first 14 years of life. These are all potentially preventable and treatable disease conditions. Appropriate interventions for these conditions in this age group would pay the greatest dividends. The data clearly shows that the projected increase in non-communicable diseases vis-à-vis infectious diseases is unlikely, given the present scenario.

There is no doubt that life-style diseases are expected to increase but the drastic decrease in communicable diseases does not seem probable. There are no major break throughs in the offing. Diarrhoeal diseases are here to stay, unless a concerted effort is made to

improve water and sanitation or finding excellent multi-disease vaccines. Similarly, environmental conditions are central to spread of vector borne diseases like malaria, Japanese encephalitis, dengue, kala-azar and filariasis. HIV is on the increase and with it the opportunistic infections. There is no preventive tool on the horizon that can arrest it in its tract. Though there are vaccines available against some of the organisms responsible for deaths due to respiratory infection their cost stands between the vaccines and the children.

These estimates are likely to change once some of the recent factors like spread of emerging and new infections, spread of resistance among organisms to commonly used drugs, and to insecticides in vectors, effects of global warming and climatic changes, and instances of animal pathogens crossing over to human are also taken into account, and representative and good quality data becomes available for calculating these estimates. Unless all round human development takes place in India, communicable diseases would continue to dominate the health scene.

6

Tenth Plan Proposals

Spill-over liabilities, maximizing benefits

Emerging Technologies and promising areas of research

Spill-over liabilities

These are activities which have been started during the 9th Plan period but would need to be continued for a variable period in the 10th Plan to reach to logical end. These include capital works and research programmes.

I. Capital works

Following are some of the important capital works which will spill - over in the 10th Plan :

Budget : Rs 61.81 crores

S.No.	Name of Institute	Details of Capital woks	Amount Rs. in crores
1	Indian Council of Medical Research, New Delhi, Headquarters office	Purchase of space, facilities in office New buildings additional	0.90
2	National Institute of Cholera and Enteric Diseases, Kolkata	P3 Lab and other works, Animal House	4.60
3	Regional Medical Research Centre, Bhubaneswar	Auditorium, Residential Quarters OPD and indoor treatment facilities	0.55
4	Regional Medical Research Centre, Port Blair	Auditorium, Labs Animal House	0.80
5	Regional Medical Research Centre, Jabalpur	Campus development, Animal House	4.70
6	Malaria Research Centre, New Delhi	Campus Development	10.80
7	Microbial Containment Complex, Pune	P3 lab Reagent lab & staff	2.00
8	National Institute of Virology, Pune	Campus development Animal House	0.50
9	National Institute of Occupational Health, Ahmedabad	Hostel project at ROHC(E), Misc. works at NIOH and ROHC(S)	7.50
10	Regional Medical Research Centre, Belgaum	Animal House	6.00
11	Tuberculosis Research Centre,	P3 Lab Misc./animal house	8.25
12	Central JALMA Institute for Leprosy, Agra	Upgradation of Institute & animal house	1.00
13	National Institute of Epidemiology, Chennai.	Animal House etc.	6.81
14	Institute for Research in Reproduction, Mumbai	Primate Breeding Facility at Surungam	7.40
TOTAL			61.81

II. Research programmes (Intramural and Extramural)

These are essentially studies/projects aimed at answering a specific research questions. The studies are those which are being conducted at the ICMR Institutes (intramural) or those being supported in medical colleges, universities, or other research institutes.

Budget for Intramural: Rs 13.19 crores

Budget for Extramural: Rs 3.31 crores

Critical on-going

Intramural

Critical research programmes which are to be continued in the 10th Plan are those which are addressing to crucial issues, be it in quest for new knowledge, developing and evaluating a new tool or taking research results from laboratory to land.

Fundamental Research on cell ultra structure, cell and vector biology, pathogenesis and patho-physiology, cell and population genetics, host-response would be continued.

Strategic Research on identification of immuno-dominant antigens, genotyping, fingerprinting, sibling species differentiation based on cytogenetics, outbreak

investigations, disease surveillance and monitoring antibiotic and insecticide resistance, vector surveillance, biology, biodiversity, bionomics and transmission dynamics; molecular taxonomy and phylogeny; host-parasite interaction, disease predisposing factors, identification of novel targets towards and development of insecticides.

Development and evaluation of newer tools such as diagnostics, drugs, vaccines, devices, testing and evaluation of new drug regimens, treatment algorithms and mathematical models would be continued and strengthened. Development of diagnostic/monitoring tools; development of intervention strategies; cost-effectiveness of various interventions; socio-economic research; determinants of diseases; management of insecticide/drug resistance; application of geographical information system and remote sensing for epidemiology and control of diseases; drug development; field and hospital-based trials; epidemiological investigations.

Operational Research areas would include demonstration of feasibility of interventions in different geo-ecological sites under programme conditions. Development of operational modules; disease modeling and operationalisation; morbidity management; development of early/advance-warning system; rapid response/preparedness for epidemic; health information management system; establishment of linkages; partnerships.

Budget: Rs 225 crores

Extramural

Included under this head are projects which are long-term studies and are undertaking relevant and essential activities. There are likely to be continued in present form or converted into permanent activities. Following is the list of such projects :

S. No.	Title
1.	Integrated Diseases Vector Control of Malaria, Filariasis and other Vector Borne Diseases
2.	Human Reproduction Research Centres
3.	National Nutrition Monitoring Bureau
4.	National Cancer Registry Programme
5.	Studies of Entomology and Sero-Epidemiology of <i>Japanese encephalitis</i> at Vridhachalam, South Arcot District of Tamil Nadu
6.	Malaria Parasite Bank Project
7.	<i>Jai Vigyan</i> Mission-mode Project on control of Rheumatic Fever/Rheumatic Heart Disease
8.	<i>Jai Vigyan</i> Mission-mode project on Community Control of Thalassemia Syndromes - Awareness, Screening, genetic, Counselling and Prevention.
9.	Central Biostatistical Monitoring Unit
10.	ICMR-NIC Centre for Biomedical Information

Budget: Rs 96.69 crores

Schemes for Maximising benefits

Given here are few examples of activities which would be undertaken for maximizing benefits of the on-going activities

A. Upgradation

1. Equipments and computers of newer models
2. Biosafety levels of laboratories
3. Insectories
4. Increase capacity of indoor and outdoor patient care facilities
5. Storage of records
6. Production capacity of reagents and tests etc.

Budget: Rs 33.75 crores

B. Modernization

1. Animal houses
2. Laboratories
3. Meeting and Conferencing facilities
4. Training facilities
5. Tools to conduct studies in modern biology e.g., micro-array, proteomics, protein chemistry, computational and structural biology, functional genomics
6. Repositories

Budget: Rs 56.25 crore

C. Replacement

1. Vehicles
2. Equipments which are obsolete or those beyond repairs
3. Consumables like chemicals and glassware
4. Debilitated parts of buildings beyond repair
5. Laboratory and office furniture

Budget: Rs 22.50 crore

10TH PLAN SCHEMES

The thrust areas for the 10th Plan have been described under four heads :

1. Priority Areas identified in Draft National Health Policy 2001
2. Cutting-edge areas in health research
3. Centrally sponsored schemes transferred to ICMR by the Ministry of Health
4. Neglected areas in medical research not address by other agencies.

I. Priority Areas identified in Draft National Health Policy 2001

Health statistics

There are no reliable and acceptable estimates of disease burden in India. The burden of disease estimates based on methodology developed by the Harvard Centre for Population have been published by the World Bank. Extension of the burden of disease methodology to national and local population has a lot of promise but requires availability of reliable local data.

The World Bank's World Development Report, 1993 used a new measure of population health status, the disability adjusted life years (DALY). Many agencies use DALY as a common denominator for priority setting and resource allocation. The disease burden estimates mostly consist of traditional disease burden profiles consisting of cause specific mortality and disease prevalence data. Cause of death statistics are an important input and anchoring point for burden of disease estimates.

Unfortunately, the cause of death reporting in India is quite unsatisfactory. In the rural areas, medical certification of cause of death is usually not feasible since a lot of deaths happen without any prior medical attention for the deceased. The country depends on a system of lay reporting of cause of death using verbal autopsy methodology. The strategy suffers from poor data quality, which in turn contributes to low credibility of vital statistics. In urban areas, a medical certification of cause of death scheme is operational but the level of compliance varies in different states. Low coverage makes it impossible to estimate the causes of death with any accuracy.

The ICMR plans to fill this gap by taking up the task of generating data on the burden of diseases. Scientists have been trained in the technique used by the World Bank. In the first phase, the existing data would be used for these estimates and simultaneously efforts would be made to generate reliable data, which would be used to compute disease burden. This would form a continuous activity in collaboration with the State Governments.

Disease surveillance at the molecular level

Molecular Epidemiology has come to be recognized as an integral part of most epidemiological studies and outbreak investigations. Disease surveillance is incomplete without the application of molecular tools. The discipline of molecular epidemiology would be developed in both communicable and non-communicable diseases. Molecular Epidemiology would contribute significantly to characterization, detection and diagnosis of existing and new and emerging infections as also to an understanding of biological processes involved. The application of appropriate molecular tools will aid in the surveillance of infectious

agents, determining source of infection and tracking its spread. It would help in monitoring effects of treatment failure from recurrent infections. In the field of cancer, molecular tools are being applied to study the Molecular Epidemiology of cervical and pre-cancerous lesions with special reference to various etiological factors. Several institutes engaged in communicable disease research have started molecular epidemiology. Others are being strengthened to undertake such research.

Bio-informatics

A Health Research Information System is being set up at the ICMR Headquarters, New Delhi. It would develop into web based, one point interactive health research information system which would provide information about the health and biomedical research projects carried out in medical colleges, research institutes, universities, government departments, NGOs, private sector etc. This information could be used by policy makers, planners, programme managers, researchers etc. This would provide access to national and international biomedical databases and health research websites. The system would act as an information portal for published and un-published work. It would provide direct link between the ICMR Headquarters and the Institutes.

Environmental/Occupational Health

Environmental quality is an important determinant of human health. Deteriorating environmental conditions are major contributing factors to poor health and poor quality of life and hinder sustainable development. To a great extent, the degree of economic development determines the type of environmental health hazards. The Indian economy is in a state of transition and under these conditions, the population is at risk both from the 'traditional' environmental health hazards and from the 'modern' hazards such as air and water pollution, hazards waste, unsafe use of chemicals including pesticides, workplace hazards and traffic accidents. Potential relationship between various exposures and health conditions like acute respiratory infections, diarrhoeal diseases, vector borne diseases, injuries and poisonings, mental ill health, cardiovascular diseases, cancer and chronic respiratory diseases is being increasingly recognized. The Council has already generated

databases on occupational diseases, pneumoconiosis and other respiratory illnesses in coal miners; exposure to noise, heavy metals, pesticides etc. It is planned to expand the research with the use of molecular biology to develop biological markers of exposure, susceptibility and effect. Analytical techniques for detection of minute quantities of toxicants would be developed and epidemiological studies on environmental health are planned.

Intellectual Property Rights/Technology Transfer

The existing skeletal facilities of IPR Cell are proposed to be upgraded to cope with the post-GATT scenario. There would be regular monitoring of the global databases in the areas of drugs, vaccines, diagnostics and other biologicals to help Indian scientists face the new challenges and plan appropriate strategies. This will be done through acquiring of new databases, journals and other reference sources which will be made accessible to all ICMR users in-house. In addition, technology transfer issues would be strengthened through legal and technical assistance to help upscale laboratory inventions to pilot scale and subsequently to the industry level. Academia-industry interactions would be held to help scientists to take their products to market.

Mental Health

Amongst the non-communicable diseases, mental health is an important cause of morbidity. Realizing its importance, the WHO has declared 2002-03, as year of mental health. The Council proposes to institute studies on the following areas during the 10th Plan period.

Suicide behaviour: descriptive epidemiology, identification of contributing factors and process, mental health care for urban areas, mental stress associated with urban life.

Depressive disorders: early detection and interventions, acute undifferentiated psychiatric disorders.

Schizophrenia: etiology, prevalence, factors associated with outcome.

Mental health consequences of disasters and child and adolescent mental health will be studied.

Pharmacogenomics

Pharmacogenomics is the study of how genetic differences influence the variability in patient's responses to drugs. Through its use it will be possible to profile individuals DNA to predict responses to a particular medicine. It will provide information on the likelihood of efficacy and safety of a drug for an individual patient. The vision of pharmacogenomics is that the discovery of genetic variances that affect drug action will lead to the development of new diagnostic procedures and therapeutic products that enable drugs to be prescribed selectively to patients for whom they will be effective and safe.

The combined use of all of these highly parallel methods, along with sequence information, computational tools, integrated knowledge database and the traditional approaches of biology, increases the hopes of understanding the function and regulation of all genes and proteins, deciphering the underlying working of the cell, determining mechanisms of diseases and discovering ways to intervene with or prevent aberrant cellular process in order to improve human health and well being.

All these technologies and many more are complementary like protein arrays, the yeast-two hybrid system, phage-display antibody libraries, surface-enhanced laser description and ionization, and biological activity profiling of families of proteins such as proteases, will undoubtedly play prominent roles in armories of proteomics and functional or structural genomic based approaches. Parallel development of high quality informatics facilities is also essential involving not only genetic and protein sequences, but also the experimental conditions to unravel the biology. All of the above will be relevant to ICMR's effort to strengthen national disease control activities.

Vaccines and diagnostics

The following are the areas that would be addressed: to develop new generation of vaccines

which can provide intrinsic and long term immunity; to make subunit polyvalent vaccines that are more potent; development of vaccines based on bacterial toxins; develop vaccines directed against core and envelop proteins of HIV virus with optimal protection to block viral replication and effective against the associated antigenic drift; develop genetically engineered vaccines for measles, cholera, *Streptococcus*, haemophiles etc; designer vaccines including edible vaccines; identify the parasite proteins which bind the host cell receptors and raise vaccines against them; develop more effective and easily manufacturable vaccines for dengue and encephalitis. Vaccine testing facilities would also be developed within and outside the ICMR network.

HIV/AIDS Vaccine Development : With the current estimate (3.7 million) of infection and spread in low risk group in India, there is a need to utilize all available strategies to arrest the march of HIV/AIDS. There are several vaccine development concepts being applied presently worldwide. The ICMR has embarked upon a research programme in collaboration with NACO for development of preventive vaccine(s) against HIV. The present programme has been designed for the construction of indigenous HIV-1 subtype C candidate vaccine against HIV infection using Modified Vaccinia Ankara (MVA) as a vector. The vaccine would be based on HIV-1 subtype C virus strain, which is the most prevalent strain in India. Cooperation of International AIDS Vaccine Initiative, USA is being sought in technology transfer. The vaccine related research would be carried out at the National AIDS Research Institute, Pune, National Institute of Cholera & Enteric Diseases, Calcutta, National Institute of Virology, Pune and Tuberculosis Research Centre, Chennai. The other three vaccine approaches which would be perused in research mode are:

- * Multi-epitope based vaccine
- * Modified BCG as vector
- * DNA based vaccine

Vaccine development involves complex and complicated steps starting from isolation of HIV-1 characterization of strains and selection of strains suitable for vaccine development. This candidate

vaccine would go through pre-clinical and toxicity studies to be followed by Phase-I, II and III trials in human. Basic work has been started.

In the area of diagnostics the areas of study would be to develop DNA based kit for rapid diagnosis of various diseases. Various projects undertaken during 9th plan period will be further developed with the genomic information Identification of Indian mutations and to evolve appropriate diagnostic kits are also planned.

Medical Ethics in Gene Manipulation and Stem Cell Research

The stem cell research involves concerns regarding that of equity, ethics, affordability and practicality. The profound characteristic of a stem cell is its capacity for extensive self-renewal and retention of multilineage differentiation potential. Recent research suggests that human stem cells can give rise to many different types of cells, such as muscle cells, nerve cells, heart cells, haematopoietic cells etc, giving the hope for major advances in health care. The era of clinical marrow, tissue and organ transplantation is poised for breakthrough with the possibility of stem cell transplantation and therapy. Council proposes to take up following areas in this respect during the 10th Plan period

Realising the potentials of this new technology in modern therapeutics and biomedical research the council proposes to promote the Stem cell research and its clinical applications in the country.

Council has recently set up a committee for tackling various issues related to this research and already specific recommendations have been laid regarding the issues of regulation of adult, embryonic, mature/umbilical cord stem cell research in the country. Further action on these recommendations will be taken up during 10th Plan period.

Separate and updated guidelines specific for any research or therapy with cord blood stem cell need to be prepared and updated during the 10th Plan period as an addendum to the *Ethical Guidelines for biomedical research on Human beings* released by the ICMR in Sept. 2000 , with respect to timing of collection, informed consent from mother/couple,

safety to the new born child etc. Other issues related to Transplantation Research for the centres dealing with cord blood collection which will take up not only collection but also cryopreservation, in vitro expansion and transplantation for repair/replacement of the diseased tissues or organs.

Ethical issues related to cord blood once collected with informed consent of the mother/ couple, if IPR issues are involved.

Food quality monitoring

Globalisation has led to increased movement of food commodities in international trade. Of particular importance is the introduction of genetically modified (GM) foods. GM foods are produced by recombinant DNA (rDNA) techniques and are called transgenic, GM or biotech foods. GM foods are recognized by an altered genome that may lead to the expression of a new protein. The predominant crops that are genetically engineered include soyabean, corn, cotton and canola or rapeseed. Corn and soyabean comprise the largest group. The production of GM plants is increasing rapidly. There has been more than 20-fold increase in the global production area for transgenic crops over the last four years. The plant traits which are modified using gene technology include agronomic traits like increase in yield, herbicide and insect tolerance, viral, fungal and bacterial resistance and also quality traits such as delayed ripening, modified oil content, fatty acid profile, improved nutritive value etc.

The main commercial production of GM crops is in USA, Canada and Argentina. GM foods are not yet approved for commercialisation in India. However, under the current global scenario it can be expected that GM foods will soon be imported into and later also produced in India. The Indian Government has to set out rules, regulations, guidelines and other legal provisions concerning the safety assessment of these foods produced by rDNA techniques. There are many issues that need attention before GM foods are permitted in India. These are: (1) toxicity (2) testing of GM foods, both imported and those which will be produced in the country (3) nutritional evaluation, including study of anti-nutrients, as well as the nutritional

balance and nutritional mix in the people diets, as a result of consuming GM Foods, especially fortified products including impact of vitamin fortification through GM. (4) labelling issues and (5) ethical issues, including use of GM in baby foods. Relevant guidelines will have to be developed after appropriate research studies. Currently, no laboratory in India is testing GM foods. However, there are several national laboratories like the National Institute of Nutrition, Central Food Technological Research Institute, Industrial Toxicology Research Centre and Central Food Laboratories that have the technical manpower to undertake the testing. Extra inputs in the form of certain equipment and training of manpower will be necessary. Infrastructure needs to be developed for detection as well as for safety assessment of GM products.

II. Cutting-edge areas in health research

Health Research Policy

The ICMR shall provide leadership in the development of National Health Research Policy, translating it into national plan and priorities. It shall improve links and co-ordination between the initiatives of various biomedical and health research groups. It shall facilitate the setting of national regulations and standards relevant to various aspects 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 laid down to channel efforts and funds in the right direction. A draft Health Research Policy has been prepared and is being circulated for generating a discussion.

The Policy aims to facilitate generating the evidence-base for health systems and services, so that they will be significant promoters of equity and contribute to national development. It would also help in establishing linkages between health research and national health programmes to facilitate the operationalisation of evidence based programmes and to obtain feedback for optimization of health research. The policy would encourage the development of fundamental research

in areas relevant to health to ensure that a national critical mass of scientists who can contribute the benefit of modern technology to health research is developed. It envisages setting up of a National Health Research Management Forum to efficiently coordinate planning and financing of the national health research system.

Priority setting in Health Research

The overall health status in terms of indicators appears to be improving but the inequalities in health have become more prominent. Improving the opportunities for health calls for a careful examination of the bases of decisions made locally and nationally. During the 9th Plan period, the ICMR in consultation with other partners did an exercise on priority setting. An ICMR-WHO-GFHR-AIIMS workshop has been held. The first phase of the activity has been completed. A 5-step process of GFHR-WHO was followed, and research priorities identified. Phase II would be taken up in partnership with different stakeholders. Further development and refinement of method and tools would be done in the 10th Plan. These priority areas can help reduce health inequalities by ensuring that the products of research reach the poorer sections of population who need it the most.

In view of the competing priorities for scarce health research funds, priority setting for health research is as critical as conducting health research. The process of priority setting is an important activity. A continuous review of priorities and priority-setting mechanisms is essential since research priorities change over time as a result of epidemiological, demographic and economic changes.

Steps would be taken to conduct and support research which would generate data which are critical for priority setting e.g. burden of disease; economic impact; cost-effectiveness of potential interventions etc.

Medical research support during disasters

India often faces natural (e.g. floods, cyclones, earthquakes) as well as man made disasters (gas leaks, industrial accidents), and health issues become very critical. The ICMR has been called to help in identifying health problems and to suggest feasible

solutions. The contributions made by ICMR in gas leak Bhopal, earthquake in Latur and cyclone in Orissa are well recognized. As part of the strategy to be in a state of preparedness to provide technical expertise and assistance, it is proposed to set up a Central Unit at Headquarters with a rapid action team in each Institute of the ICMR.

Drug Development

Several compounds having therapeutic potential developed by various agencies are perforce kept in cold storage for number of years pending proper pre-clinical and clinical evaluation. Till such studies are carried out as per the regulatory requirements of the Drug Control Authority, new compounds cannot see the light of the day, as their safety and efficacy would be questionable otherwise. Hence, to develop and strengthen capabilities in all these related areas the ICMR proposes to create national facilities and develop human resources for carrying out the much needed research in the specific areas of drug research and clinical pharmacology. For this purpose, the following initiatives will be taken:

- * Establishment of net work of pre-clinical toxicology centers for carrying out animal toxicology studies taking appropriate care to maintain good facilities for laboratory animals.
- * Identifying special centers for conducting mutagenicity, teratogenicity and reproductive toxicity studies on new molecules.
- * Identification of Clinical Pharmacology Units to undertake Pharmacokinetics and Bioavailability studies using Good Laboratory Practice (GLP) protocol.
- * Establishing clinical trial methodology for traditional medicine research with a strong support of trained statisticians having experience in formulating study designs and monitoring of clinical trials in this area.
- * Issuing ethical guidelines for biomedical research as a whole with special emphasis on clinical trials on drugs/diagnostics/vaccines and herbal remedies.

Traditional Systems of Medicine

In order to strengthen research in therapies in traditional systems of medicine, the ICMR has taken initiative in setting up two Centres for Advanced Research :

- * Pharmacological research for Drug Development in Selected Traditional Remedies at Central Drug Research institute (CDRI), Lucknow: specific areas of research involve studies on standardised (plant) extracts which include *Picroliv* (Hepatoprotective), *Centella asiatica* (wound healing), *Terminalia chebula* (adaptogenic / antistress);
- * ICMR Advanced Centre for Research in Traditional Medicine at Seth G.S. Medical College and KEM Hospital Mumbai : studies are being focussed on traditional remedies for wound healing; Medicated oral rehydration preparation in diarrhoea; mechanism of action of *Vijaysar* in diabetes; and training programmes in clinical pharmacology of traditional remedies.

For further strengthening research in traditional systems of medicine it is proposed to validate the traditional knowledge, finger print some of the selected herbal preparations, develops new molecules from plant sources, and encourage agrotechnology.

Development of Animal Facilities

National Centres for Primate Research at Mumbai and Hyderabad are being established and strengthened to develop resources including facilities, professional and technical expertise for biological testing of potential drugs and vaccines. These centers would also undertake research programmes on significant human health related problems where non-human primates are the animal model of choice, and breed non-human primates of defined health status and pedigree. The Centres would focus on evaluation of drugs, devices and toxicology, studies on reproductive and developmental biology, infectious diseases, gerontology, behavioural biology and immunology.

There is need to have good laboratory animal facilities so that data generated is acceptable to regulatory

authorities like USA as well as European Community for obtaining global marketing rights for drugs. The overall design of a laboratory animal facility is important. In most of the institutes the animal units are buildings or rooms originally designed for other purposes. Facilities for cleaning, storage and ventilation are often inadequate.

Microbial Containment Facilities

Rapid urbanization, industrial and other developmental activities, ecological changes, deforestation and rapid means of transport have increased risk of new and emerging infections. The threat is not only from within, but also from infections crossing over international borders. ICMR Institutes are asked to investigate outbreaks of unknown etiology. Many of these organisms are highly infectious and require handling under specified levels of safety. Research on these agents could be hazardous not only to personnel handling them, but also to the community and the environment at large. It is imperative to set up facilities with appropriate biosafety levels in which micro-organisms of highly infectious nature could be handled and stored safely. The ICMR proposes to establish one BSL-4 facility at MCC, Pune and one BSL-3 facility each at National AIDS Research Institute, Pune; Enterovirus Research Centre, Mumbai; Tuberculosis Research Centre, Chennai; and National Institute of Cholera and Enteric Diseases, Kolkata.

Genomics

The human genome project the publically funded international collaboration of 20 groups of scientists from USA, Japan, UK, France, Germany and China completed the working draft of mapping of human genome in June, 2000. The first human genetic code was presented on February 2001. There is currently a global consensus that analyses of genomic sequences of animals, plants and other organisms will revolutionise biology both with respect of understanding of basic biological processes and application. Now the job of figuring out the genomic information and reaping benefits is just beginning. Council has been making efforts almost a decade ago on molecular biology. The genomic information is being used for finding dozens of disease promoter genes.

Main focus will be to :

- * Investigate further molecular biology of human pathogens and the mechanism of infection using genomic information.
- * Analyse genetic variation of different pathogens.
- * Develop transgenic animal models of carrier state diseases.
- * Understand the neurotropic sequences of *Japanese encephalitis* virus genome for use in the construction of gene transfer vectors to target genes to brain.
- * Determine the antigenic component of HIV and construct detailed map of the viral genome in various functional domains in Indian population and also to investigate the genetic causes of cell destruction by this virus.

Genome Sequence data base

A national uniformly formatted database of all genome sequences, possibly with multiple mirror sites to enable easy accessibility needs to be created. Genome sequences that are already available in various public domain databases will be downloaded into this national database. Sequences, and information relevant to their analyses and use will also be collected from scientific literature. Regular updating will be carried out.

The genome sequence data would be very useful to develop new methodologies and solutions for prevention and treatment of diseases of public health importance, identify genes responsible for various genetic diseases for planning, prevention and treatment. It would be possible to answer some major unanswered questions in biology, using leverage of information technology with application in health and medicine.

DNA Microarray

This is among the most powerful and versatile tools for genomics. Nucleic acid arrays work by hybridization of labeled RNA or DNA in solution to DNA molecules attached at specific locations on a surface. The DNA arrays can be used for many different purposes, most prominently to measure levels of gene expression for tens of thousands of genes simultaneously.

DNA microarray has attracted tremendous interest among biologists. This technology promises to monitor the whole genome on a single chip so that researchers can have a better picture of the interactions among thousands of genes simultaneously. An array is an orderly arrangement of samples. It provides a medium for matching known and unknown DNA samples based on base-pairing rules and automating the process of identifying the unknowns. DNA Microarray Technology can be used for Gene discovery, Disease diagnosis, vaccine development, Pharmacogenomics, Toxicogenomics etc.

It is proposed to support studies :

- * Using DNA microarrays in conditions like Cancer (esophageal cancer, retinoblastoma) and infectious diseases (tuberculosis and leprosy)
- * To determine the gene expression profile of human Esophageal cancer for understanding the mechanisms implicated in esophageal tumorigenesis, identifying putative diagnostic/prognostic markers and novel drug targets.
- * Cisplatin, anticancer drug, is used for ovarian carcinoma and teratoma of the testes and to identify whether a test tumor is sensitive or resistant to cisplatin to design newer therapeutic programs.
- * Identification of genes involved in the tumor development (retinoblastoma and meibomian cell carcinoma) by hybridizing cDNA samples from normal and malignant tissues and helps predict the clinical consequences of the treatment.
- * To generate global gene expression profiles of a culture model of skeletal muscle stem cells
- * To analyze the differential gene expression between different strains of *M. tuberculosis* and to develop novel leads for vaccine.
- * To identify genomic differences among strains of *M. leprae* within the human host and to help in better management of disease
- * To identify differentially expressed genes in parasites isolated from Post Kala-azar Dermal Leishmaniasis patients (PKDL) to develop specific diagnostic targets and therapeutic drugs.

Gene Therapy

The basic principle of gene therapy is either the insertion of a functioning gene into the cell of a patient to correct an in-born error of metabolism or provide a new function to a cell. The concept of gene therapy has now widened the view of the conventional classical genetic disorder like thalassaemia or haemophilia. It may be a useful treatment for a variety of acquired diseases. The ability to manipulate the genetic make-up of tumor cells, disease susceptibility gene identification is a priority area of research in area of communicable diseases (e.g. leprosy, tuberculosis), non-communicable diseases (e.g. RF/RHD, Schizophrenia) and genetic diseases (Handigodu disease).

Stem cell research and therapy

The profound characteristic of a stem cell is its capacity for extensive self-renewal and retention of multilineage differentiation potential. Recent research suggests that human stem cells can give rise to many different types of cells, such as muscle cells, nerve cells, heart cells, haematopoietic cells etc, giving hope for major advances in health care. Research on stem cells also promises to improve our understanding of the complexities of human development and the disease processes. Realizing the potentials of this new technology in modern therapeutics and biomedical research, stem cell research and its clinical applications should be promoted in the country. The major sources of stem cells are embryonal stem cells (embryos or foetal tissue) and adult stem cells (peripheral blood, tissue or bone marrow).

In view of the sensitivity and ethical issues involved in utilizing the stem cells, it is proposed to put in place a regulatory mechanism for research and therapy. Detailed guidelines are being worked out to regulate IVF clinics, cord blood transplant and embryo research while the ethical guidelines are already enunciated in the recently released *Ethical guidelines for Biomedical research*.

Gene and stem cell therapies hold the promise for treatment of wide variety of inherited and acquired

human diseases. Identification of genes involved in human diseases and development of novel vectors and devices for delivering therapeutic genes to different tissues *in-vivo* and exciting new techniques which hold great promise. Isolation of stem cell from organs previously thought to have no regeneration power, demonstration of stem cell plasticity and creation of human embryonic stem cells highlight feasibility of human stem cell therapy.

Prenatal diagnosis through mutation analysis

Prenatal diagnosis of major genetic disorders is one for the thrust areas of future work in Indian context. Prenatal diagnosis of haematological disorders like thalassaemia, sickle cell anaemia, G6PD deficiency, haemophilia, von Wille Brandt disease have already been taken up. It is proposed to expand the use of this technology to other genetic diseases.

Proteomics

Proteomics is the large-scale study of proteins, usually by biochemical method. This technology will contribute to understanding of gene function. It is complementary to genomics because it focuses on the gene products, which are the active agents in the cell. For this reason proteomics directly contributes to drug development. Because it is often difficult to predict the function of a protein based on homology to other proteins or even their 3-D structure, determination of components of a protein complex or of a cellular structure is central in functional analysis. This aspect of proteomic studies is perhaps the area of greater promise.

The ICMR would support biomedical application of proteomics-based approaches ranging from understanding of pathogenesis of cardiovascular neurological disorders and cancers to drug and vaccine design for infectious diseases.

Social and Behavioural Research

There is a need for major emphasis on social and behavioural issues in order to achieve the goals of the National Population Policy 2000. Bio-medical specialties of ICMR need a proper and meaningful social and behavioural research interface so as to transfer the benefits of existing and newer biomedical

knowledge/technologies to the people for better health and development and population stabilization.

Some of the priority areas relate to women's health and development, adolescents, HIV/AIDS, gender issues, *Panchayat Raj* Institution and health, and genetic risk behaviour of the communities, in addition to newer challenges in non-communicable and communicable disease areas involving social and behavioural interventions.

Human Resource Development

Resource capacity strengthening is one of the most powerful, cost effective and sustainable means of advancing health research. There have not been any organized and focused efforts towards human resource development. It is not only an issue of numbers and the skills, but also giving attention to generate a demand for research among policy makers. A long term comprehensive human resource development plan would be put in place which would address to the wide range of related issues including leadership and management, capacity for use of research, policy and systems analysis priority setting etc.

The issue of fewer and fewer medical graduates opting for a career in academics and research is of great concern. The course curricula both at the undergraduate and postgraduate levels also do not lay much emphasis on research methodology or the execution of research programme. Moreover accomplishments through research are not considered essential for career advancement of faculty in most medical colleges in India. The on-going activities of manpower development include programmes like 'Short Term Summer Studentship Programme', *Kishore Vaigyanik Protsahan Yojana*.

The Council has recently initiated a Junior Research Fellow(JRF) programme for biomedical research, and is also in the process of initiating MD and Ph.D. programme, providing financial support for electronic copy of MD thesis in priority areas of research. Various training programmes for in-service scientists and related officials are also being carried out through its institutes. Many ICMR institutes have been accredited for Ph.D. programme of Indian Universities.

Niche areas of human resource development for 10th Plan are :

- * Good clinical practices
- * Good laboratory practices
- * Social and economic research
- * Health economics
- * Data analysis
- * Protocol development
- * Scientific communication skills
- * Intellectual Property Rights
- * Bio-ethics in human and animal research
- * Epidemiology
- * Molecular medicine
- * Bio-informatics
- * Animal technologies

The Council plans to create a Division of Human Resources Development to address this issue in a focused manner.

Specific research programmes and budget requirements

Given here are salient research areas and the budget requirements. The details about the programmes are given in the Annexure.

The budget estimates for the 10th Plan have been projected in three scenarios, viz optimum requirement, at 50 % and 60% stepdown. The budgetary requirements for different levels of funding have been calculated while retaining the amounts required for spill-over activities and critical on going programmes on the basis of actuals.

INTRAMURAL Communicable Diseases Tuberculosis

Budget	Rs in crores
Optimum	8.87
50% step-down	3.46
60% step-down	2.37

Research programme

- * New generation of TB vaccines: inactivation or removal of selected genes from slow growing mycobacteria, targeted manipulation of immune responses by novel vaccine delivery system

- * Drug development : using proteomic studies to identify several targets crucial for bacterial survival *in-vivo*
- * Identify newer HLA and non-polymorphisms: using genomic and immunological techniques
- * Study of transmission dynamics through molecular epidemiological studies using computational graphics and micro-array studies
- * Identify promoters and regulators of metabolism of mycobacteria for expansion of antigens and molecules that can be utilized as candidate vaccines and drug targets
- * Validate newer diagnostic methods
- * Develop rapid and reliable diagnostics for early diagnosis and monitoring of treatment
- * Develop and test more effective and shorter duration regimens for pulmonary and extra-pulmonary tuberculosis
- * Demographic distribution of types of drug resistance using modern biological techniques
- * Chemotherapy trials and epidemiological studies in relation to HIV

Infrastructure Development

Tuberculosis Research Centre, Chennai

- * Evaluation of newer chemotherapeutic drugs and regimens
- * Immuno pathogenesis and molecular biology of mycobacterial diseases
- * Molecular Epidemiology of tuberculosis
- * Studies on HIV and TB
- * Design of newer anti-tuberculosis drugs
- * Development of new TB vaccine
- * Development of diagnostics
- * Facilities for quality control
- * Establishment of a Centre of excellence to work on transfer areas of modern biology
- * Setting up of a BSL-3 laboratory

Leprosy

Budget	Rs in crores
Optimum	25.03
50% step-down	9.77
60% step-down	6.71

Research programme

- * Develop serological techniques and DNA probes for diagnosis of leprosy at a very early stage
- * Study drug resistance in animal model
- * Design new drug regimens to shorten treatment and prevent relapse
- * Early prevention of deformities
- * Follow up patients released from treatment to assess relapse rate

Infrastructure Development

Central JALMA Institute for Leprosy, Agra

- * Strengthening of Pathology, Microbiology, Molecular Biology and Biochemistry

Diarrhoeal diseases

Budget	Rs in crores
Optimum	66.74
50% step-down	26.04
60% step-down	17.89

Research programme

- * Molecular epidemiology of enteric pathogens
- * Understanding of molecular mechanisms of pathogenesis of diarrheal agents
- * Develop candidate vaccines *V.cholerae*, shigella dysenteriae, rotavirus
- * Diagnostic kits: DNA based
- * Genome mapping of entire pathogens like *E.histolytica*
- * Molecular analysis of circulating strains of diarrheal pathogens
- * Elucidate nature of un-typeable strains of rotavirus
- * Effect of micronutrients and vitamins in pathogenesis and management of diarrhoea
- * Active community and hospital based surveillance of diarrhoeal diseases
- * Risk factors in acquiring diarrhoeal among malnourished and low birth weight babies

Infrastructure Development

National Institute of Cholera & Enteric Diseases, Kolkata

- * Center for genomics and proteomics
- * Setting up of a BSL-3 laboratory

Malaria

Budget	Rs in crores
Optimum	20.33
50% step-down	7.93
60% step-down	5.44

Research programme

- * Mapping and updating information on distribution of mosquitoes and malaria vectors
- * Develop a comprehensive molecular system for characterization of anophelines
- * Molecular parasitological studies to develop markers for population genetic analysis, differentiation of primary infection from relapses and recrudescence, drug resistance detection and to understand mechanisms of drug action and drug resistance
- * Screen and develop new anti-malarials especially herbal-based products
- * Malariogenic stratification for planning effective control strategies using remote sensing and geographical system
- * Monitor drug and insecticide resistance
- * Evaluate new drugs and insecticides
- * Health impact assessment of developmental project
- * Develop and evaluate parasite diagnostics
- * Maintain parasite bank, insectaries, and reference specimens

Infrastructure Development

Malaria Research Centre, Delhi

- * Operational research on integrated disease vector control
- * National Malaria Parasite Resource
- * Institutional and Research capacity strengthening

Filariasis

Budget	Rs in crores
Optimum	16.86
50% step-down	6.58
60% step-down	4.52

Research programme

- * Develop transgenic mosquitoes using molecular entomology technique
- * Taxonomic revision and preparation of identification keys
- * Immunological and molecular basis of vector susceptibility to parasitic infections
- * Understand natural protection in acquiring infection/disease
- * Identification of novel targets towards development of insecticide for vector control and newer drug development
- * Clinical trials with new and existing anti-filarial drugs to formulate suitable regimen
- * Application of geographical Information System and remote sensing for epidemiology and control of vector borne diseases
- * Disease modeling
- * Operational research to develop and implement social intervention packages to improve acceptability and proper use of anti-filarial drug regimens.

Infrastructure Development

Vector Control Research Centre, Pondicherry

Setting up of new Cells for :

- * Culicid Biodiversity
- * Remote sensing and GIS for control of vector-borne diseases
- * Lymphatic Filariasis Elimination
- * Monitoring of Insecticide Resistance in Vectors

Leishmaniasis

Budget	Rs in crores
Optimum	189.76
50% step-down	73.99
60% step-down	50.86

Research programme

- * Development and evaluation of highly effective, less toxic and economical treatment regimens

- * Develop and evaluate diagnostic tools for early visceral leishmaniasis and post kala-azar dermal leishmaniasis (PKDL)
- * Transmission dynamics through molecular epidemiology studies
- * Studies on persistence of parasite
- * Role of CD-2 antigen in modulation of signal transduction of T-cell activation in kala-azar
- * Biochemical and molecular characterization of SAG responsive and unresponsive isolates
- * Develop epidemic prediction tools through use of GIS and satellite images
- * Efficacy of impregnated bed-nets
- * Social and behavioural studies
- * Clone and characterize stage specific genes in clinical isolates of *Leishmania donovani*, use molecular genetic techniques to develop parasites with an attenuated virulence phenotype with an aim to develop vaccine
- * Genomic micro-assays for identification of specific genes of *L.donovani*, drug screening for kala-azar and PKDL
- * Set up assays with axenic amastigotes grown in a defined medium to facilitate screening of newer drugs
- * Immunohistological studies on skin lesions in PKDL

Infrastructure Development

Rajendra Memorial Research Institute for Medical Sciences, Patna

- * Upgradation and strengthening of patient care capacity to 150 bedded hospital cum research facility.

HIV/AIDS

Budget	Rs in crores
Optimum	10.46
50% step-down	4.08
60% step-down	2.81

Research programme

- * Develop HIV/AIDS vaccines using different approaches

- * Immunological studies to define immunotypes
- * Mucosal immune response
- * Clinico-pathological progression of HIV in various sub-populations
- * Develop cost-effective treatment algorithms
- * Natural history of TB in HIV +ves
- * Evaluate efficacy of vaginal microbicides and female condoms
- * Prevention of HIV transmission in HIV discordant couples
- * Behavioural surveillance
- * Epidemiology of mother to child transmission and assess feasibility of interventions
- * Prevalence and incidence studies using novel methods
- * STD profile in different regions of the country and drug resistance pattern
- * Studies in IDUs.

Infrastructure Development

National AIDS Research Institute, Pune

- * Develop HIV/AIDS vaccines using different approaches
- * Immunological studies to define immunotypes
- * STD profile in different regions of the country and drug resistance pattern
- * HIV-TB
- * Epidemiology, Clinical Research, Prevention Studies, Operational Research
- * Drug Resistance pattern to be done as ongoing surveillance for four years
- * Setup BSL-3 laboratory.

Poliomyelitis

Budget	Rs in crores
Optimum	29.78
50% step-down	11.63
60% step-down	7.99

Research programme

- * Containment of wild poliovirus in laboratories, establishment of BSL-3 facility

- * Characterization of OPV derived poliovirus isolates and other enteroviruses
- * AFP surveillance and environmental monitoring for wild polio virus

Infrastructure Development

Enterovirus Research Centre, Mumbai

- * Construction of new laboratory building
- * Environmental surveillance for wild polio detection
- * Molecular characterization of sabin derived polio virus isolates
- * Characterization of entero viruses
- * Biosafety level 3 containment facility
- * Electron microscope STEM

Research programme for other viral diseases

Japanese encephalitis

- * Develop DNA and peptide based vaccines
- * Ultra-structure aspects of JE virus morphology and intracellular morphogenesis
- * Nucleotide sequencing to understand genetic variability
- * Molecular approaches to identify subspecies of vectors in relation to their vector dynamics
- * Use of novel software's for predictive models

Dengue virus

- * Pathogenesis of dengue to develop therapeutic modalities
- * Factors involved in growth of dengue virus in peripheral blood cells.
- * Develop bed-side diagnostic test.

Hepatitis B

- * Molecular epidemiology study to detect escape mutants
- * Nucleotide sequencing studies for studying intra familial clustering of wild/mutant viruses
- * Improved vaccine

Hepatitis C

- * Genotype distribution
- * Sensitive diagnostic assays

Hepatitis E

- * Identify non-human hosts responsible for maintenance in natural environment
- * Development of HAV plus HEV dual vaccine

Measles

- * Multi-site serologic and virologic studies
- * Create measles strain bank
- * Efficacy of measles vaccine against atypical strains
- * Evaluate measles vaccine efficacy given to children under 9 months of age

Infrastructure Development

National Institute of Virology, Pune

Budget	Rs in crores
Optimum	44.60
50% step-down	17.40
60% step-down	11.95

- * Upgradation of Central Electron Microscopy facility
- * Civil work to be carried out at NIV complex

Microbial Containment Complex, Pune

Budget	Rs in crores
Optimum	107.71
50% step-down	42.00
60% step-down	28.87

- * Establishment of one Biosafety level-4 Containment facility at MCC, Pune

ICMR Virus Unit, Calcutta

Budget	Rs in crores
Optimum	32.15
50% step-down	12.54
60% step-down	8.62

- * Upgradation of the existing facility for research on viral diseases in the region

Centre for Research in Medical Entomology, Madurai

Budget	Rs in crores
Optimum	11.53
50% step-down	4.49
60% step-down	3.09

Leptospirosis

Research programme

- * Understanding the mechanism of pathogenesis
- * Development of rapid diagnostics
- * Characterization of isolates
- * Molecular epidemiology
- * Vaccine development

Epidemiology

Budget	Rs in crores
Optimum	118.53
50% step-down	46.23
60% step-down	31.77

Research programme

- * Training programmes: develop epidemiology as a discipline FETP 2 year course and others
- * Epidemic preparedness and response to emerging re-emerging and new infections.
- * Assist in establishing surveillance programme in various states
- * Molecular and genetic epidemiology studies

Infrastructure Development

National Institute of Epidemiology, Chennai

- * Infrastructure strengthening: construction of new building
- * Human resource: Training course in Epidemiology, Clinical trials, Biostatistics

Biostatistics

Budget	Rs in crores
Optimum	5.33
50% step-down	2.08
60% step-down	1.43

Research programme

- * Statistical techniques in epidemiology
- * Develop mathematical models in communicable disease
- * Establish statistically risk factors and preventive measures associated with non-communicable diseases
- * Develop analytical information system related to health and allied fields
- * Improve survey methodologies
- * Analysis of health and demographic transitions
- * Economic impact studies

Infrastructure Development

Institute for Research in Medical Statistics, New Delhi

- * Construction and equipping of a new building

Tribal Health

Research programme

- * Study of risk factors for life style diseases among tribal and non-tribal population
 - * Health and nutritional status of tribes with special focus on micronutrients
 - * Prevalence and clinical profile, management of haemoglobinopathies including genetic studies
 - * Studies related to communicable diseases using tools of molecular biology
 - * Socio-demographic and socio-economic studies
- (The budget requirement is given under infrastructure development of RMRCs pages 40-42)

NON-COMMUNICABLE DISEASES

Cancer

Budget	Rs in crores
Optimum	30.84
50% step-down	12.03
60% step-down	8.27

Research programme

- * Identification of biomarkers and genetic factors responsible for transformation of pre-cancerous lesions to invasive disease and spread of disease for common cancers, like cervical, oral and breast cancer.
- * Studies on etiological factors and pathogenesis of common cancers of the country, namely those of oral cavity, cervix, breast, gall bladder, stomach, oesophagus, etc.
- * Understanding the role of infectious diseases, especially viruses in etiology of common cancers with special reference to HPV and reproductive tract infections.
- * Design of model for in-vitro cytotoxicity in malignancies, e.g. haematopoietic lymphoid malignancy.
- * Expansion of network of National Cancer Registry Programme.
- * Preparation of cancer atlas for India.
- * Operational research to assist in planning and evaluation National Cancer Control Programme.
- * Chemoprevention and tumour biology

Infrastructure Development

Institute of Cytology and Preventive Oncology, Delhi

- * Clinical complex and associated facilities.
- * Preventive Oncology-setting up of a Field Station.
- * Molecular diagnostic and development of therapeutics and vaccines
- * Molecular Genetic basis of cancer.
- * Bioinformatics
- * Strengthening of research in Cytopathology

Occupational and Environmental Health

Budget	Rs in crores
Optimum	27.90
50% step-down	10.88
60% step-down	7.48

Research programme

- * Use of Molecular Biology to develop tools including biological markers (biomarkers) of exposure, susceptibility
- * Early diagnosis of the toxic effects of a chemical.
- * To identify workers who are more sensitive to adverse effects.
- * Development and standardization of Analytical Techniques for detection of nano-quantity of toxicants
- * Epidemiological studies in occupational and environmental health including silicosis, tobacco workers, agate industry, asbestos and pesticides.
- * Use of Information Technology (IT) and computers in collection of information from various sources and dissemination.

Infrastructure Development

National Institute of Occupational Health, Ahmedabad

- * Control Technology Centre
- * Bio-information Division
- * Poison Information Centre
- * Medical Epidemiology Division for ROHC (S), Bangalore
- * New building for ROHC (S), Bangalore
- * Creation of common hostel facilities for ICMR at ROHC (E), Calcutta
- * Division of Bio-statistics at ROHC (E), Calcutta
- * Strengthening administrative wing of NIOH

Nutrition

Budget	Rs in crores
Optimum	36.57
50% step-down	14.26
60% step-down	9.80

Research programme

Clinical Research

- * Experimental studies on effects of periconceptional maternal nutrition and nutrition during pregnancy on growth of foetus
- * Micronutrient status in pregnancy and its effects on foetal growth.
- * Relationship between low birth weight babies and adult chronic diseases.
- * Role of dietary n-6 and n-3 PUFA in prevention of maternal mortality, morbidity and low birth weight babies.
- * Innovative approaches for nutritional management of LBW and sick new borns.
- * Understand cellular basis of nutrition-infection interaction.
- * Determine effects of malnutrition on immunocompetence and response to newer vaccines.
- * Nutritional needs of adolescent girls, sports personnel.

Basic Research

- * Expand scope of food fortification and micronutrients
- * Functional significance of phytochemicals and role of antioxidants in prevention of diet related chronic diseases.
- * Role of PUFA on gene expression.
- * Nutritional and health significance of quality and quantity of dietary fibre.
- * Pre-clinical toxicological studies of drugs, vaccines and foods.
- * Effect of malnutrition on genetic susceptibility to diseases.
- * Effects of nutritionally stressed environment on host genomic structure and that of pathogens.

Applied Research

- * Community models to achieve reduction in malnutrition.
- * Simple techniques to assess micronutrient status.
- * Over nutrition and chronic diet related disorders vis-à-vis life styles and food habits.

Infrastructure Development

FDIRC, Hyderabad

Infrastructure Development

National Institute of Nutrition, Hyderabad

- * Upgradation of facilities for the conduct of PCT studies Est. a flow cytometry facility
- * Expanding the studies on intrauterine/postnatal malnutrition and Nutritional immunology
- * The status and control of micronutrient malnutrition
- * Establishment of Sports Nutrition Cell.
- * Automating analytical chemistry/Generation of data base/photochemical development of functional foods.
- * Effect of nutrients on gene interactions in aging and chronic disease
 - Cataract
 - Insulin resistance and CVD
 - Progressive cell death, aging and cancer
 - Fetal metabolic programme
 - Expansion of Tissue Culture/Microbiology/Molecular biology Laboratory

Food Toxicity and Safety

Budget	Rs in crores
Optimum	13.24
50% step-down	5.18
60% step-down	3.55

Research programme

- * Develop simple methods to detect toxins and contaminants in food.
- * Toxicological evaluation of routine foods, tribal foods, genetically modified foods, herbal products, dietary supplements and nutraceuticals.
- * Promote Hazard Analysis Critical Control Point approaches for preventing food hazards in preparation of foods.

Laboratory Animal Sciences

Budget	Rs in crores
Optimum	49.11
50% step-down	19.14
60% step-down	13.15

Research programme

- * DNA finger printing of mutant models using micro satellite and AFLP markers.
- * Explore utility of mutant models for understanding molecular and biochemical mechanism of aging, cataract development, infertility, carcinogenesis etc.
- * Obtain and propagate genetically and microbiologically defined stocks of animals.
- * Establish Regional Breeding and Research centers for primates and dogs.
- * Centers for production and propagation of transgenic animal models.
- * Establish centers for developing, validating techniques and in-vitro models as alternatives to animal experiments.

Infrastructure Development

Upgradation of NCLAS

- * Animal production facility and animal feed production facility
- * Human resource development programme
- * Upgradation of Murine Biology lab.
- * Establishing the IEC Centre
- * Construction of library/Conf. Hall

Reproductive Health

Budget	Rs in crores
Optimum	119.89
50% step-down	46.79
60% step-down	32.16

Research programme

- * Fertility regulation: develop improved and new technologies for fertility regulation including emergency contraception.

- * Identify causes of unmet needs for fertility regulation and develop appropriate strategies.
- * Infertility and reproduction disorders: detect causes of infertility and develop better diagnostic methods and management techniques including operationalisation of graded infertility services through health care delivery system.
- * Reproductive tract infections: understand relations of RTI and other disorders.
- * Screening/diagnostic tools for reproductive tract infections and development of algorithms for their early detection, management and prevention.
- * Maternal and child health: ensure that babies are free from consequences of various metabolic and genetic disorders in adulthood.
- * Development and implementation of strategies for preventing avoidable maternal deaths at peripheral level.
- * Unsafe abortions: assess prevalence and associated morbidity and mortality.
- * Improve methods of MTP in 1st and 2nd trimester.
- * Menopause: prevalence of osteoporosis especially in women, criteria for its diagnosis in Indian context and understand mechanism. Prevention and management of post menopausal osteoporosis and genito-urinary dysfunction;
- * Functional genomics: Facilitate identification, characterization and elucidation of functional role of various gene/gene-products in reproductive processes.
- * Child Health: Simple criteria for diagnosis of neonatal sepsis; molecular tools for diagnosis of microbial etiology, home management of neonatal sepsis, testing available interventions for asphyxia and its long term

Infrastructure Development

Institute for Research in Reproduction, Mumbai

- * Preclinical reproductive and genetic toxicology unit
- * Functional /genomics in reproductive health
- * Bio-informatics
- * National Primate Breeding Centre

Haematology

Budget	Rs in crores
Optimum	20.36
50% step-down	7.94
60% step-down	5.46

Research programme

- * Establishment of DNA bank for hereditary haematological disorders
- * Development of umbilical cord haemopoietic stem cell bank
- * Set up stem cell transplant unit
- * Gene therapy
- * Establishment of experimental haematology Unit
- * Clinical trial unit to undertake drug trials to be used in haematological disorders
- * Non-deletional -thalassemia in India

Infrastructure Development

Institute of Immunohaematology, Mumbai

- * Regulation of globin gene expression
- * Perimplantation diagnosis of Thalassemia Syndrome
- * Genetic risk factors for premature CHD and stroke in young
- * Gene therapy in Hemophilia B
- * Cytogenetic and DNA repair study in MDS
- * Concordance between serological and molecular typing strategies for HLA class I and class II antigens
- * Endothelial cell biology.

Pathology

Budget	Rs in crores
Optimum	22.12
50% step-down	8.63
60% step-down	5.93

Research programme

- * Molecular biology with emphasis on development of micro-array technologies for research in infectious diseases and breast cancer.
- * Development of a pre-clinical toxicology referral center for use by organizations involved in new drug development.
- * Development of keratinocyte culture systems for auto grafting in burns patients.
- * Development of trace element laboratory for environmental pollution monitoring.

Infrastructure Development

Institute of Pathology, New Delhi

Infrastructure Development of Regional Medical Research Centres

Regional Medical Research Centre, Port Blair

Budget	Rs in crores
Optimum	8.96
50% step-down	3.49
60% step-down	2.40

- * Strengthening of Regional Medical Research Centre and National Leptospirosis Reference Centre, Port Blair

Regional Medical Research Centre, Bhubaneswar

Budget	Rs in crores
Optimum	11.59
50% step-down	4.52
60% step-down	3.11

- * Lymphatic filariasis, clinico-pathological and immunological perspective in endemic areas of Orissa.
- * Clinical and haematological profile, morbidity pattern and molecular characterization of G6PD deficiency with special reference to G6PD Orissa (44 ala-Gly) among malaria endemic tribal populations of India

- * New strategy and epidemic module for prediction of vector borne diseases using geographic information system and remote sensing
- * Molecular studies on species identification, vector incrimination, susceptibility to insecticide and host parasite interaction
- * Lymphatic filariasis in young children: An immunological perspective
- * Immune response to parasite lipids in Human filariasis
- * Epidemiological investigation alongwith drug sensitivity status *P.falciparum*/*P.vivax* malaria parasites

Regional Medical Research Centre for Tribals, Jabalpur

Budget	Rs in crores
Optimum	31.00
50% step-down	12.08
60% step-down	8.31

- * Laboratory building under construction. New building for the second phase like the auditorium, library block, animal house, hostel and guest house
- * Staff and equipments required for creation of the new departments which has been approved by the SAC Community Medicine, Epidemiology, Clinical Research, Genetics, Microbiology, Parasitology, Virology, Immunology, Pathology, Haematology, Radiation Medicine/Isotope Lab., Nutrition, Biochemistry, Entomology and department of extension and training apart from departments of anthropology, bio-statistics and health economics
- * Staff and equipment required for the following new and ongoing projects:
 - * Genomic diversities among the tribal populations of M.P.
 - * Role of the TNF alpha and TNF alpha promoter variants in the patients with mild and severe *Plasmodium falciparum* malaria
 - * A search of biomarkers in relation to *Plasmodium falciparum* in a malaria hyper endemic tribal population of M.P.

- * Morbidity profile of sickle cell disease and related disorders in Central India A cohort study

Regional Medical Research Centre, Belgaum

Budget	Rs in crores
Optimum	11.45
50% step-down	4.45
60% step-down	3.07

- * Completion of laboratory building and strengthening of staff component and functional capacity

Regional Medical Research Centre, Dibrugarh

Budget	Rs in crores
Optimum	14.37
50% step-down	5.61
60% step-down	3.84

- * Medicinal Chemistry section at RMRC (NE), Dibrugarh
- * Public Health Research/Operational Research cell at RMRC (NE), Dibrugarh
- * Establishment of high technology laboratory set up for Drug abuse and HIV research at RMRC (NE), Dibrugarh
- * Development of molecular biology/ biotechnology at RMRC Dibrugarh

Desert Medicine Research Centre, Jodhpur

Budget	Rs in crores
Optimum	10.24
50% step-down	4.00
60% step-down	2.75

- * Construction of Administrative cum Laboratory building and Guest House
- * Strengthening research on tuberculosis, physiology of desert adaptation, surveillance, urolithiasis, malaria

ICMR Headquarters

Budget	Rs in crores
Optimum	163.79
50% step-down	63.88
60% step-down	43.90

- * Establishment of legal cell
- * Strengthening Finance and Administration Section
- * Setting up Technology Utilization cell
- * Strengthening Hindi Unit
- * Funding of Indian component of Indo-foreign projects
- * Strengthening of the following Technical Divisions at ICMR Hqrs:
 - Epidemiology & Communicable Diseases
 - Non-Communicable Diseases
 - Reproductive Health & Nutrition
 - Indo-Foreign Cell
 - Basic Medical Sciences
 - Medicinal Plant Unit
 - Publication & Informations

(Budgetary details for annual requirements at three levels of funding are given in Appendices 3.1-3.4)

EXTRAMURAL

Communicable Diseases

Budget	Rs in crores
Optimum	145.50
50% step-down	56.75
60% step-down	39.00

Tuberculosis

- * Development of diagnostic kits for early diagnosis and validation of newer diagnostic methods
- * Study of multidrug resistance in TB.
- * To develop effective and shorter duration regimen for treatment of pulmonary and extrapulmonary tuberculosis.
- * Assessment of epidemiological impact of DOTs by assessing ARI and disease surveys.

Leprosy

- * Field trials of various promising newer regimens to consider their incorporation into the programme.
- * Surveillance of drug resistance, role of smears in the follow-up, importance of long term follow-up etc.
- * Molecular approaches for research in diagnosis of neuritic leprosy.
- * Research on reactions/relapses/nerve damage.
- * Assessment of classification into PB/MB based on criteria such as 5 lesions etc. may be done through multicentric studies.
- * Surveillance studies on rifampicin resistance using molecular approaches.
- * Operations aspects related to integration, role of NGOs, studies on predictors, evaluation and testing of epidemiological models to facilitate leprosy programme.

Diarrhoeal Diseases

- * Surveillance programme for the Diarrhoeal Diseases to monitor changing spectrum of enteric pathogens and to identify newer pathogens
- * Development of tools for disease surveillance
- * Development of rapid diagnostic techniques for Diarrhoeal pathogens
- * Studies on Molecular Epidemiology of Enteric Pathogens
- * Drug resistance pattern of enteric pathogens
- * Studies on rotavirus surveillance to estimate the disease burden and to elucidate untypable strains as well as strain variations
- * Impact of micronutrients in management of diarrhoea

Malaria

- * Cost effectiveness studies on various intervention measures.
- * Molecular characterisation of malaria parasites, *P. vivax* and *P. falciparum* with reference to relapses/recrudescence/primary infection, resistance to antimalarials and population genetic structure in different epidemiological situations.

- * Epidemic preparedness and response by developing early warning signals for prediction of outbreaks.
- * Drug resistance and alternative treatment regimens for resistant parasite
- * Vector bionomics and behaviour
- * Social marketing, distribution, community acceptance and evaluation of insecticides impregnated bednets/curtains etc. for personal protection.
- * Health Impact Assessment and Management Information Systems (MIS) and its efficiency.

Filariasis

- * Control/elimination of vector borne diseases with emphasis on filariasis. (Disease burden estimation, diagnosis, prevention, management and control, surveillance and monitoring)
- * Development of newer tools for diagnosis and control of vector borne diseases. (tools for vector control, parasite control, surveillance and morbidity management, molecular/immunological/genetic markers and diagnostics)
- * Epidemiological studies including mapping, stratification and establishing cause and effect relationship using Geographic Information System (GIS) site specific dynamics of infection, transmission and disease and estimation of disease and economic burden.
- * Application of decision making tools, particularly mathematical models for forecasting the trend of infection/disease and predicting the long term impact of intervention and selection of appropriate site specific strategy and duration of intervention(s) (Statistical/Mathematical models, economic evaluations, rapid assessment procedures and mapping, sampling protocols, algorithms for morbidity management, molecular epidemiology, DNA fingerprinting for exposure studies).

Leishmaniasis

- * Initiate molecular epidemiology studies to understand transmission dynamics.
- * Use GIS and satellite images to develop an epidemic prediction tool.
- * Diagnostic tools for early detection of visceral leishmaniasis and post kala-azar dermal leishmaniasis (PKDL)
- * Behavioural surveillance
- * Cloning and characterisation of stage specific genes from clinical isolates of *Leishmania donovani*
- * Identification of specific genes of *L.donovani* using genomic micro-assays
- * Study the biochemical and molecular characteristics of SAG responsive and unresponsive isolates
- * Develop vaccine

HIV/AIDS

- * Natural history studies in HIV infected individuals
- * Identify immunological parameters for pathogenesis, progress and therapy in infection
- * Assessment of impact of intervention in mother to child transmission
- * Development of new products (vaginal microbicides) and evaluation of efficacy of new as well as old products.
- * Drug resistance pattern of the virus in different parts of the country
- * Initiate basic, operational and preventive studies on HIV-TB.
- * Initiate studies on chemoprophylaxis of TB in HIV-TB patients.
- * Development of HIV-AIDS vaccine.
- * Development of combined HIV-TB vaccine
- * Social behavioural studies

Viral Diseases

- * Characterisation of vaccine-induced poliovirus isolates.
- * Host and viral factors associated with different clinical presentations of dengue.
- * Identification of transmission modes of HCV in different parts of India and genome analysis.

- * Hepatitis B & C in tribal communities from India: problem & prevention
- * Role of RSV in causing respiratory infections in different parts of India
- * Studies to understand the pathogenesis of dengue to develop therapeutic modalities
- * Evaluation of efficacy and safety of anti-influenza drugs.
- * Surveillance for acute flacid paralysis.

Tribal Health

- * Studies on Haemoglobinopathies in the Tribal population.
- * Health and Morbidity Profile
- * Study on the causes of childhood mortality and morbidity and prevalence of anaemia and iodine deficiency disorders among the primitive tribes
- * Health and nutritional status of tribes with special focus on micronutrients

Non-communicable Diseases

Budget	Rs in crores
Optimum	117.52
50% step-down	45.84
60% step-down	31.50

Cardiovascular diseases

Preventive cardiology

- * Use of molecular biology techniques to understand patho-physiology of Cardio-Vascular Disease (CVD), identify new targets for drug delivery, cell cycle regulation and apoptosis
- * Development of modules for control of rheumatic fever and rheumatic heart disease
- * Congenital heart diseases : burden and possible etiology
- * Childhood and adolescent CVD : magnitude, risk factors
- * Atherosclerosis : morbidity and mortality data, pathogenesis
- * Hypertension among children

Mental Health

- * Suicide behaviour : descriptive epidemiology, identify contributing factors and process
- * Mental Health care for urban areas
- * Mental stress associated with urban life
- * Depressive disorders : early detection and interventions
- * Acute undifferentiated psychiatric disorders and schizophrenia: etiology, prevalence, factors associated with outcome
- * Mental health consequences of disasters
- * Child and adolescent mental health

Neurosciences

- * Neuroepidemiological studies : prevalence of neurological disorders, clinical and sub-clinical forms, community based services.
- * Epilepsy : especially among women
- * Stroke : risk factors and rehabilitation
- * Dementia and Alzheimers disease
- * Cysticercosis
- * Multiple sclerosis
- * Gullain Barre syndrome
- * Parkinson's disease.

Ophthalmic disorders

- * Glaucoma : prevalence, epidemiology and management.
- * Cataract : identify risk factors at genetic and molecular level ; role of antioxidants ; evaluate results of cataract surgery.
- * Diabetic retinopathy : population based studies, management.
- * Age-related macular degeneration : risk factors, development of low cost vision aids.
- * Corneal diseases : etiology, risk factors.
- * HIV related disorders of eyes.

Diseases of digestive system

- * Crohn's disease and ulcerative colitis: burden, risk factors, association with colo-rectal cancers,
- * Interferon therapy in chronic hepatitis C: causes of non-response.
- * Pancreatic diseases.

Asthma

- * Genomic studies to understand correlation between disease phenotypes and gene polymorphism.
- * Potentiation of allergic asthma by air pollution: role of anti-oxidants, a-tocopherol and ascorbic acid in management.
- * Relationship between various sensitizing factors of allergies and bronchial asthma.

Geriatrics

- * Assessment of nutrition status and requirements among rural and urban elderly
- * Restriction of activities of daily living and effect on quality of life.
- * Management of chronic diseases in elderly.
- * Rational usage of drugs in elderly.

Rehabilitation

- * Disability prevention and Rehabilitation
- * Epidemiology of disabilities
- * Strengthen disability prevention among children
- * Develop interventions to prevent specific disabilities
- * Formulate integrated approach to rehabilitation

Basic Medical Sciences

Budget	Rs in crores
Optimum	113.20
50% step-down	51.95
60% step-down	35.70

- * Research in basic biochemistry and molecular biology of pathogenic organisms with special reference to cloning the genes for vaccine development e.g. *P. falciparum*, *M. tuberculosis*, *M. leprae*
- * Development of nucleic acid probes for early diagnosis and molecular epidemiology of hereditary, acquired and infectious diseases
- * Development of molecular therapeutics
- * Studies on transgenic animals, vectors and knock out animals for understanding mechanisms of host resistance

- * Molecular haematology
- * Production of recombinant proteins
- * Drug Development
- * Development of animal facilities
- * Development of new generation of vaccines
- * Development of DNA based kits for diagnosis of various diseases
- * Diseases susceptibility genes
- * Thalassaemic Control Programme

Human genetics

- * Identification of Indian mutations
- * New disease genes
- * Analysis of genotype-phenotype correlation
- * Study gene-gene, gene-environment interaction to understand heterogeneity of genetic disease
- * Patho-physiology of genetic disease

Traditional Medicine

- * Validation of traditional knowledge
- * Finger printing of selected herbal preparations,
- * Agrotechnology
- * Development of new molecules from plant sources

Medicinal Plants

Budget	Rs in crores
Optimum	16.79
50% step-down	6.56
60% step-down	4.50

- * Establishment of knowledge base/information resource, and development of databases on various aspects related to medicinal plants/plants based drugs/products
- * Integration of leads from ancient knowledge, modern system of medicine and scientific evidence
- * Standards of therapeutically important Indian medicinal plants.
- * Heavy metals and persistent pesticide analysis of medicinal plants

- * Retrieval, analysis and dissemination of information related to medicinal plants, plants based drugs/products
- * Human resource development/strengthening infrastructure and facilities

Reproductive Health & Nutrition

Budget	Rs in crores
Optimum	138.76
50% step-down	54.11
60% step-down	37.19

- * Reproductive tract infections
- * Infertility
- * Adolescent health
- * Psychosocial and behavioural research
- * Osteoporosis
- * Assessment of multiple micronutrient status
- * Low birth weight epidemiology
- * Community based trials of double fortified salts
- * Genetically modified foods

Intellectual Property Rights

Budget	Rs in crores
Optimum	2.24
50% step-down	0.87
60% step-down	0.60

- * Strengthen the IPR-based services to ICMR intramural scientists and for the extramural projects
- * Continue training programmes on patent awareness and technology issues for biomedical scientists with national and international collaboration
- * Expand the scope and expand infrastructure to handle technology transfer issues in-house
- * Initiate studies in respect of current international developments to inform, appraise and advise scientists towards achieving national capability in R&D on indigenous and affordable vaccines, diagnostics and other biologicals

Publication, Information & Communication

Budget	Rs in crores
Optimum	5.63
50% step-down	2.19
60% step-down	1.51

- * Set up IEC Centre at the NIN to evolve strategies for improving health/nutrition status of population
 - * Expand scope of scientometric and R&D evaluation studies
 - * Establish video conferencing facilities
 - * Set up a National Health Research System
 - * Set up Bioinformatics Centre
- (The Budgetary details for extramural research programme requirements at three levels of funding are given in Appendix-4)*

III. Centrally sponsored schemes transferred to ICMR by the Ministry of Health & Family Welfare

1. Diabetes Control Programme
2. Diseases to which SC and ST are generally prone
3. Environmental Health and Risk Assessment
4. National Programme for Control & Treatment of Occupational Diseases
5. Medical Care for remote and marginalized Tribal and Nomadic Communities

IV. Neglected areas in medical research not addressed by other agencies

1. Supporting Extramural research in medical colleges, University, Research Institutions
2. Research capacity strengthening in medical colleges and other institutions
3. Human Resource development for research in medical colleges

HUMAN RESOURCES NEEDED FOR 10TH PLAN

The Indian Council of Medical Research has not been able to get any new posts for almost a decade due to the ban on their creation. Induction of young blood and fresh ideas has been very limited. Rapid developments in modern biology have provided hosts of opportunities, but the Council has not been able to exploit them to the fullest for lack of human resources. Many of the frontiers areas of biomedical sciences could not be adequately attended. Compounding the situation is the advancing average age of ICMR scientists (between 45 and 50 years). The addition of new posts is critical.

Over the couple of years, Memoranda for Expenditure Finance Committee (EFC) and Standing Finance Committee (SFC) for some of new activities have been approved (like that of RMRC, Belgaum, and NARI. During the 10th Plan it is proposed to obtain permission to create staff positions for these activities. An EFC for upgrading and strengthening the patient-care facilities at Rajendra Memorial Research Institute of Medical Sciences, Patna to 150 bedded research-cum-hospital for tropical diseases has already been submitted for consideration of the Govt. of India.

The ICMR has also accepted and adopted recommendations of Chattopadhyya Committee for strengthening libraries of the Institutes/Centres for compiling to these recommendations, too positions would need to be created.

Finally, there have been few long term extramural projects addressing to Health Programmes related issues. Keeping in view their importance and the significant contributions they have made to the programmes, the Governing Body of the ICMR has recommended their permanency. Such projects include the Integrated Disease Vector Control Project, National Nutrition Monitoring Bureaux, Human Reproduction Research Centers, Central Biostatistical Monitoring Bureau, ICMR-NIC Centres for Biomedical Information, Control of JE at Vridhachalam in South Arcot district, Tamil Nadu.

In addition to the above, it is proposed to get additional staff to work in cutting-edge areas of modern biology. The complement of staff for such activities has been worked out on the CSIR pattern of staffing.

Additional staff requirement

	Optimum	50% stepdown	60% stepdown
<i>Recommended for permanency</i>			
Scientific	263	263	263
Technical	674	674	674
Administrative	229	229	229
Sub-Total	1166	1166	1166
<i>Additional staff on pattern of CSIR</i>			
Scientific	502	260	202
Technical	277	162	101
Administrative	198	120	72
Sub-Total	977	542	375
Total	2143	1708	1541

BUDGET REQUIRED

The total funds required during the 10th Plan at different levels of operations are :

Budget	Rs in crores
Optimum	2500
50% step-down	1250
60% step-down	1000

Additional funds would be needed to run the centrally sponsored schemes transferred to ICMR

7

Epilogue

We have dreamt of a changed ICMR. An ICMR equipped, both physically and technically, to respond to the current and future health research needs for next five years. The focus has been to consolidate the gains of infrastructure development and capacity strengthening and to generate and build upon new knowledge to develop new tools and technologies to control diseases and improve health.

What has been given in preceding pages is a bird's view of major achievements during the 9th Plan and the new initiatives taken. The future health trends and emerging technologies have guided the formulation of 10th Plan proposals. The activities of 9th Plan, which would be continued during the 10th Plan, have been identified. Zero based budget approach has been adopted while projecting all activities.

An effort has been made to strike a balance between upstream and downstream research. An array of promising new and emerging technologies would be harnessed and used to find solutions to health issues. At the same time steps would be taken to move technologies from research into action.

It is hoped that adequate resources would be available to seize this opportunity and pave the way for taking research initiatives from the drawing board to the community.

Indian Council of Medical Research

Requirement for Tenth Plan (Rs in crores) at the levels of funding



	Optimum	50% stepdown	60% stepdown
1. Spillover liability			
i Intramural	13.19	13.19	13.19
ii Extramural	3.31	3.31	3.31
iii Capital	61.81	61.81	61.81
Sub-total (a)	78.31	78.31	78.31
2 Critical on-going schemes			
i Intramural	225.00	225.00	225.00
ii Extramural	96.69	96.69	96.69
Sub-total (b)	321.69	321.69	321.69
3 Maximizing benefits			
i Upgradation	84.38	42.19	33.75
ii Moderziation	140.63	70.31	56.25
iii Replacement	56.25	28.13	22.50
Sub-total (c)	281.25	140.63	112.50
4 New schemes			
i Intramural	1259.11	491.10	337.50
ii Extramural	559.63	218.27	150.00
Sub-total (d)	1818.74	709.37	487.50
Total (a+b+c+d)	2499.99	1250.00	1000.00
5 Additional funds required for Centrally sponsored schemes transferred to ICMR (at minimal requirements)			
i Diabetes Control Programme			20.00
ii Diseases to which SC and ST are generally prone			2.00
iii Environmental Health and Risk Assessment			32.00
iv National Programme for Control & Treatment of Occupational Diseases			41.50
v Medical Care for remote and marginalized Tribal and Nomadic Communities			1.61
Sub-Total			97.11
Grand Total			1097.11
6 Additional staff requirement			
6.1 Recommended for permanency			
i Scientific	263	263	263
ii Technical	674	674	674
iii Administrative	229	229	229
Sub-Total (e)	1166	1166	1166
6.2 Additional staff on pattern of CSIR			
i Scientific	502	260	202
ii Technical	277	162	101
iii Administrative	198	120	72
Sub-Total (f)	977	542	375
Total (e+f)	2143	1708	1541

