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FOR

THE ELEVANTH FIVE YEAR PLAN (2007 – 2012)

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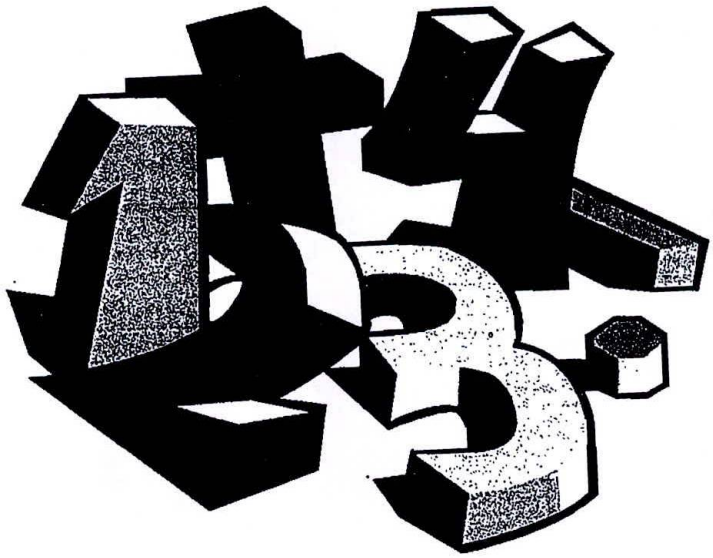
Sl. No.	Title	Pages
1	Report and recommendations of subgroup-I on Health Informatics for the XI Five Year Plan	
2	Report of the working group on Health Systems Research, Biomedical Research & Development and Regulation of Drugs & Therapeutics	
3	Report of the working group on Health Care Financing Including Health Insurance for the 11th Five Year Plan	
4	Report of the working group on Clinical Establishements, Professional Services Regulation and Accreditation of Health Care Infrastructure for the 11th Five-year plan	
5	Report of the working group on Population stabilization for the 11th Five Year Plan	
6		
7		
8		
9		

Report and Recommendations of SubGroup-I on Health Informatics for the XI Five Year Plan



10TH FIVE YEAR PLAN (FYP) – FOCUS

INITIATIVES TAKEN DURING 10TH FYP

MAJOR THRUST AREAS DURING XI FYP

MANPOWER & FINANCIAL REQUIREMENT

Sub-Group --II

(TOR 3) To suggest modification in policies, priorities and programmes during 11th Plan period, New initiatives and strategies such as tele-medicines etc., so to improve quality and coverage of services at affordable cost and also cope with ex isting, re-emerging and new challenges in diseases, emerging problems of non-communicable diseases due to increasing longevity, life style changes and environmental degradation.

(TOR 4) To indicate Manpower requirement and financial outlays required for implementation of these programmes during the 11th Plan period.

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Report & Recommendation of Sub Group – I for XI Five Year Plan

In its first meeting of the Working Group on Health Informatics held on 5.7.2006 under the Chairmanship of DGHS, the sub-group I was constituted with Dr. Arvind Pandey, Director, National Institute of Medical Statistics (NIMS), as the Convener and other members. This sub-group focused on three terms of references (TORs) of the Working Group viz. (i) **to assess the availability and quality of data, their accuracy and reliability and problems in making estimates. Methods for improvement in XI FYP (ii) to review the present Health Management Information System (HMIS), its capability to provide up-to-date information for effective timely response to policy makers & implementing agencies so as to make HMIS an integral part of National Rural Health Mission** and (iii) **to indicate Manpower requirement and financial outlays required for implementation of these programmes during the XI Plan period.**

The sub-group I in its meting held on **17.7.2006** discussed at length the present scenario of the health information, its limitations and inadequacies. It was noted by the sub-group that accurate, relevant and up-to-date information is essential to health service managers if they are to recognize the weaknesses in health service provision and take actions that will improve service delivery. Accordingly, the development of effective information systems is a necessary precursor to managerial improvement. It was observed that a health management information system is a process whereby health data (input) are recorded, stored, retrieved and processed for decision-making (output). Decision making broadly includes managerial aspects such as the planning, organizing and control of health care facilities at the national, state and sub-state levels and clinical aspects which can be subdivided into (i) providing optimal patient care (ii) training of medical personnel to generate appropriate human resources, and (iii) facilitate research and development activities in various fields of medicine.

Subsequently after the **second meeting** of the working group held on 1st August 2006 the chairman expressed his satisfaction about the progress made so far. However, he also suggested both the sub-groups to design their plan in a more focused manner linking with the outcome of the plan. He suggested concretizing and finalising their plan with due inclusion of the manpower and financial requirement for the Eleventh Plan and submit report by 11 August 2006. Accordingly, a meeting of this subgroup was organized on **8.8.06** to review the recommendations and to finalise the report of subgroup – I.

HMIS is an essential management tool for effective functioning of the health system. During the Eighth Plan the Central Bureau of Health Intelligence and the state Bureaus of Health Intelligence developed a HMIS system for sending district level information on morbidity reported by the government primary health care institutions through National Informatics district computer network. Though some states responded initially the system was never fully operationalised in any state. The HMIS system did not take root due to the several inherent deficiencies. The **major problems** faced in the implementation of HMIS were:

a) HMIS proforma requires continuous maintenance of detailed Subcentre Registers, numbering 13, along with the Reporting formats. This involves substantial recurring expenditure for printing of forms and registers. The States/UTs expressed inability to meet the recurring expenditure for printing of forms and registers.

b) Lack of hardware, software and trained personnel at the district and lower levels and the NIC facilities were inadequate to meet computing requirements of HMIS

c) Separate programme wise Information System - required by some users

d) No legal provisions for collecting data from non-government sector.

e) No compulsion at State / UT level to implement the system.

As a result there is no system through which **reliable data** on morbidity in different districts/states could be collected and analyzed and used for decentralized district based planning. So far there has not been any effort to use the currently available IT tools to build up a comprehensive HMIS and use it to improve efficiency and functional status of the health system.

2. 10TH FIVE-YEAR PLAN (2002-07) – FOCUS

During the Tenth Plan the focus was to **ensure** that effective two way management information system is built up throughout the country; all data pertaining to health and family welfare programmes to be collected, collated and reported from all districts and utilized to improve functional status and efficiency of the health system. **Efforts** would also be made to build up a fully functional, accurate HMIS utilizing currently available IT tools; this real time communication link requires to send data on births, deaths, diseases, drugs, diagnostics and equipment and status of ongoing programmes through service channels within existing infrastructure and manpower and funding. It also facilitates **decentralized** district based planning, implementation and monitoring.

The Tenth Plan envisaged a **comprehensive review** of **(a)** disease surveillance programmes which was being implemented in different states under different disease control programmes and under the project on disease surveillance. Private sector provides over 75% of curative care. However, data from private health providers is not yet included in any disease surveillance system, **(b)** laboratory facilities available for investigation of epidemic prone diseases and **(c)** also the reporting systems currently in use. However, health and family welfare issues continued to follow two different pathways which were far from the concept of integration necessary for a unified health information system. Efforts also need to be made to integrate the ongoing programmes for disease surveillance and develop a comprehensive disease surveillance programme at the district level.

Thus tenth five year plan (2002-07) focused on:

- **Building up** a fully functional, accurate Health Management Information System (HMIS) utilizing communication link will send data on births, deaths, diseases, request for drugs, diagnostics and equipment and status of ongoing programmes through service channels within existing infrastructure and manpower and funding; it will also facilitate decentralized district based planning, implementation and monitoring.
- **Building up** an effective system of disease surveillance and response at the district, state and national level as a part of existing health services.

3. INITIATIVES UNDERTAKEN DURING X FIVE YEAR PLAN

3.1 Constitution of National Statistical Commission

The Union Ministry of Statistics & Programme Implementation (MOSPI) during the year 2001 constituted the National Statistical Commission (NSC) under the Chairmanship of Dr. C. Rangarajan which had articulated the deficiencies observed in the health and family welfare statistics. It had **observed** * that as extensive data are being collected by various agencies and compiled, there exist various problems, deficiencies and gaps. The system was not successful on account of non-reporting, under-reporting, variable coverage, delays in receipt of reports, data not being gender-specific and age specific, data not catering to the needs of the general public, etc.

The **major problems** faced in the implementation of HMIS in the past were lack of hardware, software and trained personnel at the district and lower levels. The National Informatics Centre **(NIC)** facilities were inadequate to meet the computing requirements

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* – Report on National Statistical Commission published by M/o SPI 2001

of HMIS. Further, while the information for various programmes is collected separately by the peripheral worker and sent upwards from sub-centre, primary health centre and community health centre to the district and

State levels, there is no coordination between the various health programmes implemented by the several Departments of Ministry of H&FW. Maintenance of patient care records is also very poor in most of the Government hospitals. The information from the private sector is not properly collected and included in the data generated by the official sources. Most of the States have not paid attention to implement the programme due to various reasons including lack of funds and trained manpower resources. As a result the HMIS has failed to achieve the objectives for which it was set up and has not functioned satisfactorily.

Due to **poor implementation** of HMIS by the States, the earlier system of collection of information by various programme authorities has continued to be in existence along with HMIS, which has created an undue burden on the peripheral workers as they have to fill up a number of proforma and maintain a number of records related to various programmes namely, malaria eradication, goitre, immunisation, MCH, family planning, blindness control, tuberculosis, AIDS and leprosy.

The Commission observed that a computerised health information system at all treatment facilities is an essential prerequisite for establishing an effective Health Management Information System. The HMIS has a good potential to provide a comprehensive database on working of health programmes at the decentralised level up to the district. The HMIS if properly implemented would reduce delays in the information flow, provide qualitative information in a standardised form, avoid duplication and facilitate quick retrieval of information by all agencies concerned. Some of the key recommendations of the Commission are:

(a) A comprehensive **assessment** of the Health Management Information System (HMIS) should be made by a small Committee quickly and HMIS be reintroduced in the country in a phased manner with necessary modifications. The combined HMIS format should be separated into programme-wise modules. While revising the programme modules, care should be taken to meet the data requirements of both the Central and State Governments. Flexibility should be given to the States and UTs to include additional items to meet their State specific data requirements.

(b) Steps should be taken to **rationalise and minimise** the number of records and registers maintained by the peripheral health workers such as ANMs and public health inspectors to **reduce their burden** and to improve the quality of data. The minimum data set on which data from the grass root levels should be regularly collected along with their periodicity should be clearly identified.

(c) A suitable **mechanism** to collect the data at the grass roots level and its upward transmission to the district, State and the National level should be evolved and for that methods of data collection, transmission, and processing must be modernised. As NIC facilities are inadequate to meet the requirements of HMIS, adequate funds need to be provided for necessary hardware, software and connectivity and training of personnel.

(d) The Central Bureau of Health Intelligence **(CBHI),** which is at present a part of Directorate General of Health Services (DGHS) should be separated and **upgraded** to a full-fledged Directorate of Health Statistics (DHS) directly under the Department of Health. An officer from the Indian Statistical Service at the Additional Secretary level should head this Directorate and act as the Statistical Adviser to the Ministry. Also required posts of supporting officers should be created. The DHS should be the nodal agency in matters of health statistics and should advise the Department in all matters related to the collection of Health Statistics; coordinate with the National Statistical Office the Central and State Governments as well as international agencies in matters related to health statistics.

(e) The CBHI upgraded as DHS should be strengthened with adequate **Electronic Data Processing (EDP)** personnel and existing personnel should be **trained** in EDP operations, to enable the processing, tabulation and presentation of the large volume of data on health. Adequate funds out of the national health programmes should be earmarked for development and maintenance of information system as well as for verification of field level performance data through independent agencies.

(f) In order to facilitate effective implementation of the HMIS in the States and UTs, the State Department of Health and Family Welfare in every **State should have a Statistical Division** headed by a senior level statistical officer. In the districts, a health statistics cell should be set up in the Office of Chief Medical Officer (CMO) to implement HMIS and to take care of all health and family welfare statistical activities of the district.

3.2 Constitution of a committee by MOHFW/GOI to review HMIS & its recommendation

Accordingly, Union M/o Health & Family Welfare **constituted a Committee*** under the chairmanship of DGHS with 13 members from MOHFW/GOI, CSO, Planning Commission and NIC and Director CBHI as the Member Secretary, with the following **terms of references**:

I. Comprehensive Assessment of HMIS for re-introduction with modifications and schedule of re-introduction in phased manner.

II. Separation of combined format into programme-wise modules.

III. Flexibility of States/UTs to include additional items to meet States specific data requirements.

IV. Setting up of detailed action plan with definite milestones and target dates for implementation of recommendations of National Statistical Commission, keeping in view result of HMIS assessment.

The committee **met twice**, on 5.10.2004 and 2.12.2004 and reviewed the HMIS and its functioning in the country.

Keeping in view of **National Health Policy** (1983) and to achieve the **goal of Health for All** by 2000 AD through Primary Health Care Approach there was a strong need for efficient Management Information & Evaluation System in health sector. As a combined effort of Dte.GHS/MOHFW, State Health Departments, NIC, Planning Commission and WHO (1986-88), the need based HMIS was developed and field-tested in 1989 in one District each of Gujarat, Haryana, Maharashtra and Rajasthan. It was only meant to cover rural health services. In a review meeting during 1989 HMIS found to be satisfactory and merited implementation throughout the country in phased manner. Also it was decided that the system should be given a computer compatible format and to operate the same through **NICNET** in due course. Accordingly the system was made computer compatible by NIC/ CBHI and PHC/District Hospital/Private Hospital Formats were developed **(HMIS version 2.0)** in 1990. **During 1992,** under HMIS Ver. 2.0, NIC/CBHI developed thirteen Sub-Centre Registers, three Model Reporting Formats and Control Charts for PHC & District levels. In all 13 States were included for HMIS Ver. 2.0 implementation and the States were requested to examine the model formats and adapt accordingly to specific needs with minimal set of essential information.

In a review meeting held in **March 1996** it was observed that only two States (Haryana & Sikkim) had implemented HMIS 2.0. This review **recommended** that **(i)** a task force with adequate and appropriate representation from various programme and states be constituted which should inter-alia look into desirability of devising a unified programme by consulting the existing machinery at sub-centes, PHC, District, State and Central level programme officers to

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(*) - Vide Order No. Z – 18021 / 5/2002 – PH(CBHI) dated 31.12.2003

come up with suitable recommendations for changes in the existing formats, **(ii)** since the district NIC facilities are inadequate to meet the computing requirements of HMIS, this set up needs to be suitably strengthened in terms of manpower, equipment and infrastructure, for meeting the HIS requirements, **(iii)** also to make the HMIS more comprehensive and effective, the urban health care system should also be studied, **(iv)** the training programmes required more funding and manpower to make the implementation rapid and effective, and (v) the respective State Governments may consider bringing an Act with a view to formulate guidelines making it obligatory on the part of private sector, Local Self Govt. Departments (LSGD) to provide information related to various health services being rendered by them.

In a subsequent workshop held in **December 1997** on HMIS reviewed the extent of computerization of distt. Chief Medical & Health Officer & their connectivity to NIC-NET. Following important **recommendations** emerged:

i) Computers at NIC district centre are hardly available for entry of HMIS and other health data. It is, therefore, necessary that the requisite hardware with accessories and the latest operating softwares are provided to the District Chief Medical Officer and Directorate of Health Services at State/UT HQrs. with common software.

ii) The trained personnel may be available at district and state level for operation and maintenance of computer hardware and softwares. Each programme should have a component of training in "General awareness to computer, data entry, programming etc." at district and state level. The requisite fund may be kept at the disposal of District Chief Medical Officer and Directorate of Health Services/State Bureau of Health Intelligence at State/UT HQrs. Distt. Programme Manager to ensure data entry in Distt. CMHO office computer.

iii) It was strongly felt that 15% of the total cost of hardware may be earmarked for annual maintenance and a fixed amount in every district may be provided towards purchase of computer consumables and other stationery items. There should be a nodal agency at the national level and also at the state level for all the programmes responsible for drawing funds from different programmes and make available the registers and formats.

iv) HMIS format to be revised to independent programme wise modular formats keeping in view that the modular formats may be uniform over States/UTs and contain gender information and also information by specific age groups wherever applicable.

v) NIC to Centrally Develop Data entry software with flexibility for add on information.

This Committee under the chairmanship of DGHS/GOI after due deliberations observed that over last two decades an appreciable advancements have taken place in the development of health information systems in India, especially National Health Programmes like RNTCP, NVBDCP, NBCP, NLEP, etc. have utilized the modern information technology/software for their information system. The Union Ministry of Health & Family Welfare after due planning has **launched** (November 2004) the World Bank supported Integrated Disease Surveillance Project **(IDSP)** with cost of more than Rs.400 Crores and this projects envisages the further strengthened and efficient health information system from periphery with computer/server facilities at each district and State / UT and with due flexibility to State / UT to incorporate information in the system.

Under this project, **care has been taken** to link all the program specific computers in each district with IDSP server so as to make integration of all health information. With this advancement and commitment by the MOHFW / GOI, there is a **need to integrate** HMIS with IDSP with an appropriately designed information format and indicators at various levels of health care delivery for an appropriate timely corrective measures.

The **final recommendation** of this committee was communicated to M/o Statistics & PI * clearly indicating that "it will be desirable to strengthen this IDSP as a national health information system with appropriate computer connectivity rather than pursuing the HMIS which was conceived about two decades back and could not succeed for various reasons. In the present context, this Union M/o Health & FW is committed to ensure the efficient implementation of IDSP which is one of the major projects undertaken with World Bank loan. This Ministry is also tracking the **information** on financial, logistics, manpower and implementation aspects for ensuring timely corrective appropriate measures I hope this will suffice fulfilling the need of aforesaid recommendation of NSC on the subject matter. Your further suggestion will be appreciated".

3.3 Launch of Integrated Disease Surveillance Project (IDSP)

Integrated Disease Surveillance Project **(IDSP)** is a decentralized, State based Surveillance Program in the country. It is intended to detect early warning signals of impending outbreaks and help initiate an effective response in a timely manner. It is also expected to provide essential data to monitor progress of on-going disease control programme and help allocate health resources more efficiently.

D.O. letter no. Z –18021 / 5/ 2002 – CBHI dated 28.1.2005 from Union Secretary MOHFW to Union Secretary, M/o Statistics & PI.

The **IDSP was launched** by Hon'ble Union Minister of H&FW in November 2004 with following **objectives** to:

i) Establish a decentralized district based system of surveillance for communicable and non-communicable diseases so that timely and effective public health actions can be initiated in response to health challenges in the urban and rural areas while establishing Public private Partnership.

ii) Integrate the existing surveillance activities (to the extent possible without having a negative impact on their activities) so as to avoid duplication and facilitate sharing of information across all disease control programmes and other stake holders, so that valid data are available for decision making at district, state and national levels.

A **brief** on IDSP indicating (a) diseases covered in Regular Surveillance, Sentinel Surveillance, regular Periodic Surveys, State Specific Diseases, (b) Organization Structure, (c) Training of District Surveillance Teams, (d) Procurement of Goods (e) Development of software for diseases surveillance (f) Baseline study on Public Health Laboratories (g) External Quality Assurance System (h) Participation of Private Sector & Medical colleges (i) NCD Risk Factor Surveillance (j) budget allocated and utilized, are enclosed at **Annexure – I.**

3.3.2 IDSP Satellite Communication System

IDSP launched Satellite Linkage on 29th March 2006 with Central studio at National Institute of Communicable Diseases with a sub-hub in Nirman Bhawan and 800 Satellite Interactive Terminals (SITs) located throughout the country would be set up connecting all the State and Districts Units, Medical Colleges and premier state and national public health institutions. For a fully functional network, it is also being considered of intervention of network under National Rural Health Missions and various National Health Programmes. **EDUSAT**, a dedicated educational satellite launched by ISRO is being utilized to set up communication and information network throughout the country. Proposal has been submitted to the World Bank for clearance. This network will be utilized for distance training programmes, teleconferencing and data transmission. Funds have been sanctioned from IDSP Budget for 2005-06 to ISRO to cover 400 SITs by June 06. Remaining 400 SITs would be covered during 2006-07 and covered by December 2006.

3.4 Constitution of National Commission on Macroeconomics and Health (NCMH) by Govt. of India

The NCMH in its **Report*** titled "Building a Health System for Improving Health in India – The Way Forward" **recommended:**

- A National **Institute** of Health Information & Disease Surveillance **needs to be established** as an autonomous body consisting of Board members from other ministries, statisticians, researchers and State-level policy makers. The Institute must also have a multidisciplinary composition comprising economists, public health specialists, epidemiologists, and doctors. Disease burden estimations, National Health Accounts, cost-effectiveness studies of interventions, efficacy of vertically driven interventions including ICDS in countering the problem of malnutrition in the country, independent evaluations of programme implementation are examples of the kind of work that needs to be undertaken.
- There is a **need of reviewing** National health information system at various levels – Central, State, district and block - by various agencies - different ministries and departments in the government – method of data flow, gaps in data, utilization of the data, organizational set up, accessibility of information to various persons at various levels are aspects to be examined.
- Alongwith domestic resources, external aid, WHO assistance etc. be fruitfully utilized for processresearch capacity by earmarking fellowships every year to institutes of excellence abroad and within India. Of the total 25% must be at the doctoral level and the rest at the Master's level. It should be our target to have a pool of atleast 500 persons with a combination of such critical skills by the end of 2012. Such fellowships should be open for competition and not be confined to central government employees of the Ministry of Health. This will help develop capacity and expertise outside government and be available for policy advise in an objective manner.

3.5 Launch of National Rural Health Mission (NRHM) by Govt. of India

Recognizing the importance of Health in the process of economic and social development and improving the quality of life of our citizens, the Government of India has **launched the NRHM in April 2005** to carry out necessary architectural correction in the basic healthcare delivery system. The Mission adopts a synergistic approach by relating Health to determinants of good health viz. of nutrition, sanitation, hygiene and safe drinking water.

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* – Report of National Commission on Macroeconomics and Health – 2005

It also aims at mainstreaming the Indian systems of medicine to facilitate health care. The Plan of Action includes increasing public expenditure on health, reducing regional imbalance in health infrastructure, pooling resources, integration of organizational structures, optimization of health manpower, decentralization and district management of health programmes, community participation and ownership of assets, induction of management and financial personnel into district health system, and operationalising Community Health Centres into functional hospitals meeting India Public Health Standards in each Block of the Country.

The **goal** of the Mission is to **improve** the availability of and access to quality health care by people, especially for those residing in rural areas with specific **objectives:**

- Reduction in Infant Mortality Rate (IMR) and Maternal Mortality Ratio (MMR)
- Universal access to public health services such as Women's health, child health, water, sanitation & hygiene, immunization, and Nutrition.
- Prevention and control of communicable and non-communicable diseases, including locally endemic diseases
- Access to integrated comprehensive primary healthcare
- Population stabilization, gender and demographic balance.
- Revitalize local health traditions and mainstream AYUSH
- Promotion of healthy life styles

The NRHM **seeks to provide** effective healthcare to rural population throughout the country with special focus on 18 states, which have weak public health indicators and/or weak infrastructure. These 18 States are Arunachal Pradesh, Assam, Bihar, Chhattisgarh, Himachal Pradesh, Jharkhand, Jammu & Kashmir, Manipur, Mizoram, Meghalaya, Madhya Pradesh, Nagaland, Orissa, Rajasthan, Sikkim, Tripura, Uttaranchal and Uttar Pradesh.

3.6 Constitution of Task Force on HMIS by Union Ministry of Health & FW

A Task Force on HMIS was constituted by the Ministry of Health & Family Welfare during March, 2006 * under the chairmanship of DGHS with the **TOR's** to:

(a) Suggest a format of reporting from Districts and States that could capture health information required for purposes of planning, monitoring and review.

(b) Suggest the manpower structure at District, State and national levels for a commonly agreed system of data collection, data entry and data analysis.

(c) Agree on the formats of data collection at various levels and its analysis.

(d) Reconfigure the system of statistics and data gathering at the national level to provide for a more effective and efficient internal organization that meets the requirements of States.

(e) Develop illustrative structures of coordination among various health data interventions including IDSP at district and State levels.

(f) Weed out unwanted data collection systems and replace them with a consolidated and comprehensive data system; which can thus satisfied the need.

This task force in its two meetings held till date, viewed the HMIS of different states like Tamil Nadu, Rajasthan, Gujarat and Chattisgarh through their detailed presentations as well as through video conferencing. This **task force is in the process** of deliberation and is expected to come out with its recommendations on the above TORs by end of August 2006.

3.7 In depth Review with all the States/UTs for Improving & Strengthening Health Information System & use of ICD 10 and National Recommendations

In order to ensure electronic data flow and further improve the efficient Health Information System (HIS), CBHI had held **(a)** training workshop of States/UTs for sensitizing them on electronic data transmission, October 2003, and **(b)** followed by four regional workshops with the State/UTs for improving and strengthening the Health Information System during 2002-2004. The **Combined Report & Recommendation** (Annexure-II)** of the above said workshops were communicated to all State/UT health authorities for necessary action. This was **pursued by CBHI** officers who **visited 18 states/UTs** upto peripheral level to make an "on the spot" situation analysis & supportive supervision for efficient HIS. **During 2005**, two national workshops were organized to review the action plan of all the States/UTs to implement the above said national recommendations.

During 2006-07, CBHI has planned with selected states to concretize their District specific action plan to improve & strengthen HIS upto peripheral level, while involving Private Public Partnership and also study for electronic flow of health information from peripheral to district/state/national level.

CBHI undertook a case study of 20 hospitals belonging to Central Govt, State Govt, Local Bodies, Private Sector in cities of Delhi and Rohtak, during years 2004 & 2005 with the objective to identify the status of implementation of ICD 10, the major constraints and their feasible solutions to improve and strengthen the use of ICD 10 as well as medical record department in the country. The important recommendations of the case study are (i) Capacity Building and Trained Manpower development for using ICD 10, (ii) ensuring administrative actions to ensure and improved use of ICD 10 in all medical & health institutions in the country and

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(*) Vide order no. N-23011/13/2006-Policy dated 23.3.2006

(**) Combined Reports & Recommendation published by CBHI in August 2004

(iii) establishment of World Health Organisation Collaborating Centre for Family of International Classifications on Diseases & other Health Related Aspects for South East Asia Region in India, in CBHI.

The Executive summary & major recommendations **(Annexure-III)** * of this case study have been communicated to all States/UTs health authorities & others concerned for prompt implementation.

3.8 Health Sector Policy Reform Options Database (HS-PROD) with website address www.prod-india.com

HS-PROD is a Health Sector Reforms Database. On request of the Donor Coordination Division, MOHFW, GOI; CBHI after getting due approval from Director General of Health Services has allotted a Project of high national importance on "Health Sector Policy Reform Option Database (PROD) of India" which is being supported by European Commission through its Sector Investment Plan (SIP) with an estimated budget provision of Rs.84 lakhs (approx.). Already 152 entries have been uploaded in the website prod.india.com and this site is being brought to MOHFW/GOI through NIC. The brochure detailing on HS-PROD is placed as **Annexure IV.**

4. MAJOR THRUST AREAS SUGGESTED/RECOMMENDED DURING XI FYP

1. While prioritizing Efficient Health Information System (HIS), to begin the States/UTs should strengthen the existing **State/UT health statistics unit** in their respective health & FW directorates with identified nodal officers, trained personnel and computer so as to effectively coordinate for validated health data base & capacity building in State/UT & closely link with CBHI. Subsequently States/UTs to make efforts for establishing a dedicated State/UT Health Statistics Division, equipped with adequate infrastructure. This Division be responsible for efficient HIS, validated health database of the State/UT, monitoring & evaluation as well as capacity building, while keeping close linkages with CBHI and various reporting unit within the State/UT.
2. At district level, Chief Medical & Health Officer is responsible for all health statistical activities under whom the existing **Distt. Health Statistics** cell be strengthened by the States/UTs and efforts be initiated to equip this cell with a dedicated trained officer as its incharge and a Group C staff oriented in computer operation and atleast one computer with accessories. This Distt. Health Information Unit can then coordinate for efficient health information system in the district, including on the spot supervision and related capacity building of PHCs & other Health units in the district.

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* - Report & Recommendations Published by CBHI, 2006..

3. At **PHC/CHC/Dispensary** level, the States/UTs should make efforts to orient & reorient the medical officers and health supervisors towards health data management through continued supportive supervision and wherever necessary through in service training program organized by State/UT, CBHI and other Institutions. A close coordination with all the existing govt./non govt. health institutions in respective jurisdiction will ensure maximum coverage of health & medical data with requisite quality & timeliness.

4. Since ANMs at grass root levels are **heavily loaded** due to their multitasking operations it is necessary to reduce their workload by providing two MPW(F) in each sub-centre as per IPHS requirements. They should be given the responsibility of maintaining registers for all health and family welfare related database. The acute shortfall of MPWs* (64211 out of sanctioned strength of 81561) has been a cause of concern not only to provide basic health services but also to document the quantifiable services as a pivot for health management information system. Similarly there is an **urgent need** on part of all the States/UTs to fill in all the post of MPW (male) at both, Sub-Centre and PHC levels, that will be responsible for collection of health related information.

5. There is a **acute shortage** of CHCs too. To maintain the norm of having one CHC per 1,00,000 population, the present requirement is at least 7415 CHCs, against only 3043 CHCs. Moreover, in the 3,043 CHCs that we *do* have, only 440 have a pediatrician, only 704 have a physician, only 780 have a gynecologist and 781 a surgeon. So not only is the infrastructure inadequate, we don't even have the staff to use the existing infrastructure. Such a large shortfall in medical and paramedical personnel has got an important bearing on the low priority of the documentation of the information, which should on priority basis be attended by all concerned state/UT and central level health authorities.

6. Central & State/UT Governments may bring an **act for compulsory registration** of all *private / non govt. medical institutions and practitioners with the State/UT Government and* mandatory for them to furnish medical/health reports to appropriate Govt. Health Facility in their vicinity.

7. For Monitoring of Information & Evaluation System (MIES) an **integrated format** on different health indicators is being developed under RCH/NRHM with an aim to ensure uniformity in the health information collection system. It is expected that this format will rationalize the information system avoiding the multiplicity of formats, weeding out redundant information and thus leading to qualitative dissemination with varying periodicity

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* Rural Health Bulletin, 2006, MOHFW/GOI

8. In order to maintain **data quality** which is required to be used as inputs for any decision making, the exercise of validation at different levels hardly needs any emphasis. Since NRHM had already initiated the concept of establishing Programme Management Units at state and sub-state levels, their involvement in the validation process should be ensured. In addition, possibilities may also be explored to associate and identify a nodal officer in the district health offices so as to assume the ownership of data being transmitted from the district to the state.

9. What is most important is to remove any underlying apathy to collect the health information and document them with greater speed and accuracy. This can be achieved by putting the right people at the right place having a data sense and data use. The States have got a greater visible role to play to ensure this important aspect of HMIS. To improve the **quality of data,** the grassroots level functionaries need to understand the importance and use of data generated at their level so that the recording and reporting of data by them could be improved. Also, the monitoring system at all levels need to be strengthened and emphasis should be on monitoring of all programmes/components, strengthening feedback mechanism and utilization of data at all levels for monitoring and planning purposes. States/UTs may ensue all measures to **fully utilize the in-service training programs of CBHI** on Health Statistics and Medical Coding (ICD-10) as well as Medical Record Management, being organized for various categories of medical/non-medical staff involved in handling medical/health data, for which purpose CBHI communicates its annual training calendar well in advance to all States/UTs. For this purpose, every State/UT should prepare district wise inventory of such training needs, people trained and remaining to be trained and utilize this inventory for promptly recommending the names of untrained personnel to various CBHI in-service training courses. The **GIS mapping** is an essential tool now-a-days. NIC has already developed GIS maps up to the village level. The facility should be availed by all the State/UT authorities for GIS mapping on various health indicators.

10. The Birth and Death Registration System in the country is still way behind and there is an **urgent need** to improve the system. The Civil Registration System must be improved and strengthened. For this purpose the ASHA, recruited under NRHM can also be utilized for recording & reporting the birth and death cases to the appropriate authority with a suitable honorarium.

11. The **capacity building** of the Health manpower starting from grass root level is extremely essential and allocation of funds for providing the training must be earmarked in this plan period. The training on the electronic data management system should also be provided in association with D/o IT and NIC.

12. **ICD-10 coding system** be implemented throughout the country for comparison at both, national and international levels and the use of ICD-10 be concurrently monitored by hospital administration for timely corrective measures at various levels, including meeting the ICD-10 trained manpower needs.

13. As already decided by the MOHFW/GOI, it will be desirable to strengthen IDSP as a national health information system with appropriate computer connectivity rather than pursuing the HMIS which was conceived about two decades back and could not succeed for various reasons. In the present context, this Union M/o Health & FW is committed to ensure the efficient implementation of IDSP which is one of the major projects undertaken with World Bank loan. Apart from the work on surveillance, also attempt to collect information on financial, logistics, manpower and implementation aspects in the health sector.

14. Like CBHI has developed a central website for health information, the States/UTs may also initiate efforts to develop similar websites along with district specific health information, while utilizing the available expertise of state & districts NIC units.

15. States/UTs may initiate steps towards **computerizing the Hospital Information System** in a phased manner to begin with state/regional level hospitals. This will facilitate efficient hospital database on morbidity & mortality based on ICD-10, essential for District/State/National Statistics on morbidity & mortality. Likewise at the grass root level, on a **pilot basis** the use of Hand Held Electronic Device can be explored in association with the Ministry of Information Technology.

16. A National Institute of Health Information System, as already recommended by NCMH may be considered, for which purpose, CBHI be properly upgraded with necessary supports from public health, statistics and national health programmes to play the role effectively. This institute will also be responsible for Human Resource Development and research studies. NIMS, ICMR may be involved in taking up evolution studies and operation research periodically. The recommendation of National Statistical Commission to upgrade the CBHI as a full fledged Directorate of Health Statistics as a nodal agency to provide sufficient inputs on health statistics should be seriously pursued. The M & E division of the Department of Family Welfare which is responsible for collecting and collating all Family Welfare information including RCH should be merged in the proposed National Institute of Health Information System. Keeping in view the recommendations of NRHM, the synergy between the Health and Family Welfare Information System need to be made and this Institute should be responsible for Monitoring and Evaluation of all health related programme including RCH.

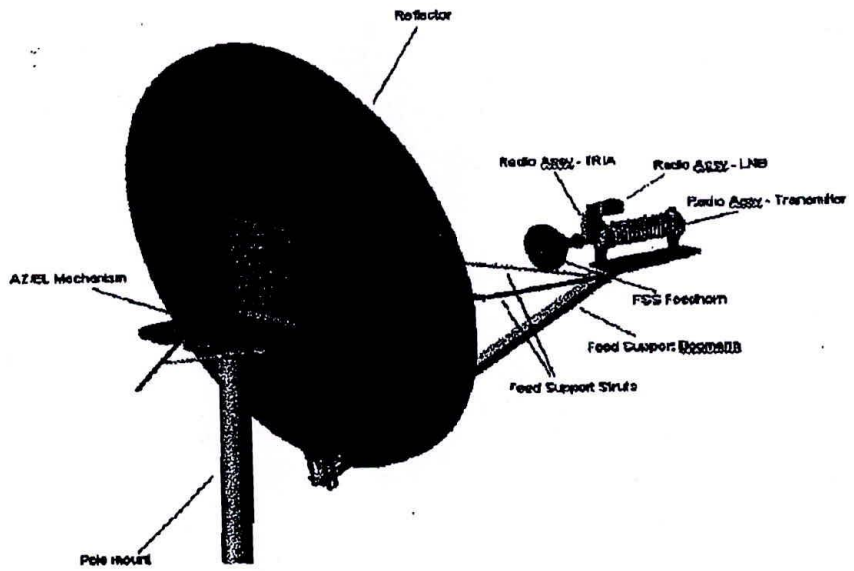
Report and Recommendations

of

SubGroup-II

on Telemedicine

for the XI Five Year Plan



10TH FIVE YEAR PLAN (FYP) – FOCUS

INITIATIVES TAKEN DURING 10TH FYP

MAJOR THRUST AREAS DURING XI FYP

MANPOWER & FINANCIAL REQUIREMENT

REPORT OF SUB-GROUP II

The Working Group on Health Informatics including Telemedicine in its first meeting on 5.7.2006 discussed the terms of reference and time schedule for its functioning. It was decided in this meeting that the terms of reference would be gone into in-depth by two sub-groups separately constituted for the purpose. Sub-group-II was constituted with Mrs Ganga Murthy, Economic Advisor/ MOHFW as Convenor to look into the following TORs: **(i) To suggest modification in policies, priorities and programmes during 11th Plan period, New initiatives and strategies such as tele-medicines etc., so to improve quality and coverage of services at affordable cost and also cope with existing, reemerging and new challenges in diseases, emerging problems of non-communicable diseases due to increasing longevity, life style changes and environmental degradation.(ii) To indicate Manpower requirement and financial outlays required for implementation of these programmes during the 11th Plan period.**

With the area of 32,87,268 Sq km, Population of 1.1 billion, urban-rural divide, inaccessible hilly regions, islands and many tribal areas, India is an ideal setting for telemedicine assisted health care delivery. Growing number of medical, paramedical colleges and schools with lack of adequate infrastructure, learning materials and teachers needs is a matter of grave concern. E health technology has the potential to create a national level GRID which can form the backbone to be shared by healthcare providers, trainers and beneficiaries. A strong fiber backbone and indigenous satellite communication technology in place with large mass of human potential trained in IT and local presence of telepathy industry, e health application and implementation should not be a problem technically. Further a number of pilot projects over last five years with successful outcome stand to its testimony. A ground work on telemedicine in the country has already been laid with the efforts of ISRO and Information Technology department partnering with many State Government and specialty Institutes/hospitals. Policy standardization and infrastructural issues have already been researched. Professional societies on telemedicine/e health have been active. Print and electronic media are participating in awareness campaign. However, a country level plan is long due to steer the Telepathy ship by the Captain (M/o Health & Family Welfare/GOI) with its crew (technology and healthcare providers/educators) and passengers (citizen) in right direction (policy, implementation, application, security, social and legal issues) to reach at the destination (Quality healthcare & wellness).

1. Focus & initiatives on telemedicine During 10th Five Year Plan period

The 10th Plan inter-alia had focused on building up a fully functional accurate health management system, utilizing available IT tools, so as to enable the real time communication link to send data on births, deaths, diseases, requests for drugs, diagnostics and equipment, facilitate decentralized district planning, implementation and monitoring.

A strong formulation for telemedicine in the country has been laid by ISRO and the Department of Information & Technology partnering with many State governments, hospitals and speciality hospitals. Issues of policy, standardization and infrastructure have been delved into by them. Professional societies on telemedicine/ e-health are actively engaged in its development.

Information Technology is now one of the major components of the technological infrastructure for health management. All sub-sectors dealing with the generation, transmission and utilization of demographic and epidemiological data such as bio-informatics, bio-statistics, HMIS and the decision support systems (DSS) are finding increasing use in health planning and management. The nationwide network of NICNET provides rapid reporting mechanism for health information; MEDLARS Biomedical Informatics Programmes provides ready access to medical databases to post graduates and research workers as well as practicing physicians. Planning Commission has provided additional central assistance to the UHSs in Karnataka, Andhra Pradesh, Tamil Nadu, Punjab and Maharashtra for strengthening of libraries and networking them through IT. This effort has to be augmented and all medical colleges need to be brought into the network.

1.1 Indian Space Research Organisation (ISRO)

ISRO has been actively engaged in applying space technology for healthcare and education through specific initiatives which include inter-alia:

(a) Providing telemedicine technology and connectivity between remote/rural hospitals and super-speciality hospital for tele-consultation, treatment and training of doctors and para-medics.

(b) Providing technology and connectivity for continuing medical education between medical colleges and post-medical institutions/hospitals.

(c) Providing technology and connectivity for mobile tele-medicine units for rural health camps in the areas of ophthalmology and community health.

ISRO's experience goes back to more than 2 decades of SatCom Application Programmes namely "Training and Developmental Communication Channel" (TDCC) and "Jhabua Developmental Communication Project" (JDCP) for application of SatCom for rural development. The Telemedicine initiative developed in selected parts of the country during the past 4 years has been one such effort to reach the Speciality Health care to the rural and remote district / trust hospitals. The technology involved the ICT based system consisting of customized medical software integrated with computer hardware along with the medical diagnostic instruments and connected through the telecom medium like ISDN or VSATs at each location. The initial pilot efforts had adopted point-to-point telemedicine system wherein at a given time one rural end could have tele-consultation with one specialist end. The telemedicine software consisted essentially of store and forward modules for tele-radiology, tele-cardiology and tele-pathology purposes alongwith video-conferencing facility.

With the growing demands of telemedicine facility by various States, "point-to-multipoint" connectivity through Local Area Network (LAN) and finally "multi point" to "multi point" connectivity with Wide Area Network (WAN) with integration of the facility for Continuing Medical Education requirement have been evolved and established. ISRO has constantly been upgrading the technology with a view of bringing down the cost both for the ICT hardware and software. Over more than 1,00,000 patients have been treated in the ISRO network including the Army network, Mobile Tele-Ophthalmology for rural eye camps, telemedicine services for special situations catering to the large pilgrim population etc. The aspects of development of business model and also the involvement of medical insurance scheme is getting evolved gradually.

1.2 Department of IT, Ministry of Information and Technology

As with ISRO, the DIT has also started tele-medicine projects in different parts of the country. DIT by acting as facilitator has taken initiatives for development of technology, launching of pilot schemes and standardization of tele-medicine in the country. Some of the achievements of DIT in this regard include:

(a) Development of tele-medicine software systems. Under the ongoing C-DAC project, technology developed has been used for connecting 3 premier institutions namely SGPGI, Lucknow, AIIMS, New Delhi and PGIMER, Chandigarh using ISDM connectivity.

(b) Tele-medicine for diagnosis and monitoring of tropical diseases has been implemented in West Bengal.

(c) An oncology network for providing tele-medicine services in cancer detection, treatment, pain relief, patient follow-up and continuity of care in peripheral hospitals of RCCs has been established.

(d) Development of State-wise telemedicine network based on terrestrial communication in the State of Himachal Pradesh.

1.3 Private Sector

A number of initiatives in tele-medicine have been made in the private sector, SGPIMS, Apollo Hospitals, Asia Heart Foundation, Escorts and others are presently engaged in extending consultations through tele-medicine and are conducting regular tele-education, tele-consultation and tele follow-up sessions with patients.

1.4 Initiatives by State Governments

State-wise location & progress of telemedicine projects is at **Annexure-III.** Several States have also come up with their own initiatives with the usage of information technology. A drug inventory monitoring and control system has been evolved in Haryana. The med-centre of Haryana is an integrated software project to capture utilization of medicine inventory data and analysis consumption pattern of various medicines location-wise to monitor disease occurrence pattern, pilferages and any other deviation in the functioning of the health institutions. The initiative of personal digital assistant provided to auxiliary mid-wife in Nalgonda district of Andhra Pradesh is another illustration in point. Through this device, ANMs could record patient information directly on the PBAs which enable them to follow up cases, whether of pregnant women for ante-natal care or of children for immunization. In electronic format, this data can be also transmitted to higher administrative levels. (Advantages of better targeting the beneficiaries for ante-natal care and immunization and identification of high risk population in terms of illness). The tele-doc initiative of the JIVA Institute provides for field health representatives in villages transmitting health information on mobile phones to doctors who then diagnose and prescribe treatments according to which medicines are supplied.

2. Need for strengthening telemedicine / e-health initiatives in India

Despite the massive public health infrastructure, **healthcare in rural areas remains a critical challenge**. The magnitude of healthcare services required in the context of the existing shortage of medical officers and trained para-medics clearly demonstrate the need for strengthening tele-medicine and other e-health initiatives over the next Plan. The National Rural Health Mission provides an opportunity for taking tele-medicine to the healthcare facilities at the primary, secondary and tertiary levels of care. Computerization of health related data would be an essential first step.

With the establishment of about **300 Telemedicine** nodes by Govt. / Private / Trust agencies of which 175 nodes by ISRO all over the country and the experiences gained by each of the implementation agencies have brought to bear some of the important issues that needs to be addressed for future implementation strategies for the development of telemedicine and e-health for augmenting the present healthcare delivery system in the country.

Internet and mobile communication can enormously enhance connectivity between grass-root health worker and medical specialists as well as translation and storage of data from the field through the Centralized units.

Telemedicine aims at equal access to medical expertise irrespective of the geographical location of the person in need. Recent developments in Information and Communication Technologies (ICT) have enabled the transmission of medical images in sufficiently high quality that allows for a reliable diagnosis to be determined by the expert at the receiving site.

Access to many different sources of medical data, usually geographically distributed, and the availability of computer based tools that can extract the knowledge from that data are key requirements for providing a standard healthcare provision of high quality.

Developments in the integration of bio-medical knowledge, advances in imaging, new computational tools and the use of these technologies in diagnosis and treatment suggest that Grid-based systems can make a significant contribution to this goal. In addition to enhancement of improved access by integration of information, the benefits are raised to a new level, over a Grid because of multi dimensional access to the information.

Medical informatics is often called healthcare informatics or biomedical informatics, and forms part of the wider domain of e-Health. Medical informatics optimises the computer analysis, storage, retrieval and transfer of patient and other health care data.

3. Lessons Learnt during X Five year Plan:

- Lack of IT infrastructure in the state governments health administration and the district/taluk hospital.
- Non- acceptability of telemedicine/e governance by doctors, patients and the associated staff due to certain "fear of the unknown" and "fear of loss of opportunity" which has retarded the speed with which the facility could be established.
- The administrative and financial constraints by the State Health Administration for supporting the implementation of telemedicine at the District Hospitals.
- Lack of requisite infrastructure and financial support for establishment of the facility.
- The cost of the equipments though progressively brought down considerably, is still expensive for most of the hospitals and the Government establishments.
- The communication bandwidth cost, presently provided by ISRO's satellites free of charge whereas others like BSNL and Private Agencies are charged which is expensive for most of the Hospitals, Health Centre and even Super Specialty Hospitals.
- Need for enhanced public awareness of the advantages of Telemedicine / Tele-health for medical consultations, treatment and postoperative follow-up.
- The present Healthcare delivery system in each state has detailed procedures established long time ago in terms of Medical Administration and practice covering diagnosis, treatment, drug prescription and distribution, surgery and follow-up, Continuing Medical Education and Training of Doctors and Paramedics etc., and they have certain policy and operational guidelines. This requires to be extended or additionally enunciated for appropriate implementing the technology based healthcare delivery system of telemedicine / tele-health.
- The policy aspects related to availability and utilization of information which constitute medical Information and Communication Technologies (ICT) which constitute the connectivity need to be integrated with the healthcare delivery system effectively.

4. MOHFW/GOI has constituted task force vide order no. T 2105/1/2004-NCD in September 2005 on Tele-Medicine in India for formulation of strategies regarding its

applications in Health Sector under the chairmanship of Secretary, Health & Family Welfare with the following **TORs:**

1. To work on inter-operability – Standards for data transmission; software, hardware, training etc.
2. To define a National telemedicine Grid and consider its standards and operational aspects. (The task force needs to consider connectivities to be provided in the next two-three years, as currently there is certain ad-hocism in this process. Available bandwidth etc. has to be most efficiently used for obtaining priority connectivites).
3. To identify all players and projects currently involved in telemedicine in India and evaluate their performance, capacity and replicabilty.
4. To prepare pilot projects for connection of super speciality hospitals/ medical colleges with district hospitals and /or CHCs / PHCs specially keeping in the mind to provide access to remote areas. (The focus would be North-East, J&K, three new States, other tribal areas and Lakshdeep).
5. To prepare National Cancer Telemedicine Network.
6. To examine possibility of utilization of stand alone centers of the deptt. Of communication in rural areas.
7. To define standards and structures of electronic medical records and patient data base which could be accessed on a National telemedicine Grid. For this purpose, the national task force may constitute sub committees for developing electronic medical records in various fields.
8. To enable the telemedicine centers in teaching institutions to impart training to all govt. medical/Dental/Nursing Colleges in 3 years time (as there is a huge shortage of teaching faculty).
9. To prepare curriculum and projects for CMEs through telemedicine.
10. To draft a National Policy on 'Telemedicine and Telemedical Education and to prepare a central scheme for the 11^{th} plan.

Five subgroups have been formed to look into different matters:

Subgroup I: On Telemedicine Standards.

Subgroup II: For formation of National Telemedicine Grid.

Subgroup III-A: To identify players and framing evaluation framework for projects involved in Telemedicine in India, prepare pilot projects (pending proposals, mobile services, national medical Colleges network etc.) (TOR 3&4).

Subgroup III-B: For ONCONET INDIA (TOR 5).

Subgroup IV: For utilization of existing tele linkage facility in rural areas by Department of Communication, Standardisation of e-records, training and CMEs in telemedicine, human resources- medical informatics.

Subgroup V: For preparation of National Policy on Telemedicine and to prepare central scheme for 11th FYP.

5. Initiatives Needed on telemedicine During XI Five Year Plan:

All these aspects will need to be carefully addressed in the XI Plan. The action plan would need to take into account the following:

- A massive **awareness** programme to the public, doctors and the hospitals staff – about the benefits of telemedicine & e-health and its efficacy.
- A proper **inter-departmental** coordination and cooperation to ensure adequate support to the doctors and hospitals for commissioning, operation and maintenance of the facility.
- A **cost effective** business model by which the system can be made self sustainable over a period of time.
- Effort by the concerned Industries to ensure availability of the equipments and facilities at reasonable and affordable costs.
- Aspects of drugs distribution at the remote hospitals when provided with teleconsultation/treatment by speciality hospitals.
- **Social aspects** of telemedicine covering the licensing aspects of medical practitioners / agencies including the legal aspects.
- Aspects of **private, public partnership** for delivery of health care to the rural and semi-urban population.
- An appropriate policy by Government of India to provide bandwidth at affordable cost.
- Aspects of **Continuing Medical Education & Training** for Doctors, Paramedics and Health care workers in the form of separate network.

- **Referral hierarchy** for medical treatment, disease prevention and health promotion aspects.
- Introduction of **academic courses** on all aspects of Telemedicine / Medical information in various Engineering and Medical Institutions.

5.1 The **National Task Force** is recommending a national telemedicine grid which will contain the following major functions / constituents. The Task Force is already looking into the connectivity, hardware, software requirements for projection under the 11th Five Year Plan which could be incorporated in the Report of the Health Informatics Working Group. Essentially the following is already under consideration of the Task Force:

a. A health portal at the M/o H&FW providing all information related to health informatics, telemedicine, disease surveillance data, medical care details and other educational material or information related to specific Indian healthcare system not available in the internet or hyper link to the internet data repository. This portal will be a constituent of the national grid for repository of information and guidance.

b. An All India Medical Institution network connecting the various recognised medical institution, national institutes like PGMER, AIIMS, JIPMER, SGPGI etc., and major super speciality hospitals (Govt. & Private) in the country for medical education, exchange of knowledge, CME etc.

c. An All India Network connecting the various selected district hospitals in the country to be connected to major super speciality hospitals (Govt. /Trust/ Private) for specialist referrals for consultation and treatment and also medical informatics, disease information and health promotion aspects from different states of the country. (super speciality hospital network).

d. A national network for medical training connecting various agencies in the country and also establish/integrate similar networks at state levels. (National Medical Training Network).

5.2 State Telemedicine/e-Health Grids (STG)

As a part of e-health program and digitalisation of health records some of the states have been operating Telemedicine Networks initiated by ISRO and other agencies like Department of Information Technology (DIT) under Closed Usage Group (CUG) concept e.g. Chhattisgarh, Karnataka, and Kerala. Many more states are planning to implement such state level networks. There is a need to formalise the state Telemedicine networks into standard State Grids for specific purposes of application and usage like; providing State Health Information, Monitoring and Surveillance of Disease/Epidemic outbreak, identification and mapping susceptible areas and population etc., as mandated by MoH&FW for health governance.

5.3 National Medical Education Institutions Network (NMEIN)

A National Medical Education Institutions Network if created would act as a useful resource base for knowledge sharing for Medical Education, Research and training including CME. The teaching and practical sessions can be configured in live or recorded video, audio and information data broadcast, accessed on the grid, for an effective learning experience.

5.4 Association / Society / Health portals Network (ASHPN)

Several associations/agencies are hosting and maintaining diverse health portals like DOCTORYANYWHERE.COM in health care services.

It is necessary to pool the resources available with the various autonomous/government/trust medical associations like Indian Medical Association (IMA), Cardiology Society of India (CSI), Neurological Society of India (NSI), Federation of Gynaecological and Obstetrics Society of India (FoGSI) etc and form an Association/society /health portals Network.

5.5 Digital Library & Medical Informatics Network (DLMIN)

It is required to establish a Digital Library & Medical Informatics Network, that will be a network of pooled information in the form of digital library of data bases and Medical/Health Information that can be accessed through Internet / Intranet and used for administrative/research and / or clinical purposes.

Some of databases of immediate value would include, but not limited to:

1. Manuals of illness, diseases, symptoms, and diagnostic tools.
2. National registry of speciality hospitals and specialists: names, contact information.
3. Health education programs and curricular materials.
4. Medicines: description, side effects, location, costs.
5. Online journals, abstracts, preprints.
6. Environmental profiles by state/region
   - (a) Locations of safe water supplies.
   - (b) Location of polluted sources (symptoms and treatment).
   - (c) Location of emergency food supplies.
   - (d) Location and description of health services.
   - (e) Location of disease outbreaks.
   - (f) Changing environments.

5.6 Disaster Management Support Network (DMSN)

It is required that the health care services in times of disaster can be effectively provided through establishment of Disaster Management Support (DMS) Network. This network is required to integrate identified disaster Monitoring Stations (current and proposed) across the country and provide periodic and timely information both statistical and remedial to the central station for necessary advice/action through the power of medical informatics and digital connectivity.

Capacity building: Thrust of health informatics education should be use of health information standards, storage of health information in electronic health records and research and extra collation of health information for better healthcare. Clinicians, healthcare managers, technologists, researchers would all need to specialize in various aspects of healthcare technologies. The course for skill development to include, certificate course in computer application, education framework for general, para-medical and nursing staff. These course would need to be certified by Medical Council of India.

6. Major thrust areas for 11th Five Year Plan

Focus in the XI Plan should be on:

- Establishment of e-Health department in M/o H&FW in states D/o H&FW with support of state IT Department.
- Computerisation of health care delivery system and health records at state, institutions, district and taluk / block level for the flow of information over the network.
- Computerisation of three tier healthcare system: CHC/PHC & SC.
- To acquire and implement IT equipments like servers and client systems, multicast video conferencing facilities, data storage and archival facilities in all the speciality hospitals, medical institutions and other centres of excellence who will be providing teaching and training facility.
- To identify agencies within the medical institutions / speciality hospitals / research institutions to develop content for medical education / CME / training modules.
- To acquire and implement terrestrial / wireless / satcom technologies required for various connectivities from taluk / block to district to the state capital.

- To plan for one dedicated medium weight class Communication satellite (HEALTHSAT) for satcom based connectivity which will have the capability to meet the broadband connectivity requirements for various applications of the National Grid.
- The cost of HEALTHSAT with launch, operations and maintenance of the satellite is around Rs.400 crores. Apart from this, the various connectivity charges by other technologies have to be incorporated. The present cost of a standard telemedicine node including computer hardware/software and video conferencing system is around Rs.4.0 lakhs at the district hospital level. Whereas at the CHC / PHC level the cost will be around Rs.1 to1.5 lakhs. . Hence number of nodes which will come up during the 11th Five Year Plan upto the block level may have to be worked out.
- All tele-medicine network should evolve around a National tele-medicine grid. Ultimately, every individual would need to have a unique ID.
- Formal specific training programmes in tele-health for all levels (grass-root to policy makers depending on requirements) and facilitate a support system to provide current information to doctors in the management of patients through new data bases, software packages etc.
- Medical Council of India to include Information Technology in healthcare in the curriculum of all medical and para-medical degree courses. Information Technology to be also included in all IT and MBA courses.
- Introduce at least one mobile van in each district.
- Trauma care, ambulance on National Highways to be provided with technology for transmitting audio-video images using EDGE, GPRS, MMS etc. Pilot studies using tele-medicine and ambulances would be required.
- Setting up of a Tele -health Corporation of India. Given the highly specialized and technical nature of tele-medicine, a Tele-medicine Board of India needs to be established under the aegis of the Ministry, which will include a set of technical experts with representatives from major healthcare organizations and NGOs working for tele-medicine. The basic objective of this Board would be to oversee the growth of tele-medicine, develop R&D tools, provide software, manage the National tele-medicine grid and interact with international organizations.
- E prescriptions at all levels by the end of XII Plan but to cover atleast PHCs and above during the XI Plan. This will necessitate availability of computers and net facility at all healthcare facility.

- Minimum standards of treatment to be documented and made available on the Ministry of Health website. Details should be available regarding new drugs, banned drugs, new indications, list of essential drugs, adverse effects, standard treatment protocol, drugs of choice etc. Skill, knowledge and care should be the corner stone of what we strive for.
- Magnitude of care may vary at different levels but the standard of care to remain the same. This will be possible once the standard treatment protocols are available and will help in identifying the kind and nature of drugs to be placed at each level and the financial requirements for making available these drugs at different health facilities.
- **Synergy amongst all existing initiatives and programmes between different Departments/Ministries in the area of health:**
    - TCI network being created under Department of IT.
    - North-Eastern Council initiatives with support from ISRO.
    - E-governance initiatives like common service centres under Department of IT.
    - Integration of existing infrastructure like CBHI, IDSP, NICD etc. in the Ministry of Health & F.W. to have proper synergy between them and avoid duplicacy in data collection, compilation and transmission.
    - Proposed Tele-medicine project by Delhi Government.
    - Any other State initiative/Central project which will cater to health needs and requirements.

Tele-medicine would require minimum bandwidth connectivity which facilitates video-conferencing, image, x-ray, medical transcription etc.

7. Financial and Manpower requirements

Tele-medicine/Health Information Unit upto the District level

The objectives of this would be to facilitate proper data collection, compilation, storage and facilitate analysis and flow of information. The end objective would be to create the basic foundation structure and build in future the Tele-medicine grid and take on e-governance activities.

7.1 Total number of units to be covered under telemedicine programme

Sl. No.	ITEMS	Total
1	District Hospitals	604 (As per NIC website)
2	Government Medical Colleges	115 (Only Govt. Medical College excluding Trusts, Societies, Pvt.)
3	State Headquarters	36 (Jammu & Kashmir has twoseparate Division).
4	Total	755

7.2. Manpower required and financial Implication

Sl. No.	Items	Expenditure	Total cost in a yea
1	1 Supervisor	Rs.10,.000 per month	9.06 Crore
2	1 Data Entry Operator	Rs.6500 per month	5.90 Crore
3	**Total for the annual Plan**	**Rs.16, 500 per month**	**15 Crores**
4.	**Provision for XIth five year plan:**		**80 Cr**

(a) Equipments

Sl. No.	ITEMS	Total Cost
1	Financial assistance for equipments @ Rs.10 lakh each unit f units	Rs. 75.5 Crs.
2	Maintenance @Rs. 2 lakh per annum/unit X 5 years for 755 un	Rs.75.5 Crs.
	Total	**Rs. 151 Crs.**

This can be provided in a phased manner (in three years) with a provision of Rs. 50 Crores in annual plan 2007-08, 2008-09 and Rs. 51 Crore in 2009-10

(b) Cost of Computerization at PHC level:

Sl. No.	ITEMS	Total Cost
1.	Computer with 5 years on-site maintenance with spares & trainir @ Rs.35, 000 per PHC per annum X 23109 (PHC).	**Rs. 80.90 crores**

This also can be provided in a phased manner (in two years) with a provision of Rs. 40 Crores in annual plan 2007-08 and Rs. 41 Crore in 2008-09.

(c) Health Channel

There should be one dedicated Health Channel from Doordarshan. It should cover the areas like Education to UG, PG and Post PG Courses; Education to medical practitioners; Consultations; News at certain intervals; National programmes, disease forecast, helpline one hour a day, live OPD etc. It should be made mandatory to all cable operators to beam this channel.

- 30 minutes programme
- 12 hours per day
- 30 days every month
- 30 X 24 = 720 programmes per month
- Total cost per month = 720 X 2 lakhs = Rs. 14.40 crores
- Total cost per year = Rs. 14.40 X 12 = Rs. 172 crores
- Software development of programme can be for **Rs. 100 crores** instead of Rs. 172 cores
- Also equipments = **25 Crores**
- Total cost in the entire plan period = 125 Crores (Entire expenditure to be taken during the first year of the Plan period)

7.3 Other Expenditure

7.3.1 Digital ECG Machine at District hospitals Rs. 20,000 X 604 Hospitals = 1.2 Crore

7.3.2 Web-site and Content Development = Rs. 5 crores

There should be a national health website covering various aspects like Standard Treatment Protocols, links to various health related website etc.

7.4 GRAND TOTAL: Rs. 443.2 Crores – for the entire Five Year Plan

Year wise Annual Plan requirement

Year	2007-08	2008-09	2009-10	2010-11	2011-12	Total
Amount Rs.in Crores	236.2	108.0	67.0	16.0	16.0	443.2

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WG:

REPORT OF THE WORKING GROUP ON HEALTH SYSTEMS RESEARCH, BIOMEDICAL RESEARCH & DEVELOPMENT AND REGULATION OF DRUGS & THERAPEUTICS

11th FIVE YEAR PLAN (2007–2012)

सत्यमेव जयते

GOVERNMENT OF INDIA
PLANNING COMMISSION
September-2006

CONTENTS

	Preface	i
	Executive Summary	ii
1.	**Introduction**	1
2.	**Biomedical Research : Current scenario and future projections**	11
3.	**Product Development and Evaluation**	32
4.	**Inter-agency Collaboration and Translating Research into action**	50
5.	**Human Resources Development for Health and Biomedical Research**	54
6.	**Biomedical Research Information Technology**	58
	Bibliography	68
	Annexure	69

Preface

The Planning Commission had constituted a Working Group on Health Systems Research, Biomedical Research and Development and Regulation of Drugs and Therapeutics for the 11th Five Year Plan vide its order No.2(11)/2006-H&FW of 25th May, 2006 (copy placed as Annexure). The Director-General of the Indian Council of Medical Research was named the Chairman with 21 other members.

The membership included representatives of various Departments (CSIR, Health & Family Welfare, Science & Technology, Biotechnology, and AYUSH) Directors of relevant Institutes (Central Drug Research Institute and Industrial Toxicology Research Centre, Lucknow; Indian Institute of Health Systems, Hyderabad, Indian Institute of Technology, Chennai, Indian Institute of Science, Bangalore) Drugs Controller General of India, eminent scientists (Dr. Ranjit Roy Choudhary, Dr. Somnath Roy, Dr. Y. Atal), representative NGOs (Voluntary Health Association of India, Centre for Equity into Health & Allied Themes) and officials from Planning Commission and Ministry of Finance.

Dr.Gerald Keusch, Director, Global Health Initiative, Boston University, who was a member of the Performance Appraisal Board (PAB) of the ICMR, was in New Delhi during one of the meetings of the Working Group. He was also invited to interact with the members.

The Chairman had co-opted Prof. Indira Chakroborty, Director, All India Institute of Hygiene and Public Health, Kolkata and scientists/officials from the ICMR for their inputs in view of their experience and expertise (Dr. A. Pandey, Director, National Institute of Medical Statistics; Dr. Bela Shah, Sr. Dy. Director General, Division of Non-Communicable Diseases; Dr. V. Muthuswamy, Sr. Dy. Director General, Division of Basic Medical Sciences; Dr. D. Mukherjee, Chief, Division of Epidemiology; Dr. K.K. Singh, Chief, Manpower Development and Dr. Malabika Roy, Coordinator, Division of Reproductive Health and Nutrition).

The Working Group met twice. In the first meeting, the members deliberated on the *modus operandi* and offered suggestions. They agreed to provide their own and/or their parent organization's inputs on each Term of Reference. Based on these, a draft report was prepared and circulated to the members. The second meeting was taken by the Chairman to finalize the report.

This report is the outcome of invaluable contributions provided by the members.⊡

Health of a country depends to a large extent on the quality and reach of the health system as well as the support provided by the health research system to respond to the health challenges. With the development and use of sophisticated tools of modern biology, a better understanding of complex interplay between the host, agent and environment is emerging. This is resulting in the generation of new knowledge. One of the greatest challenges that the health community faces today is to find means of bridging this *know-do* gap. This scientific knowledge is to be used to develop drugs, diagnostics, devices, and vaccines which should find a place in the health systems of the country. A vibrant inter-phase between the research community, the industry and the health systems is the only way to facilitate this.

In order to make meaningful suggestions and recommendations for the 11th Plan period on the areas identified in the Terms of Reference, it is prudent to look at the existing scenario, the lacunae therein, and the future challenges. From this would emerge the areas that need strengthening as well as the new initiatives required. The Reports of the National Commission on Health and Macroeconomics, the Performance Appraisal Board of the ICMR, and several other national and international publications were reviewed.

As a result of the advances made by the country in various fields, the health of the common man has improved but it could have been better. It is not only the technological advances in public health and medicine that influence health of the population. The epidemiology of disease extends beyond biology. A sociological perspective is important to understand the occurrence, persistence and cure of a disease. The diseases are not rooted in biological causes above, but are multifactorial. This calls for an inter-disciplinary approach to health research. The 11th Plan, therefore, should mark a departure in its orientation. No amount of pure bio-medical research will be able to find solutions to health issues unless it addresses upfront the social determinants of health.

1. The absence of a national health research policy, weak health research system, neglect of health systems research, inadequate capacity to plan and implement, lax monitoring and evaluation system, priority setting not done on accepted scientific principles, inadequate budget for health and in turn for health research, narrow research base in medical colleges and other institutes, lack of policy, plan or management of human resource development for health research, neglect of translational research, and not-so-strong inter-agency collaborations all have contributed to the current state. Many of these factors have been repeatedly highlighted in reports of various committees the latest one being that of the National Commission for Health and Macroeconomics.

Several of these factors would be addressed once the decision of the Ministry of Health & Family Welfare to create a new Department of Health Research within the Ministry is implemented. This decision has been hailed as one of the most significant steps the Government is taking to elevate health research to centre stage of health promotion and care. It is hoped that with this initiative health research would be able to contribute effectively towards country's economic and human development.

Each agency involved in health research has worked out a detailed plan of activities for the 11th Plan period which they would submit to their respective Ministries. Some important cross-cutting generic issues which need attention are:

- enunciate National Health Research Policy
- develop a National Health Research System
- formulate a National Health Research Plan
- attach high priority to Health Systems Research
- inculcate a culture of research in medical colleges and other institutes by providing opportunities to participate in capacity building and infrastructure development programmes
- promote good governance of health research
- Strengthen partnerships at all levels-local, regional, national and international among all the stakeholders.
- identify current and future needs of human resources
- enhance allocation for health and health research
- facilitate translational research

New Institutes have been recommended to address some of the important areas. For example, Schools of Public Health, Clinical Trial Centre, Centre for Cardiovascular Disease, Diabetes and Stroke, Animal Resource Facility, Institute for Research on Ageing etc.

2. In order to address the issues surrounding development, testing and quality control of drugs and devices, the Government had set up several committees. Most prominent among them was Mashelkar Committee which was mandated to undertake a comprehensive examination of drug regulating issues including the problem of spurious drugs. This Committee has recommended creation of a well equipped and professionally managed CDSCO which could be given the status of Central Drug Authority of India. It also calls for strengthening of the State level regulatory apparatus, use of scientifically and statistical valid methods for quality checks, and amendment of Drugs and Cosmetics Act to check manufacture and sale of sub-standard drugs.

Specific recommendations have been made on ethical and IPR issues; regulation of recombinant pharmaceuticals, food including nutritional supplements, genetically modified foods; biologics, biobanks; stem cell

research and devices. The need for establishing clinical trial centers and a registry has been emphasized.

The AYUSH component has negligible visibility in terms of Drug Controllers, Drug Inspectors, Drug Analysts and other manpower required to regulate quality of formulations of indigenous systems of medicine. Though the Department of AYUSH has launched a scheme to develop Standard Operating Procedures of manufacturing process to enable maintaining of quality of these products, still lots of work needs to be done for standardization and quality control. During the 11th Plan period strengthening/upgrading of various drugs, testing laboratories, ensuring of availability of genuine raw materials, strengthening of drugs control department of states and at central level, development of herb garden/museum/herbarium are other priority areas that need to be addressed.

3. The human resources capacity for health research is a measure of country's capacity and capability to effectively address the existing and future research agenda. Though the ICMR and other agencies and Institute offer some very high quality training, but such opportunities are few and only a small number of scientists get trained. It is therefore, important to assess the current and future needs of scientific manpower in various disciplines using appropriate analytical methods. There should be an organized and focused effort towards formulation of a long term comprehensive human resource development policy and plan to address wide range of related issues. The career opportunities should be made more attractive for scientists. The compensation package being offered to scientists should be made generous to retain and attract bright brains.

4. Each agency engaged in health research has an elaborate peer review system of its research activities to address and monitor research in priorities areas. In addition, there are strategies to facilitate better utilization of results of research by the health systems. During the 10th Plan period, new initiatives to enhance inter-agency collaborations have been taken like the Golden Triangle (AYUSH-CSIR-ICMR) and DBT-ICMR MOU to work together on areas of mutual interest. There is significant scope of further improvement in inter-agency collaborations for addressing priority areas and to avoid duplication of efforts. An overarching National Health Research Management Forum is suggested. In this, all key stakeholders would be represented and it would advise on and evolve national health research policies and priorities and suggest mechanisms and action plan for their implementation; facilitate utilization of research results and review research management and recommend strategies to overcome problems in implementation of polices.

5. Access and utilization of health research information is critical for research. There are thousands of journals, reports, status papers and other documents that are produced every year. Many of these do not come in the realm of formal literature. Their availability is limited in the existing system of information and communication. To effectively search and retrieve the most relevant information the availability and use of appropriate technology like computers, computer readable data-bases, CD-ROM technology, and satellite based tools etc. is necessary to meet the requirement. ICMR and other agencies have taken very concrete initiatives to improve the access to national and international health information. MEDLARS Biomedical Informatics Programmes provides ready access to medical databases to researches. Ground work on telemedicine in the country has already been laid with efforts of ISRO and Information Technology Department. The NCMH has already recommended setting up of a National Institute of Health Information System. A National Medical Education Institutions Network is also suggested for the country. This would act as a useful resource base for knowledge sharing for Medical Education, and Research. The country should also have a Digital Library and Medical Informatics Network. This would be a network of pooled information in the form of digital library of data bases and health information that can be accessed through internet/intranet and used for research purposes also. The libraries of medical colleges and other institutes should be modernized to bring them to a certain minimum benchmark in term of infrastructure, databases and services offered. Steps toward national resource sharing and networking of the libraries should be taken. This would also help to improve the accessibility of health information. ⊡

CHAPTER - 1

Introduction

A sort of revolution in health research is underway. New insights have been gained into the human body. Humans are understood as social beings whose health is influenced by an intricate interplay amongst the biological, genetic, social, economic and environmental determinants of health. Outcomes of this revolution in health research are transforming the way diseases are diagnosed, treated, and prevented as also the methods for promotion of health.

Significant advances in better understanding of human health and disease are also being boosted by new ways of thinking, new technologies, new partnerships, and new industries. The complexity and scale of today's health research challenges increasingly require that researchers reach out beyond their own areas of expertise and establish partnerships that bring people who share a common vision and interests together.

Health challenges and disease know no boundaries. Public safety and security requires a health system and a research community that can respond quickly and appropriately to rapidly emerging health concerns.

While health research has made appreciable progress there remains an unacceptable lag time in translating the research outcomes into tangible health products or in application of the knowledge generated through research. Thus, the task is of how best to mobilize research to bridge the gap between what is known and what is done – the 'know-do' gap. Equally important is to ensure that the products of health research reach and are used for and by the people who need it most. Health research should be directed to provide ways and means of bringing about equity and improving access to health technologies.

The health of the population would not only be influenced by the technological advances in medicine and public health but also by the changes in structure of the society. Some of these changes are bound to happen like the demographic transition, (increasing in age-segment of more than 60 years), modification of life styles (increased consumption of alcohol and tobacco and consequent effects on health) and the changing environment (urbanization, occupational diseases, injuries and accidents). The 11th Plan should aim to create a healthy environment which can decrease the admissions to hospitals. This cannot be achieved by actions of health sector alone. Health is an outcome of interplay between various

variables like clean environment, potable and safe drinking water, sanitation, housing, infrastructure facilities, education and income. An inter-sectoral and inter-disciplinary approach would be critical.

The crude birth rate has decreased from 41.7 in 1951-61 to 24.8 in 2002-03, and crude death rate has fallen from 25 to 8 in the same period. Maternal mortality ratio has decreased from more than 5 to less than 2 and infant mortality rate has decline from 146 to 60. The total fertility rate has declined from 6 (1970-71) to 3 (2002-03). Small pox and guinea worm have been eradicated. Leprosy has been eliminated as a public health problem. Significant progress has been made in fight for polio eradication. It is believed that since the introduction of Directly Observed Treatment Strategy (DOTS) in the country over 500,000 deaths have been averted due to tuberculosis. The number of malaria cases have been contained at about 2 m a year.

The country is burdened with infectious diseases alongside the emergence of non-communicable diseases. Management of some of these is quite costly for example diabetes, vascular diseases, hypertension, mental health, cancers, injuries, respiratory infections etc. Contrary to popular belief, these *lifestyle* diseases do not spare the poor. The investment in public health is low and the state of health systems is unsatisfactory. Coping with these set of new diseases along with existing diseases calls for reforms in India's health system.

The Report of the National Commission on Macroeconomics and Health (NCMH) builds a strong case for investing in indigenous research and encouraging Indian companies and universities in partnership to engage in R&D for drugs, medical devices and vaccines relevant to the needs of India's poor. For developing a culture for research, the Report suggests that the Government should initiate steps to debureaucratize procedures, introduce greater transparency, provide incentives and adequate flexibilities to enable engaging and retaining the best minds to undertake research - both in public and private universities and research institutions. There is also a compelling need to build multidisciplinary research blending physical, medical and social sciences. Besides, there is also an equal urgency to establish regulations, strict ethical norms and transparency, standardize methodology and international standards of research. Such capacity is necessary for undertaking operational research as also large-scale trials of drugs of both modern and traditional systems of medicine.

The Planning Commission's Approach Paper to the 11th Plan provides the general directions, and the recommendations of the National Commission on Macroeconomics and Health the road-map to develop a blue print for health systems research, biomedical research and development, and regulation of drugs and therapeutics.

Future Challenges

Report of the National Commission on Macroeconomics and Health has provided a glimpse of the future challenges that the country is likely to face by the year 2015. This would provide the basis of development of research agenda.

Demographic Changes

At present, the elderly population in India constitutes approximately 7% of the total population. This is likely to increase to about 20% by 2050. India will have a population of 137 million of older persons in year 2020. Chronic diseases disabilities, mental illnesses, visual, locomotors and hearing impairment are major health challenges in this age group. It is important to ensure that living longer should mean living healthily. The focus of research should be on how to prepare for this change in demographic structure. It should not be adding years to life but life to years – how to ensure that years added to life are not the years of ill health and disease. In addition to equipping medical facilities to handle the disease profile of the aged, a healthy environment has to be created so that old age does not become a victim of surrounding million and become a resident of hospices and hospitals. With growing number of senior citizens, there would be substantial increase in health care needs. Increasing availability and awareness about technological advances for better understanding of these problems raise the expectation of the population for acceptable, affordable and sustainable interventions. Health research will have to gear up to make available necessary preventive, promotive, curative and rehabilitative strategies for growing population of senior citizens.

Disease Burden

I. Communicable Disease

1. *HIV*

   Based on the surveillance data, it is estimated that there are 5.1 million adults with HIV infection between 15 and 49 years. An estimated additional 50 million people are likely to become HIV positive by the year 2025; and some 15-18 million by 2015. Women have a two-fold higher incidence, largely due to female sex workers as well as higher biological

susceptibility of women to HIV-1 infection. What is worrying is the projection of an increasing number of HIV infected women from among the low-risk category.

2. *Tuberculosis*

According to ICMR's Tuberculosis Research Centre, an estimated 3.8 million bacillary cases and 3.9 million abacillary cases, (totaling to 7.7 million) were suffering from TB in 2000. In this estimation the possible association of HIV and multi-drug resistant (MDR)-TB are not included. An estimated 400,000 die of the disease each year. This makes TB the single most important cause of death in India. While no future projections for TB in India are currently available, it is expected that an expanded HIV epidemic will greatly increase the numbers with active TB weakening the affected individuals' immune system in a population with high rates of *M.tuberculosis* infection.

3. *Malaria*

Malaria, dengue and some other conditions fall in the category of 'malaria and vector-borne diseases'. In 1998, these were estimated to account for 1.6% of India's total disease burden. This is likely to be an underestimate of the true disease burden of these conditions.Data show that the prevalence of reported cases of malaria (per 1000 population) declined in India during the period 1995 to 2003 but the proportion of Plasmodium falciparum cases, a serious form of malaria that is also expensive to treat, increased during the same period at the all-India level-from 38.8% in 1995 to 47.5% in 2003. With increasing resistance of the malarial parasite to available drugs, and without effective interventions, one may even see an increase in the disease burden from malaria in the future.

4. *Emerging Re-emerging infections*

During the last three decades, 30 new infections have been reported globally. India too had some experience of SARS and later of avian flu. Outbreak of encephalitis due to Chandipura virus was reported in Andhra Pradesh and Gujarat. Nipah virus outbreak happed in Siliguri, a new strain of *V.cholerae* 0139 emerged, diarrhea due to Group B adult rota virus was detected in Kolkata so was *V.parahaemolyticus* 03:K6. The threat is also posed by terrorist groups using natural or genetically engineered strains of microorganism with evil intent. Stepping up specialized disease surveillance is corner stone to emerging infectious disease threat. Laboratories with adequate biosafety levels would be needed and trained staff to work in them. Repositories of important microorganism would be needed to compare and study genetic changes. Animal facilities would be required to under take animal studies and development of diagnostics and other tools. Japanese encephalitis is spreading from rural to urban areas and dengue from urban to rural

areas. The annual number of cases are increasing and so is the number of deaths. And now Chikungunya is reported to be spreading.

II. Non-communicable Diseases

1. *Cardio-vascular Diseases*

   Starting from a level of about 38 million cases in the year 2005, there may be as many as 641 million cases of cardiovascular disease (CVD) in 2015; and the number of deaths from CVD will also more than double mostly on account of coronary heart disease - a mix of conditions that includes acute myocardial infarction, angina pectoris, congestive heart failure and inflammatory heart disease, although these are not necessarily mutually exclusive terms. The rates of prevalence of CVD in rural populations will be lower than in urban populations, but will continue to increase, reaching roughly 13.5% of the rural population in the age group of 60-69 years by 2015. The prevalence rates among younger adults and women (in the age group of 40 years and above) are also likely to increase.

2. *Diabetes*

   Diabetes, also associated with an increased risk for CVD, is emerging as a serious health challenge in India, even though it accounted for only about 0.7% of India's disease burden in 1998. It is estimated that there may be a significant load of diabetes cases in India-rising from 31 million in 2005 to approximately 46 million by 2015, and particularly concentrated in the urban population.

3. *Cancers*

   In India, cancers account for about of 3.3% of the disease burden and about 9% of all deaths. These estimates will, however, surely change as many of the common risk factors for cancers, such as tobacco and alcohol consumption, continue to become more prevalent in India. It is estimated that the number of people living with cancers will rise by nearly one-quarter between 2001 and 2016. Nearly one million new cases of cancers will be diagnosed in 2015 compared to about 807,000 in 2004, and nearly 670,000 people are expected to die.

4. *Mental Health*

   Nearly 65-70 million people in India are in need of care for various mental disorders in all age groups. This estimate excludes a large group of common mental disorders like phobia, anxiety, disassociative disorders, panic states, mild depression and substance abuse (varying spectrum of associated hazardous use). It is difficult to establish the true burden of all these disorders but has been estimated to be nearly 20.5 million people. Alcohol related problems are increasing in India nearly 62

million people predominantly men - are likely to be current alcohol users with nearly 10.2 million being alcohol dependants and about 30 million alcohol users.

5. *Chronic and Obstructive pulmonary diseases and asthma*

   It is estimated that there were roughly 15 million chronic cases of COPD in the age group of 30 years and above, and 25 million cases of asthma in 2001 in India. These numbers are projected to increase by nearly 50% by the year 2016, including 'severe' cases, some of whom may require greater levels of care, including hospitalization.

6. *Accidents and injuries*

   Data from Survey of Causes of Death and Medical Certification of Causes of Deaths reveals that 10-11% of total deaths in India were due to injuries. It is estimated that nearly 8,50,000 persons die due to direct injury related causes every year in India during 2005, with 17 million hospitalizations and 50 million requiring hospital care for minor injuries. By 2015, the toll is expected to rise to 1.1 million deaths and 22 million hospitalization and 53.0 million minor injuries in the absence of any positive intervention. While official reports capture majority of these deaths, domestic and occupational injuries, falls, drowning, animal bites and injuries in disaster go unreported.

7. *Oral Health*

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

8. *Suicide*

   Suicide is major public health problem and is among the top ten causes of death in most countries. In India, total numbers of suicides were 38829 in year 1967, which has increased to 110851 in the year 2003 (National Crimes Records Bureau). The numbers of suicides (during decade 1993-2003) have increased at an annual compound growth rate of 3.11 per cent as against the corresponding population growth rate of only 1.9 per cent. Recently, suicides by students (pressures of examinations) and farmers (economic pressures) have brought into sharp focus the need for research in this neglected though important area. With increasing urbination, the stress factor is likely to also increase and may prove to be a trap for larger number of suicides among the vulnerable population.

9. *Strokes and Neurological Disorders*

   The estimates for the burden of NCD by ICMR indicated the prevalence rate of stroke to be 1.54/1000 in age group 20 years and more with a death rate of 0.6/1000 (2004). The number of cases of stroke in India increased from 0.79 million in 1998 to 0.93 million cases in year 2004,

whereas DALYs attributable to stroke increased from 5.8 million in year 1998 to 6.4 million in year 2004.

III. Problems of Urban Health

India's urban population is 285 million which amounts to nearly 30% of the total population. The urban growth will account for over two thirds of the total population increase in the first quarter of this century. Slum population growth will continue to outpace growth rates of India, urban India and mega cities. Demographers refer to this as the 2-3-4-5 syndrome; in the last decade, India grew at an average growth rate of 2%, urban India grew at 3%, mega cities at 4% and slum population increased by 5%. By 2030, the urban population is expected to reach 297 million. Official estimates do not account for unrecognized squatter settlement and other populations. Population projections postulate that slum growth is expected to surpass the capacities of civic authorities to respond to the health and infrastructure needs of the urban population.

Lack of water and sanitation and the high population density in slums facilitates rapid spread of infections. Poor housing conditions, exposure to heat or cold, air and water pollution and occupational hazards add to the environmental risks for the urban poor. The urban health is also vulnerable, as they do not have back up savings, food stocks or social support systems to help them during illness. Thus, even though there is a concentration of health care facilities in urban areas, the urban poor lack access to health care. Urban health initiatives in the country to date have been limited and fragmented. The challenge of increasing urbanization with growth of slums and low-income families in cities has made access to health care for the urban poor a matter of priority. It may be necessary to create a separate unit with multi-discipline expertise to address this issue.

IV. Nutritional Problems

The incidence of nutritionally poor population, particularly the rural poor, is the quite high in Orissa, Bihar, Madhya Pradesh, Uttar Pradesh and Andhra Pradesh. Another related issue is the problem of *hidden hunger* - as the problem of micronutrient deficiency. While estimates suggest that 800 million people are undernourished, the number of people suffering from micronutrient deficiency is as high as 3.5 billion globally; a very high percentage of these are in India. In India, the magnitude of iron deficiency is perhaps the greatest. Thus, for example, 70% of pregnant women in India suffer from iron deficiency anaemia (IDA); and the figure for young children is also high. Between 10 and 20 million children in

India suffer from vitamin A deficiency (VAD) and 60,000 annually go blind because of VAD. The consequences of these deficiencies, in terms of impaired physical and cognitive development, disability and mortality are correspondingly staggering. There is a need to develop appropriate vehicles for these micronutrients. With the increase in the availability of processed food and development of food industry, food safety has emerged as an important issue. High levels of certain chemicals in ground water (like arsenic) and use of unacceptably large amounts of pesticides in agriculture, find their way in food stuffs consumed by people. There is an urgent need to develop technology to deal with such toxic agents in the food chain. Energy requirements for special groups like women who have to walk several kilometers to draw potable water or collect wood for fuel needs to be addressed by development of low cost technology.

V. Reproductive and Child Health (RCH)

According to the NRHM maternal, perinatal and childhood conditions account for a significant percentage of the disease burden. The IMR is about 66 per 1000 live-births, a substantial improvement over the levels nearly 30 years ago. The under-five mortality rate (U5MR) was estimated at 95 per 1000 live-births in 1998-99, and is declining at a rate similar to that of the IMR. Two-thirds of deaths occur within the first week of birth. About 35 babies of every 1000 childbirths die within one month; 30 before one year and 26 between 1 and 5 years of age. In India, the ratio of the neonatal death rate to the 1-5 year death rate is 1.3, against 10 in developed countries. Therefore, any strategy to reduce child deaths must focus on all three age periods, as focusing on any one may result in merely shifting the burden to the other. There is a reported decline of the maternal mortality rate (MMR) from about 580 per 100,000 live-births during 1982-86 to 540 per 100,000 live-births in 1998-99(NFHS-II).

Significant improvement has taken place in reproductive health of the population. The couple protection rate has increased from 1.4% in 1970-71 to 50-52% in 2002-03 and total fertility rate has declines from 6 to 3. However, there are problem areas which need to be tackled. Maternal mortality, infant and neonatal mortality are still very high. Main causes of maternal mortality are unattended delivery, obstructed labour, post-partum complications and unsafe abortions. Use of spacing method (about 6%) and male participation (7-8%) are very low. Unmet need for contraception is very high, particularly among young women below 20 years. (27%) resulting in high rate of unplanned and undesirable pregnancy, compelling them to resort to unsafe abortions.

In addition to the unset need for reproductive health care, there are my idle of sociological factors which have contributed to the continued reproductive ill health.

Research would, therefore, be needed to, for example, how to alter gender perceptions, strategies to build rational and healthy sexual attitude and behaviour amongst adolescents and youths, approaches to ending discrimination and injustice, better understanding of barriers to girls education, empowerment and development, improve men's participation in reproductive health care, needs of under-privileged sections of population like the tribal, inequities related to poverty and access to health care.

Need for a different orientation to 11th Plan

Conventional response to persisting and new emerging health challenges would be to step up research in control method and improving the health systems research. epidemiology of the disease goes beyond biology. Sociological perspective is important to understand the occurrence of a disease and its cure so that the patient returns and normalcy and contributes to functioning of society.

It is now increasingly realized that this is not enough. No amount of pure bio-med research would be complete unless it is extended to social determinants of health. Many of them are embedded in the circumstances in which people live and work. All forms and shades of poverty, inequity, food insecurity, social discrimination, poor conditions of housing, unsafe working conditions, poor access and/or utilization of health services are some of the important social factors influencing disease burden. The 11th Plan, therefore, should mark a departure in its orientation to health research.

Health care does not end once the fever is down and stitches are out. Disease are persisting, and/or emerging because of sociological changes, life-style changes, and social disruptions (riots, violence etc.). Diseases are not solely rooted in biological causes, but are multifactorial. This calls for a multi and inter disciplinary approach to health research.

Central to health systems research and biomedical research and development is improvement in public health and making available to then the 'goods' required for attaining positive health. This requires partnerships with various stakeholders' viz. donors, pharmaceutical industry, IT industry,

engineering sciences, science and technology and biotechnology, social sciences, town planners, architects. It requires strengthening research capacity of medical schools, colleges, universities and institutions, development of skills and infrastructure. Human resource development, creating an enabling environment for researchers, setting up new infrastructure to address gap areas and creating effective networks are also priority areas. Undertaking these activities would translate into allocation of more funds for health and to health research. Underpinning all these principles are the attainment of targets laid down Millennium Development Goals (MDGs) meeting the objectives of the National Rural Health Mission, addressing the Government's Common Minimum Needs Programme.

Biomedical Research: Current scenario and future projections

CHAPTER - 2

Terms of Reference

- To review the position/progress/problems in basic, clinical, applied and operational studies during the 10th Plan period and to suggest priority areas for research in these areas, and mechanism to avoid duplication/overlapping and to bring about transparency and social control in research work including ethical issues during the 11th Plan.
- To review the current investment in bio-medical research and health systems research by various agencies and project requirements to address the identified priorities during the Eleventh Plan period.

Introduction

The group reviewed the present position, progress and problems in basic, clinical, applied and operational studies in biomedical research during the 10th Plan period. The major achievements in areas of health research of the ICMR, CSIR, DBT and Deptt. of Science & Technology were reviewed in the backdrop of the Planning Commission thrust areas of the 10th Plan period.

The thrust areas identified during the 10th Plan covered basic, applied and operational research in the area of health, family welfare, nutrition and the indigenous systems of medicine. During the 10th Plan period, based on these identified thrust areas, the different agencies involved in biomedical research have carried out significant work that has contributed towards achieving many of the objectives. These have been reviewed in detail in the 11th Plan document submitted by ICMR, DBT, DST and CSIR respectively.

The Group deliberated on the reasons for tardy improvement in the health indices for the country. Some of the major concerns include:

National Priority Setting

New policy initiatives in the health system are at times taken on inadequate evidence-base due to lack of adequate research in evaluating the policy experimentation. The work initiated by many state governments on Public-Private Partnership point to the fact that successes are announced and attempts made without undertaking rigorous research on such initiatives.

At present while one may talk about the dominance of the private health research funding upsetting the national health priorities, but the fact is that

the country has no transparent evidence based mechanism for priority setting in health research. Unless such a mechanism is set up, the institutions and researchers, and the ethics committees as local/institutional regulatory bodies, will not be in a position to resist the research proposals pushed by the multinational and Indian corporate firms looking for the markets abroad using the Indian biomedical research data. Therefore, it is imperative that the Government of India set up an expert group to make recommendations on the priority setting for the health research – particularly the clinical trials in biomedical research. This work of priority setting must be reviewed periodically say every three years so that the national health research priorities are updated on a regular basis. Due to lack of clear national priorities and committed resources for the health research, there has been an increasing influx of the foreign governmental, private foundation and corporate sponsored health research. There is a great danger that such research could distort the health priorities of the country.

Insufficient thrust on Health Systems Research

Even as India needs to contain and reduce prevalence of existing diseases, it is burdened with a growing emergence of non-communicable diseases (such as diabetes, cardio-vascular diseases, hypertension, mental health, cancers, injuries, respiratory infections etc) which are very expensive to treat. There is also increasing evidence that these 'lifestyle' diseases affect the poor due to low resilience to infections, poverty induced malnutrition and stress. Coping with these double burden diseases calls for reforms in India's health system. Health systems research is likely to provide feasible solutions.

The Group recognized the neglect of the health system research by institutions. The problem in health systems research in India is not that research on new topics is not conducted, but that there are system blocks in improving the health of people using the research outcomes. Thus, unless the health systems research is provided a prime place it deserves and its findings are used in shaping policies to remove system blocks in improving people's health, the expensive biomedical research would remain on paper or would be useful only to the health systems in developed world. Another worrying trend relates to the hiring of the for-profit market research and consultancy firms – Indian as well as from abroad or multinational, at times of questionable credentials to undertake health system research at very high cost. This has gradually led to financial and scientific undermining of the public and NGO research institutions undertaking health system research.

Need for Performance-based monitoring

No method is currently available within the health system to measure or assess on a concurrent basis the efficacy or utility of an intervention to identify critical problems and suggest corrective action. In the past, for every corrective system that was put in place, a more ingenious system of statistical manipulations evolved. Correcting this implies setting up a system of monitoring and review which are transparent and frequent such as, for example: (i) statistical sampling every quarter, and (ii) social audit.

Inadequate Capacity to plan and implement

According to the NCHM, there is an acute shortage of epidemiologists, biostatisticians and other personnel trained in public health. Specialists in certain disciplines often work as generalists in public health, which is an inefficient use of a scarce resource. Even generalist bureaucrats who serve as Project Officers for special programmes often lack the technical capacity to provide the desired level of comprehension and quality of leadership, proving to be a serious handicap. Lack of relevant technical expertise and non-availability of even the critical minimum at the Central and State levels are reasons for public health programmes lacking in focused design, non-development of national treatment protocols and standards, non-integration with other related sectors/programmes such as TB with HIV, HIV with maternal health, maternal health with malaria, health with nutrition or water, etc. The inability to provide required technical leadership to States and districts on the operationalization of interventions based on technical norms or the inability to assess and build the technical skills and human resources required by the programme is yet another reflection of the lack of technical leadership. More important is not utilising operational research for designing better targeted programmes in keeping with the wide social and geographical disparities that characterize this country has been a serious shortcoming.

Need for Regulation of quality of drugs and devices

The quality of drugs sold in the market has been a major concern. The common man often ends up buying spurious or sub-standard drugs. The Supreme Court of India, the National Humans Rights Commission and MPs have time and again expressed concern about this and have urged the Government to improve the drug regulatory system. In the past, several committees have been constituted to examine the issue and have made many recommendations. Some of these have been implemented, but the core issue has remained unresolved. The NCMH's report has too flagged the need for strengthening of regulatory mechanism of not only drugs but also of devices. According to this report, there is no effective quality

regulation also on the sale of high-technology medical devices, with the existing BIS (Bureau of Indian Standards) mark norm limited to a small subset of low-cost medical equipment. Consequently, substandard second-hand medical devices are currently flowing into and floating around the country. The only regulation that currently exists is the protection relating to radiation. However, there is little or no control on what the equipment does relative to its claimed effects, its technical specifications, etc. Availability of good quality spare parts is also a serious problem faced by both public and private health service providers in India. While the problem is especially acute for older equipment, spare parts for which are no longer made by the original manufacturer, there are a lot of equipment suppliers who simply do not deliver follow-up services, making the search for alternative providers a costly exercise. There is severe shortage of technical experts for repairing medical equipment.

Narrow Research Base

Presently there are about 170 MCI recognized and 65 permitted medical colleges. About 20,000 to 25,000 students graduate every year. Medical schools are the cradle of health researchers of tomorrow. About 8000 of these do post-graduation in various specialties (38 PG degree courses, 32 PG diploma, 37 discipline for Ph.Ds and 24 super specialties). The quality of research in these medical colleges is low. Less than 10% are active in research, most of the papers resulting from research are published in non-indexed journals with low impact factor. More than half of the medical colleges (53%) had published less than 10 research papers in an indexed journal during 1990-94, and only 10% have 100 or more papers during that period. It is essential to inculcate a culture of research in medical colleges if the quality and quantity of health research is to be improved in the country.

Limited Human Resource

There have not been any organized and focused efforts towards human resource estimation for research or its development. It is not only an issue of numbers and skills, but also giving attention to generate a demand for research among policy makers. There has also been a ban on creation of new positions. This has further hampered human resource development. The only new blood that has been inducted has been against vacant posts. Rapid progress is being made in biomedical sciences. Fresh technologies are opening new vistas. But the country is unable to exploit them to the full in absence of adequate human resource. Cutting edge areas are being neglected.

Neglect of Translational Research

Translation of research to action involves using scientific knowledge to develop drugs, vaccines, diagnostics, devices and other interventions. There is a gap in using knowledge to inform policy and practice in health systems countries. Some challenges faced are limited access to technology and scientific information leading to scientific isolation, limited scientific career opportunities and the inability to synthesize existing knowledge towards improving interventions and performance of health systems. There is thus an urgent need for a health research system that would not only generate research outputs but also utilize scientific knowledge to inform policy and to promote knowledge based change in health system.

Recommendations

Setting up a Department of Health Research

The Group welcomed the decision of the Government of India to set up a Department of Health research within the Ministry of Health & Family Welfare. This Department would have the responsibility to address the shortcomings in the present system, and improve health research within the country.

National Health Research Policy

A clearly defined National Health Research Policy on the lines of Science & Technology Policy is the basis for maximising the return on investment in health research. The Government should therefore, enunciate a National Health Research Policy. The draft policy which has already been prepared by the ICMR should be quickly finalized and adopted.

This policy should aim to generate the evidence-base for Health Systems and Services, so that they will be significant promoters of equity and contribute to National Development; establish linkages between health research and national health programs to facilitate the operationalisation of evidence based programs and to obtain feedback for the optimisation of Health Research; encourage the development of fundamental research in areas relevant to health to ensure that a national critical mass of scientists who can contribute the benefits of modern technology to health research is developed. The proposed Policy would also ensure that the optimum benefits of modern technology are harnessed to promote national health; build and integrate capacity for research in National Health Programs, research institutions and in the private sector (profit and non-profit organisations) utilising as far as possible areas of excellence already

available in the country. The Policy would facilitate optimal use of information, communication and networking technology to ensure that the global knowledge base is available for national programs, and that research is channelled in relevant directions without unnecessary duplication; manage global resources and transactional collaborations optimally to ensure that collaborative health research primarily facilitates the development of national health systems and services. It would also ensure that health research is truly intersectoral and can harness the resources in areas such as social sciences, economics and traditional systems of medicine; optimum harmonisation of National Policies is essential to facilitate intersectoral collaboration and partnership, so that maximum developmental returns can occur from health research.

National Health Research System

Health Research in the country should be developed into a National Health Research System (NHRS) wherein all research agencies, cutting across ministries and sectors identify priority areas of research and coordinate with each other to avoid duplication, fragmentation, redundancy and gaps in knowledge, in order to enable the results of research to transform health as a major driving force for development. The NHRS would generate and communicate knowledge that helps to form the national health plan and guides its implementation, and thus contributes, directly or indirectly, to equitable health development in the country; adapt and apply knowledge generated elsewhere to national health development; and contribute to the global knowledge base on issues relevant to the country.

National Health Research Plan

A National Health Research Plan would be developed based on a transparent priority setting exercise involving all stakeholders. It shall be a rolling Biennial plan, to be reviewed and updated annually in the framework of a 5-year projection. A medium term (5 years) and a long-term (10 years) vision for health research would be developed for the entire country in consultation with all governmental agencies and others who provide funds for health research.

National Health Systems Research

A high priority should be accorded to support health systems research to generate the evidence for health policy to enable informed decisions for improved health service delivery. This would include assessing health needs of the country, the availability, acceptability and accessibility of health interventions, health technology assessments such as cost effectiveness of

interventions, the tracking of resources for health (including for health research) as part of the National Health Accounts, the availability and means of financing of health interventions. An interdisciplinary team would be set up to identify priorities for health systems research.

Recent studies of the economic impact of health research suggest that the health and wealth dividends from investment in research far outweigh the costs of the research. In partnership with other organizations, new concepts of both financial and non-financial benefits should be applied in the Indian context, to help build the evidence base and give a clear picture of the broad-ranging impact of health research.

Research which focuses on improving the health status of vulnerable populations, particularly Indians living in poverty; residents of rural areas; tribal populations; immigrants and refugees; people facing gender inequities; the homeless; children; seniors; the disabled and chronically ill; and victims of violence; and to support research on improving access to effective delivery of health services for these same vulnerable populations. Research that emphasizes the following should be encouraged:

- access to and equity in health services for vulnerable populations;
- biological, social, economic, cultural, and structural/environmental factors that influence vulnerability and disparities;
- identification, description and analyses of health disparities at the population level;
- Intervention research that informs the development of responsive programs, policies, and practices.

Research should also be supported on how social disadvantage is mediated by and interacts with other determinants of inequality, including poverty, social cohesion, gender and ethnicity, and how such factors influence health. There should be a continued need for research that will help to develop and evaluate ways to reduce social and health inequalities and to inform public health and social policy. A particular priority should be the impact of inequalities on women and children, rural populations, those belonging to underprivileged sections of society (like the SC, ST, and the OBC) their development and their long-term health.

The health system research is a multi-disciplinary social science, public health and policy research. There is a need to recognize (a) contribution of the social scientists and public health specialists in the research; (b) involve health system researchers before undertaking biomedical research and

clinical trials to ensure that there would be possibility of such research reaching to the people of the country and would not become only preserve of few; (c)sponsor multi-disciplinary intervention research to understand how the system can be improved and the new biomedical research could be disseminated.

Several priority areas for the health system research can be identified:

- Encouraging intervention research for seeking evidence useful for policy making: A wide range of intervention research projects may be financed in order to understand what works and what does not, and the reasons for the same.
- Many state governments have embarked upon the public-private partnership without creating good evidence based on its impact on the public health services, on the state finances, and whether they really bring about the equity in health access.
- *Studies on health insurance:* Increasingly, social health insurance is emerging as one of the major instrument for financing health care, and the private health insurance is also increasing. In both areas, major studies are needed.
- *Urban health:* Issues of health care access in urban areas despite high availability of private health care are not adequately studied. Besides, the health problems of urban poor, the migrants etc. need more attention.
- *Research on violence and health care in conflict situations:* This is a grossly under-researched area of health care despite increasing violence in the society.
- *Health care in disaster situation:* More work is needed in this area.
- *Gender and health:* The gender issues in disease prevalence, access to health care, and medical education, etc. must be paid priority attention.
- *Studies on the use and misuse of medical technologies:* While more and more health care technologies are being introduced in health care services, particularly in private sector, there is very little research on their relevance or appropriateness, misuse and irrational use, the additional financial burden on the users due to misuse etc. Such studies should cover prescription practices to the new medical technologies such as genetics, assisted reproduction, life prolonging technologies, organ donation and transplantations etc. etc.
- *Medical audit and audit of research:* Through research, we need to establish various ways of undertaking medical audit of health services at different levels.

- *Research on nursing practices*: The nursing is a much-neglected area of research in India. It is high time to encourage more nursing research by the nursing as well as social science and bioethics institutions in India.

Strengthening health research in medical colleges and other Institutes

The ICMR as a major funding agency of health research, should commit itself to strengthen India's health research communities by broadening, deepening and sustaining health research excellence. A skillful cadre of researchers working in state-of-the-art facilities with adequate and appropriate equipments and committed trainees, is the best strategy to ensure that India has the capacity and expertise to mobilize in order to address important health issues.

The best ideas of the researchers across the full spectrum of health research should get funded allowing them to pursue their own creative ideas for novel and significant research projects. At the same time, build on this foundation of research excellence through targeted research investments focused on emerging opportunities and challenges. Health research agencies should invest in strategic research initiatives designed to take advantage of new knowledge flowing from scientific progress, and to respond to the challenge of the health research priorities.

The convergence of disciplines should be encouraged that underlie the most exciting and important discoveries in health research, and to resolve ever-more complex health problems. Thus, the support for multidisciplinary and multi-sectoral teams of researchers as well as individual researchers working in medical colleges, universities and research institutes should be increased.

The right balance and mix of health researchers should be supported to realize its mandate and strategic objectives. It should continue to reach out through its extramural research programs and activities to those research communities that can contribute to health research. New investigators bring new ideas and ways of thinking and the energy of youth to health research. The ICMR should explore mechanisms to attract and encourage new investigators to establish themselves in health research.

Finally, attracting and mentoring the young to the exciting, relevant and important career in health research is key to ensuring the strength and vitality of India's health research system in the coming decades. This would involve creating a critical number of health researcher and positions in

medical colleges. The health research agencies should develop, in partnership with relevant stakeholders, a national initiative that reaches out to young students. Progress in research requires that the best researchers should be supported, work in stimulating and supportive environments. It may be necessary to set-up new departments like that of molecular medicine in medical institutes. Research would be given top priority in medical education. A formal programme of medical research should be incorporated in undergraduate and postgraduate level curriculum. Research should be make a core requirement for career advancement. Researchers should be should be suitable rewarded and appropriate infrastructure should be put in place. The ICMR should take up this challenge. This would require a substantial allocation of funds. The Working Group agrees with the recommendation of PAB of ICMR that the allocation for extramural research programmes should be about 50% of its budget.

Good governance of health research

The agencies, like the ICMR, should promote and provide guidelines on research governance issues, including good research practice, ethics and scientific probity. Thinking has to be reviewed within a continuously developing social and legislative context, and must respond to the moral and ethical questions that new scientific developments sometimes rise. One of the important tenants of good governance of health research is to promote the use of best available scientific evidence and results of research. The knowledge must be leveraged effectively to achieve better health. The generation, sharing and management of knowledge are necessary for its effective application. The agencies should give high priority to knowledge management. Consensus should be achieved through a continuing dialogue with the general public, users of health research, government, industry, the funding agencies, scientists and health service professionals. It may be necessary to accreditate certain facilities like the IVF clinics, research centres and clinics, stem cell research and therapy, clinical trial centres etc.

Partnerships

Partnerships are integral to the health research. As the challenges facing health sciences have become more complex and multi-disciplinary, the need *for organizations to pool resources and expertise becomes increasingly* important. Partnerships should be designed to meet the needs of a jointly agreed initiative whilst respecting the autonomy of individual participants. Partnerships are about shared vision, common objectives and alignment of priorities and programs.

By building partnerships amongst its stakeholders – those that have an interest and stake in health, the health system, and health research - India will be better positioned to support stronger research initiatives that produce quality results more quickly for the benefit of Indians.

Partnerships are critical in setting research agenda, share best practices in research, build research capacity, make more effective use of resources for research and eliminate redundancy in research activities and funding. Finally, partnerships are key to any successful knowledge translation strategy.

International collaborations

In recent years there has been an increasing number of new international partnerships in health research as organisations have come together to tackle some of the main scientific and medical issues of modern time. Initiatives would include partnerships with international research funders. National and international partnerships should be facilitated and nurtured in a variety of ways: through scientific workshops and meetings, bilateral interactions at agency level, and participation in consortia and other collaborations. Efforts should be made to:

- encourage and foster International collaborations based on equal partnerships, with mutual technology transfer, wherever appropriate
- Steer international collaborative health research to ensure that the country derives maximum benefit and the global goals are attained.
- Consider the possibility of extending resources and expertise to help other developing countries in their research efforts.
- Generate more financial resources as additionality to core funding to be used in research from various international agencies like BMGF, global fund for its TB and Malaria IAVI, GAVI and others.
- Set up North-South and South-South Global partnership by enhancing India's role in international health and by becoming and innovator and motivator for neighboring countries. South-South interactions should be made seamless and sufficient funds should be allocated for the purpose.

Translational research

Development of evidence-based medicine and healthcare by translating basic research outcomes into clinical evaluation is essential for their ultimate use into health policy and practice in the national health systems. A new initiative in clinical research should be developed in partnership with other research funders, industry and healthcare providers to. This will enable a

better assessments of the impact of research and the outcomes for patients. Such considerations will become integral to the research from the outset, and will ensure timely and effective implementation of new policy and practice.

An initiative should be launched to create greater opportunity to catalyze the development of a new discipline of clinical and translational science. Promising ideas for novel therapeutic interventions may encounter roadblocks in bench-to-bedside testing. While translation is sometimes facilitated by public-private partnerships, high-risk ideas or therapies for uncommon disorders frequently do not attract private sector investment. Where private sector capacity is limited or not available the public sector should step in to bridge the gap between discovery and clinical testing so that more efficient translation of promising discoveries may take place.

To make further progress in controlling major human diseases, initiatives should be launched to cultivate and train a cadre of clinical researchers with skills that match the increasing complexity and needs of the research enterprise.

Investing in interventions with high cost-benefit ratio cost-effective interventions

In a developing country like India, where a significant proportion of population is poor, a conscious decision has to be taken on the areas of investments in health research. It is important to keep in mind that key interventions that would yield the maximum improvements in population health outcomes should have the highest cost benefit ratio. According to a study, a worldwide demographic epidemiological advance between 1990 and 2020 would result in substantial decline in communicable diseases in importance among the poor and in relative terms, the significance of non-communicable disease would increase.

Modelling exercises have compared the impacts of interventions aimed at accelerated decline in communicable diseases with those targeting faster reduction in death and disability from non-communicable diseases. Such calculations indicate that an acceleration in overall progress against communicable diseases world bring about a significantly larger gain for the poor than would an acceleration of comparable magnitude achieved against non-communicable conditions. The additional 4.1 years of life expectancy that faster progress against communicable ailments would generate.

(compared to the base-line scenario) is almost 3 times as great as 1.4 year increase that faster decline in non-communicable diseases would produce.

Balanced Research portfolio for the 11th Plan

The potential to improve human health in areas where the burden of disease is most significant should be encouraged. Health needs influence the decisions about what research to support. However, the right balance has to be struck between short-term 'pay-offs' and promoting the longer-term development of fundamental science that will in time lead to improvements in health.

A number of health priorities have been identified in which new research is especially needed and where India can expect to make an impact, both socially and economically, in the years ahead. These range from well-known and long-standing causes of death and debilitation such as tuberculosis, malaria, HIV, cancer and heart disease, to problems that are on the increase, such as obesity, diabetes and respiratory problems including asthma. Infectious diseases continue to be a challenge, for example with the emergence of problems such as severe acute respiratory syndrome (SARS) and the ability of well-known viruses such as influenza to emerge in newly dangerous forms.

The research to be undertaken and supported should have an increasing relevance to health and disease, with equal emphasis on translational approaches at the basic/clinical interface.

The health research agencies, especially the ICMR should be committed to a research agenda that recognizes that future improvements in health and well-being will depend on research that:

- increases understanding of both the molecular and biological mechanisms underlying diseases as well as the psychosocial, economic and environmental determinants of health;
- supports efforts to develop new vaccines, diagnostic tools and cost-effective therapies;
- allows to understand and prevent the underlying social and behavioral causes of injuries and lifestyle diseases;
- links health with Science & Technology, engineering and related disciplines; and
- promotes healthy living and reduces risk behaviours.

There is a need to encourage harnessing of new knowledge of gene and gene functions, expand capacity for structural biology (structures of proteins and now different proteins interact). The complexity of the systems would demand development of bio-informatics as a major discipline. While fundamental and strategic research is critical, clinical research and translation of results of results of research into action should also be promoted. Clinical research capacity should be strengthened through training programme. To promote evidence-based decision making, the linkages with other health research agencies, academia and the industry should be strengthened.

The health research domains would be in accordance with the national health priorities, and address to known and emerging causes of morbidity and mortality:

- Communicable diseases
- Non-communicable diseases
- Maternal and child health
- Reproductive health
- Nutritional problems
- Environment and health
- Health issues of under privileged sections of society

To tackle problems in these priority areas, research approaches at many levels are needed: molecules, cells and tissues, animal models, whole organs and systems, individuals and populations.

The current level of knowledge provides exciting opportunities for *multidisciplinary approaches. Many diseases have complex causes involving* the interaction between genes and environmental factors, including, for example, exposure to chemicals, physical effects such as ultra-violet radiation, socio-economic status and lifestyle factors including diet, smoking and use of alcohol.

Development and use of modern biology tools (for example the micro-array, cryo-electron microscope, X-ray crystallography, magnetic resonance spectroscope etc) and disciplines (like structural biology, stem cell research, computational biology, nanotechnology, nano-medicine, bio-informatics, genomics and gene therapy) should be facilitated for a better understanding of the biology of health and disease and devise interventions. The wealth of knowledge in traditional systems of medicine should be tapped.

Comparative therapeutic trials of traditional medicines with allopathic drugs should be undertaken.

A better understanding of the processes and mechanisms involved in disease causation and progression at molecular level holds the key to development of more effective tools for prevention and cure. The Working Group supports the priority areas identified by Department of Biotechnology. Some of these include:

i. Molecular characterization of mechanisms of pathogen invasion to provide clues for identification of drug targets. Under this purview, infectious diseases like tuberculosis, HIV/AIDS, diarrhoeal diseases, encephalitis, and hepatitis, and malaria, tropical diseases like Leishmaniasis, Filariasis, Leprosy, and Dengue will be included. Pathogen virulence, disease progression and pathogenesis are governed by multiple factors that include the host genes, the genetic make up of the pathogen and immunological factors besides many others. Research into exploring the mechanisms used by the immune system to respond to bacterial, viral and parasitic diseases that will provide guiding principle for preventive, diagnostic and curative strategies should be encouraged. Research into host pathogen interactions should form a priority area within the infectious diseases research programme. For example, the interactions of HIV with host cells are an important issue as the course of the disease varies considerably among infected individuals. In this context, identification and elucidation of function of relevant host and pathogen genes are important. With the onset of AIDS, scenario for some other diseases has changed due to co-infections and increase in infection rates due to compromised immune status. In this scenario, co-infections of mycobacteria and HIV or HIV and *Leishmania* are a major problem. Studies on cells of the innate immune system that harbors the pathogens would be essential to provide clues to prevention of occurrence of such co-infections.

ii. Identification of new lead molecules of potential therapeutic interest through a combination of approaches integrating traditional knowledge, recent advances and futuristic genomics-based predictions for infectious diseases would be an area of interest. The increasing emergence of drug resistance in pathogens is a relevant area of address. For this, research-encompassing basic mechanistic like how drug resistance is acquired and activated should be encouraged. One of the interesting areas under this is the design of novel inhibitors for decimating the pathogen. Many metabolic processes within the pathogens could possibly be inhibited by small molecule inhibitors for which drugs are not available. Research into design of small molecule inhibitors and devising

of means to increase the potency of these would form an area of interest. Development in the area of design of the inhibitors.

iii. Vaccine development against viral, bacterial and parasitic diseases should be a priority area. Research initiative into the design, development, administration and efficacy studies in vaccines for a variety of diseases should be followed. Development of microbicides against HIV proteins relevant to HIV replication would be an important areas where research into developing bio-conjugates inhibiting replication proteins and assessment of their efficacy would be encouraged.

iv. Research to develop kits and reagents for diagnostic purposes should be supported for infections chikunguniya.

v. Developing systems for intracellular delivery of drugs or pharmacologically active agents selectively to specific cell types is an area which needs fortification in the context of infectious and other diseases and research in this area should be encouraged.

vi. Analysis of developmental cues that control the process of reproduction and development so as to provide clues for understanding genetic as well as environmental factors that lead to developmental defects in the systems.

vii. Autoimmune endocrine diseases, including those involving the thyroid (Graves' disease, Hashimoto's thyroiditis), insulin dependent diabetes mellitus (IDDM), and Addison's disease are among the most prevalent or common endocrine disorders. For autoimmune endocrine diseases considerable questions exist regarding the etiology, pathogenesis, and potential treatments directed at the autoimmune basis of these diseases. For IDDM, factors associated with autoimmune diseases including T-cell, and HLA markers have been implicated in disease initiation and progression. Putative role(s) played by various factors in eliciting and/or contributing to IDDM is not known. Clearly, a fuller understanding of the autoimmune basis of endocrine disorders is necessary to open the way for more effective immune (and other) system approaches to disease treatment and/or prevention. Research topics that should be considered relevant to this area would include the etiology, pathogenesis and treatment of endocrine diseases, including IDDM and autoimmune thyroid disease, the cellular and molecular basis of autoimmune endocrine diseases, the molecular basis for the increased prevalence of autoimmune endocrine diseases in women, the role of cytokines and growth factors in the etiology and/or path physiology of autoimmune endocrine diseases and potential therapeutic approaches to autoimmune endocrine diseases.

viii. Dissecting the specific molecular anatomy of a tumor is likely to be critical for the development of more specific, effective and safe treatments.

Research on understanding the cause and mechanisms of cancer, improving early detection and diagnosis, developing effective and efficient treatments should be addressed. Identifying and using specific targets for diagnosis and intervention would be critical.

ix. Because of the potential of stem cells to alleviate many disease conditions, stem cell research would be an area of interest. Research on basic biology of mammalian stem cells, culture conditions for maximal growth and their potential to be used for disease treatments should be an encouraged.

x. Research on molecular and cellular aspects of nervous system function in health and disease should be fostered. The research will illuminate the understanding of how nerve cells function and communicate in the brain, especially as they relate to the development of novel therapeutic approaches to neurodegenerative diseases.

Proposed New Institutes

Centre for Policy Research for Non Communicable Diseases

This Centre will target to systematically synthesize information relevant to comprehensive health care models and apply this knowledge in the Indian context. It would provide leadership in development and integration of policies and programs for prevention and control of non communicable diseases through partnership with relevant stakeholders at national level".

The Centre for Policy Research for Non Communicable Disease will use innovative processes to obtain authoritative, objective and scientifically balanced answers to unique problems in NCDs in India and translate this knowledge effectively into products of healthcare system so as to improve the health of Indians. The Centre would *inter alia* identify the NCD research needs of the country and obtain new knowledge, knowledge translation into products and action, supporting and developing measures for integrated surveillance of NCDs, developing a mechanism for incorporating NCD prevention in health care system, building research capacity manpower in the country establish centers for molecular medicine and creating partnership between medical institutes and universities.

National Centre for Cardiovascular Diseases, Diabetes and Stroke

This center will work out multi-pronged strategies to bring down the morbidity and mortality due the cardiovascular diseases, diabetes and stroke, thus making a significant dent in the emerging epidemic in the region. The Centre will support research efforts to promote new discoveries and enhance scientific progress through support of cutting edge basic and clinical

research related to cardiovascular diseases, diabetes and stroke, with a goal of rapidly translating research findings into novel strategies for prevention, treatment and cure of these diseases.

The Centre would among other objectives help to generate new knowledge by stimulating and sustaining interdisciplinary research for resolving complex issues in CVDs, diabetes and stroke, to undertake research activities which accelerate the translation of health research into action develop national clinical guidelines for prevention, management and control of CVDs, diabetes and stroke, create database of information on cardiovascular diseases, diabetes and stroke so as to act as national referral centre for these diseases. The Centre would be located at Chandigarh.

National Center for Disease Informatics and Research

This Centre would be set-up by upgrading the existing Coordinating Unit of the National Cancer Registry Programme at Bangalore. The proposed center besides working on collection and analysis of data on cancer would also work on establishment and running of registries related to diabetes, cardiovascular diseases and stroke. The data thus collected is expected to help in evaluation of control activities in the concerned areas. This would also provide a base for undertaking multi-disciplinary and multi-centric research projects. Surveillance programmes would also be supported by the activities of the Centre.

ICMR Schools of Public Health

For decision making in public health reliable data and information is often not available. Even if data and information is available, to use these effectively would require analytical skills which may not be readily available within the health system. There is an urgent need to enhance this very limited capacity in India for strengthening research and policy development in public health. To meet this demand trained human resources in the precept and practice of public health will have to be developed. The Government of India plans to raise public health specialists through establishing, initially two Schools of Public Health through the aegis of the Public Health Foundation of India. The ICMR plans to supplement this effort by setting up a chain of Schools of Public Health.

The National Institute of Epidemiology, Chennai would provide the core support to the regional institutions to be developed at National Institute of Cholera & Enteric Diseases, Kolkata, Post-Graduate Institute of Medical Education & Research, Chandgiarh and the National Institute of Virology and

National AIDS Research Institute, Pune. These would offer specialized training facilities in partnership with other medical colleges and research institutes. Several international schools of public health have also agreed to partner in this effort (like School of Public Health, Boston, Swiss Institute of Tropical Diseases, Minnesota School of Public Health, and Aberdeen University).

National Animal Resource Facility for Biomedical Research

For combating the health challenges posed by persisting and emerging diseases, intervention tools like drugs and vaccine would be needed. It is essential that they are evaluated for their safety, efficacy and toxicity in animal studies. Such studies it is required by law to use animals of defined quality, of genetic and disease free status in order to obtain reliable and reproducible results. Currently there is neither a private centre nor any large breeding facility in the country which can supply quality animals. It is proposed to fill this gap by setting up National Animal Resource Facility for Biomedical Research at Genome Valley, Hyderabad. This would be a major central animal facilities for large, small, transgenic animals within the health systems. There is hence, a great demand of such animals and facilities in the country.

Institute for Research on Ageing

India will have a population of 137 million older persons in year 2020 as per estimates by the Registrar General of India (SRS-1991). The older persons face physical, psychological, social and economic difficulties due to various factors. They develop degenerative disorders such as those related to joint and cario-vascular systems, suffer from mental health problems, visual and hearing impairments etc. This has direct implications for the health and social service sectors, which need to be augmented to take care of these health concerns as the population ages.

India has a National Policy on Older Persons, not though much headway ha been made. Concentrated efforts have not been made to study the process of ageing, as well as the various health, psychological and other related issues. This needs institutional set-up with proper infrastructure.

Therefore, an Institute for Research on Ageing (IRA) is required to undertake *multi-disciplinary studies.* This *multi-specialty centre* should address to various research areas like epidemiology, morbidity profile, health care management, nutritional assessment, drug metabolism, molecular biology, neurobiology, socio-psychology and studies on health systems research

would be addressed. The Institute should encompass health, socio-behavioural, and rehabilitation areas.

Budget Requirement

The Working Group agrees with the observations of the ICMR's PAB that the funding for medical research in the country continues to be abysmal and is ridiculously low. India should be spending a great deal more on medical research if it hopes to even touch the fringes of medical problems which face the country. As prescribed in the National Health Policy, the Government must keep its commitment of increasing the funds for medical research to 1% of its health expenditure by 2005 and 2% by 2010.

Medical research is an interdisciplinary, multi-agency effort involving the government, academic institutions, and the private sector, and requiring progress in many diverse fields of science to succeed. Medical research competes annually with other worthy domestic spending priorities for its share of our national budget. Medical research is the responsibility of the national government, and one in which the government is uniquely positioned to take the lead. The health research is to a large extent funded by the Govt. of India through Ministry of health, the funding for health research depends on health budget, which itself is meager in the national budget. The current level of funding for health research is grossly inadequate. Ideally, spending on health research should be at least 2% of the total spending. Currently it is less than 1%. The ICMR has been able to increase its funding in last 4-5 years and utilized the same fruitfully. However, the funds available are about one third of the demand (allocation of Rs.970 crores as against requirement of Rs.25000 million for the 10th Plan period). The ICMR and its institutes have demonstrated ability to attract funds from the Government and other funding agencies both in India and abroad. In addition, the Council has demonstrated abilities to expend the allocated finances in a timely fashion reflective of good project management practices. However, the Council needs large infusions of funds to undertake large scale expansion and embark on mission mode projects.

The Working Group reviewed carefully the budget submitted for the 11th Plan by the Council and other agencies along with their proposed strategies of action. The Group endorsed the plan of action of the Council and departments and recommended that their budget provisions are appropriate for the activities that are envisaged.

ICMR

Total Budget Required	Rs. in crores
Intramural	3504
Extramural	1496
ICMR Hqrs	
TOTAL	**5000**

New Posts Required	Numbers
Scientific	500
Technical	0
Administrative	0
TOTAL	**500**

The Working Group approved the new activities suggested by the ICMR for the 11th Plan period.

In addition, special and ear-marked funds should be made available for:

i. addressing neglected diseases and disorders; and
ii. health systems to interact with industry to develop products that the health systems need.

The budgets of CSIR, DST and DBT have presented to the appropriate controlling authorities by the respective agencies.

CHAPTER - 3

Product Development & Evaluation

Terms of Reference

- To review the current situation regarding development, testing and quality control of drugs and devices, both in the modern system of medicine and AYUSH and suggest priority areas for research and institutional strengthening during the 11th Plan period.

Introduction

With the introduction of product patent laws in India, there is a compelling need for investing in indigenous research and quality control for drugs, medical devices and vaccines relevant to the needs of India's poor. The development of new drugs from the knowledge and information possessed by a community must ensure that part of the financial benefits from the use of these drugs flows back to the community that initially owned the knowledge. The NCMH has recommended that an R&D policy needs to be formulated for assuring drug, medical technology and vaccine security and investing funds for upgrading public sector research institutions at Kasauli, Conoor and research institutions of the ICMR, DST, CSIR, DRDO, DBT, Universities etc.

Besides stepping up health systems research, there is also an equal urgency to establish regulations, strict ethical norms and transparency, standardize methodology and international standards of research for tapping the global market for clinical research. India has the possibility of becoming the international hub of clinical trials. With its quantum of well-trained physicians, pharmacologists and clinical pharmacologists, the availability of a large untreated naïve population providing numbers, the relatively low cost of conducting trials, and the recent patent regulations. India has a huge comparative advantage that gives it an opportunity to be at the forefront of drug discovery, besides earning valuable foreign exchange and providing employment to many.

Among the limitations plaguing new drug discovery are lack of GMP compliant facilities, few centres for undertaking pharmacokinetic studies and poor quality study of animals. An area in which India could make significant contribution is drugs for chronic diseases. Significant knowledge is available on traditional systems of medicine. This could be taken as a mission-project.

The research has to be innovative which can only be done by encouraging basic research in cutting edge areas. Good quality clinical trials are not

being undertaken. This is so primarily because of lack of trained personnel. Training courses in clinical epidemiology, clinical pharmacology, GCP, GLP, Quality control, toxicology, pharmacokinetics etc. would need to be expanded. Simultaneously a mechanism of accreditation of clinical trial centres should be put in place. The action of drugs at molecular levels would have to be studied along with pharmacokinetic studies (using biomarkers). Monitoring quality of these drugs would also be an important aspect which needs to be addressed.

During the 10th Plan period, the Government had set up various Committees to address several of the issues listed in this Term of Reference. The Group reviewed these Reports and recommendations made therein. The members supported these recommendations and hoped that they would be soon implemented.

The Central Drugs Standard Control Organization (CDSCO), under Drugs Controller General (India), DGHS, Ministry of Health is responsible for ensuring the safety, efficacy and quality of drugs and therapeutics as per the provision under Drugs & Cosmetics Act, 1940 and Rules 1945. The regulatory requirements pertaining to safety efficacy and quality is currently effectively implemented through:

- The State and Central Drug Regulatory Authorities
- States and the Central Drug Testing Laboratories with infrastructure and facilities to ensure speedy analysis of drug samples.
- Good Manufacturing Practices (GMP) mandatory for all pharmaceuticals production houses.
- Stringent quality regulatory process for import of drugs Le Import Registration process.
- Publication of Essential Medicine List.
- National Pharmacovigilance Programme to ensure self sustaining and viable adverse drug reaction monitoring programme.
- Regulation in respect of licensing of import as well as manufacture of 10 sterile medical devices in place since October 2005. Subsequently, guidelines have been issued for import and manufacture of medical devices.
- At present, there is an indirect control like licensing for the products exclusively for export giving for NOC for the export drugs to regularize the same in addition to manufacture, sale and distribution in India.

Regulation of Drugs and Pharmaceuticals

There has been a wide-ranging national concern about spurious/ counterfeit/substandard drugs. The Drugs and Cosmetics Act has not been reviewed in a comprehensive manner since its inception although the Rules have been amended from time to time. The Report of the Expert Committee under the chairmanship of Dr. R.A. Mashelkar on a comprehensive examination of drug regulatory issues, including the problem of spurious drugs has submitted its report in November 2003.

The Committee concluded that the problems in the regulatory system in the country were primarily due to inadequate or weak drug control infrastructure at the State and Central level, inadequate testing facilities, shortage of drug inspectors, non-uniformity of enforcement, lack of specially trained cadres for specific regulatory areas, non-existence of data bank and non-availability of accurate information.

The report of the Committee deals comprehensively with the issue of implementation of all the rules and regulations, which guide, monitor and control the activities of the providers of the healthcare system in the country and the way to bring them up to international standards. It provides the design of Central Drug Administration (CDA), its size, functions and the sharing of the responsibilities vis-à-vis the States including directions for licensing of manufacturing units by a central authority. It also deals with the regulatory health food/dietary supplements/therapeutic foods, Indian system of medicines and herbal products, over the counter drugs, medicines & diagnostics. It addresses the issue of drug development and clinical research in India with special reference to the drug regulatory agency including modern biotechnology.

Major recommendation of Mashelkar Committee include:

- Create a well equipped and professionally managed CDSCO, which could be given the status of Central Drug Administration (CDA) and strengthen the State level regulatory apparatus with complementary roles of the Centre and the States, while at the same time ensuring uniform and effective implementation,
- A scientifically and statistically valid methodology should be used to evaluate and quantify the extent of the problem of spurious drugs at various levels in the supply chain at the Regional and National levels.

- The Drugs and Cosmetics Act should be suitably amended and the maximum penalty for sale and manufacture of spurious drugs causing grievous hurt or death should be enhanced from life imprisonment to death.

During the 11th Plan, it is proposed to establish a Central Drug Authority of India as per recommendations of the Mashelkar Committee.

Regulation of Recombinant Pharmaceuticals

A Task Force on Recombinant Pharma, was appointed by Ministry of Environmental & Forestry in 2004 to suggest a new regulatory framework for recombinant pharma products. Headed by Dr R A Mashelkar, Director-General, Council of Scientific and Industrial Research (CSIR), the Task Force has submitted its report.

The Task Force has laid down the Procedure for Regulation of Recombinant Pharma Products derived from Living Modified Organisms (LMOs). Taking into consideration the regulatory objective of GEAC, which, is confined to regulation of LMOs, two protocols have been recommended: (i) products derived from LMOs but the end product is not a LMO and (ii) product derived from LMO where the end product is a LMO.

- Where the end product is a LMO (which has the potential for propagating/replicating in the environment), a higher level of regulation is needed as compared to end products which are not LMO.
- The magnitude and probability of environmental risk depends on the extent of use of LMOs within the R&D and production units. In case of imports of finished products. The risk is not there, especially in cases of therapeutic proteins in finished form.

The Task Force has also recommended that the regulatory procedure need to be rationalized for the various scenarios regarding LMOs and other linked issues. It has proposed establishing of an Independent Institutional Mechanism National Biotechnology Regulatory Authority/ Commission. This is a complex issue and it has been recommended that an inter-ministerial group be established to examine the model proposed by Secretary DBT among various others administrative Departments/ Ministries, for functioning of the proposed authority and make specific proposals with respect to the implementation including the budgetary requirements.

AYUSH Formulations

AYUSH systems are based on experience and interaction with nature and natural resources. Scientific evidence to prove the rationale of using these formulations in health care is essential not only to develop and preserve the cultural heritage but also to make them acceptable at large.

Even though Research Councils under the Deptt. of AYUSH have undertaken clinical and health care research programmes, the multi institutional support with AYUSH based approach in research at other centres was evidently lacking. Active participation of AYUSH in service oriented surveys, surveillance programme, and community health care research programme is yet to be achieved in R&D sector.

Though a number of pre-clinical and clinical studies are carried out on medicinal plants used in ISM including isolation and purification of active principles, scientific evaluation of Ayurvedic therapies and medicines based on Ayurvedic pharmacological principles and clinical parameters deserves to be carried out. The scientific evaluation of Ayurvedic drugs through placebo controlled clinical trials have to be reviewed for its appropriateness in Ayurvedic system. The comparison should be done with standard care available in modem medicine. It is, therefore, proposed to re-analyze the clinical drug trial data base incorporating Ayurvedic parameters and evaluate the hypothesis for Ayurveda driven drug studies for proving their 'equivalent efficacy and comparative safety'.

In the research front multiple agencies like CCRAS, CCRUM, CCRYN, CCRH, ICMR, S&T, CSIR and its units, various University Departments, AYUSH teaching institutions etc. are attempting to solve the same problems and creating same kind of data over the years. Such duplication should be avoided. There should be a well co-ordinated programme for execution at different institutions in accordance with their mandate. Similarly, the documentation and validation of traditional therapies being practiced in various parts of the country is required to be taken up on priority. It is desirable that ICMR in collaboration with AYUSH research councils should take up R&D on ASU drugs that could be included in the National Disease Control and health programmes

Quality Control Regulation of Drugs in AYUSH

One of the priority tasks of the Department of AYUSH is to publish pharmacopoeial standards for Ayurveda, Siddha and Unani and Homoeopathy (ASU&H) medicines both for single and compound drugs. Pharmacopoeial standards are important and are mandatory for the

implementations of the drug testing provisions under the Drugs and Cosmetics Act, 1940 and Rules there under. These standards are also essential to check samples of drugs available in the market for their safety and efficacy. The Department of AYUSH launched a Central Scheme to develop Standard Operating Procedure of manufacturing processes, to develop pharmacopoeial standards and shelf life studies of Ayurveda, Siddha & Unani Compound drugs under 10th Five Year Plan and achieved significant results, but still lots of work have to be done in the field of standardization and quality control. For this strengthening / upgrading of various drugs testing laboratories (Government /autonomous / states/other accredited laboratories), ensuring of availability of genuine raw materials of commonly available drugs as well as rare and endangered drugs of plants/animals/minerals origin, substitutes of similar species have to taken up in the 11th Plan to handle the task of drugs quality control. New area relating to drugs e.g. strengthening of Drugs Control department of States and Central, Developing Herb garden/Museum/herbarium are essential requirement for quality medicines.

It is necessary to develop the Quality Standards along with their Safety Profile for the extracts of the most common drugs used in ASU system. It is also necessary to develop pharmacopoeial and quality standards for Indian medicinal plants used for the purpose of food and cosmetics and official substitutes of non-available drugs/ plants/animals. This work should be give priority in the 11th Plan.

Other priorities for the 11th Plan are :

i) To publish SOPs and Quality standards, shelf life monographs for at least 100 compound formulations per year to complete the work on 500 ASU drugs.

ii) Revise and update the various volumes of pharmacopoeias and Formularies.

iii) Capacity Building : The new GMP provisions require regular testing during the process of manufacturing as well as for the products. Therefore, there is a need of developing and supporting large number of DTLs for ASU&H systems.

iv) Centre for Safety Evaluation/Toxicity studies for AYUSH Drugs: However, there is a felt need to establish the safety of various single drugs as well as formulations containing poisonous ingredients in various dosage forms.

v) National Herbarium, Museum, Herbal Garden for ASU Drugs: There is a need to establish/strengthen a couple of medicinal plant garden

containing all the medicine plant species used in ASU&H system. These gardens will act as Demonstration Garden as well as source of authentic raw drug samples.

vi) Training and provisions of Scholarships/Fellowship in ASU&H Pharmaceuticals, Quality Control and standardization : Degree, Post Graduate and Post Doctorate training is required in ASU&H drug sector.

vii) There is lot of scope and urgent need to work on different aspects of preparation, standardization, safety, efficacy, doses forms and pharmacology of metal based Bhasmas and Ras Aushadhis.

viii) ASU drug industry is a green industry, cause minimum pollution, make use of all indigenous material and giving job opportunities for needy people.

ix) Support the R&D based production of classical and P&P drugs, there is a need to allocate ASU&H "Pharma Industries Support Corpus" fund of Rs.100 crores to meet the bank interest (amount of interest difference between the bank rate and soft loan rate of interest) which will be recoverable in 10 year period. Similar scheme was implemented by DST earlier.

x) Scheme to supply authentic raw material for ASU&H Drug industry

xi) Strengthening of Drug Control Division in Centre and States : There is utter lack of infrastructure, human resource expertise and other requirements to regulate the provision of Drug & Cosmetics Act at Centre and State. The AYUSH component has negligible visibility in terms of Drug Controller, Drug Inspectors, Drug Analysts and other manpower required to regulate the provision of Drugs and Cosmetics Act. There is an urgent need to strengthen Centre and State Licensing and Regulatory Authorities. There is a need for comprehensive review of regulatory provisions of AYUSH products. To begin with, regulatory *changes can be started by implementing a system of registration on* AYUSH products on the basis of proper product dossier with State licensing authority on the basis of proper guidelines developed by the Central Government. There is an urgent need to support technical experts in Drug Control section of AYUSH along with supporting staff.

xii) Repository for plants used in Traditional Medicine: A national well stocked repository of drugs from the traditional medicine source in order to house crude drug samples of authenticated parts of the plants, used as medicine is highly essential. This referral facility could be accessible to pharmaceutical industry, traders, medicinal practitioners, natural product chemists, students and academics. This may provides an accessible repository of quick overviews of particular herbs and pointers for further research , describes methods for studying specific activities of plants in vitro and in animal models as well as in humans,

includes regional reviews from an international group of contributors , allows to compare and contrast information specific to geographical areas and between geographical areas and also may contains an up-to-date summary of available knowledge on plants tested for specific disease activity. The increasing prevalence of various metabolic disorders world-wide is an issue of major socio-economic concern. Scientific interest in plant-derived medicine is steadily rising, yet there is often a wide disparity in the caliber of information available. A detailed compilation of scientific information on traditional medicines plants may highlight the potential role of dietary and medicinal plant materials in the prevention, treatment, and control of various diseases and its complications.

Regulation of Food Including Nutrition Supplements

There is increasing evidence that many food based materials have potential health or medicinal benefits. Such products fall into a grey area between foods and medicines and have been described as "functional foods" or "nutraceuticals". It needs to be verified whether these so-called "health foods" really are safe for human consumption and offer the purported health benefits.

Some nutraceuticals are already in the U.S. supermarkets – eggs with fish-derived fatty acids to lower the risk of heart disease orange juice fortified with calcium to fight osteoporosis, herbal teas with anti-oxidants that may lower cancer risks : and margarine laced with a wood pulp ingredient that lowers cholesterol by 10%.

Several products are in the pipelines, Investigators are now busy using a combination of traditional plant breeding, genetic engineering, and just plain chemistry to produce foods enhanced with compounds they hope will lower the risk of many diseases. Those focusing on cancer are looking at compounds such as lycopene in tomatoes, beta carotene in carrots glucosinolates in broccoli, and isoflavones in soy. Soy protein extracts, sweeter carrots with greater concentrations of beta carotene and higher lycopene containing tomatoes, besides mushrooms, garlic are potential candidates for this food based medicine approach.

A major challenge for those involved in the research and development of functional foods is the scientific validation and substantiation of a claim in the eyes of the law. It is already clear that in some areas, manufacturers will need better clinical evidence of the overall relationship between diet and

disease, and they may need to carry out specific clinical trials on their products. The issue of substantiation of claim covers not only the safety and efficacy of the food component(s) themselves, but also the finished food as it would be used by people. In future, nutritional assessments of novel foods will need to be carried out against a background of rapidly advancing knowledge on the role of diet in the causation and prevention of many diseases, from classical nutrient deficiencies to illnesses that are major causes of morbidity and mortality, such as coronary heart disease and some types of cancer. For parts of the food industry, this is a move toward greater use of biomedical sciences, more akin to the pharmaceutical industries.

The evidence and commercial criteria for a growing inter-face between the two industries are under constant review. Whatever happens in the commercial environment the use of specific nutrients and ingredients or combinations thereof that are claimed or perceived to be beneficial to health will stimulate the reformulation and repositioning of existing products as well as product and process innovation. Key areas of interest include antioxidant substances (e.g. beta-carotene, vitamins C and E), minerals (e.g. calcium, magnesium, zinc, selenium), phytochemicals (e.g. flavonoids), probiotics (e.g. bifidus and lactobacillus), fatty acids and lipids (e.g. bifidus and lactobacillus) fatty acids and lipids (e.g. fish oils), and a range of macromolecules (e.g. dietary fibers and oligosacharides).

The Indian Food Safety and Standards Bill 2005, introduced recently is aimed to consolidate the laws relating to food and to establish the Food Safety and Standards Authority of India for laying down science based standards for articles of food and to regulate their manufacture, storage, distribution, sale and import, to ensure availability of safe and wholesome food for human consumption and for matters connected therewith. The new rule is expected to boost the level of science behind products, as it will define the scope of acceptable health and nutrition claims. Such claims will need to be based on clinical trials, protocols, or scientific studies conducted as part of their R&D and product development. All of these need strengthened during 11th Plan.

Regulation of Genetically Modified Foods

Current issues are:

- Whether testing of GM foods is necessary as regulatory exercise once, the product has been cleared for use (from the point of view of food safety) and labelling provisions are in place to advise the consumers.

- If testing is necessary then the nature of the protocols to be developed for testing both imported and domestically produced foods.
- Whether capacity needs to be built up in, Central Food Laboratories (CFLs) or specialized laboratories need to be identified where capacity is being developed and there can be networking of these laboratories, given the large resources needed.
- The development of protocols for risk assessment and generating data under the existing regulatory framework, to facilitate the manufacturers/importers to easily comply with regulatory requirements without delay or duplication of efforts
- To address the labelling concerns at the earliest and identification of an institution under concerned Ministry which could be resource centre for collection and documentation of information on GM foods.

Currently, there is no appropriate regulatory mechanism for monitoring marketed imported GM Foods and also for sale of GM Food produced in the country. The Ministry of Health and Family Welfare is responsible for making regulations for sale of safe foods including GM Foods under PFA Rules 1955. Thus, there is a need to incorporate regulatory provisions for GM Foods:

- Labelling of GM food, may however be one of the practical option for regulating post-marketing of GM Foods on one hand and on the other it would provide information to consumers who have the right to choose whether or not to consume GM food based on the information provided on the label.
- Keeping in view the current scenario, it may not be feasible to decide on the threshold level of GM foods, therefore, the Ministry of Health should consider incorporating the labeling provisions under the PFA Rules.

Based on these recommendations, notifications on labeling of GM Foods were issued in May 2006.

Regulation of Biologics

The term *"Biologics"* generally refers to any biological product that can only be made using a living system or organism, usually DNA, proteins, bacteria or other microorganisms. *Biologics* are inherently different from chemical *drugs, which are synthesized from raw chemicals using more predictable* and replicable processes. Since the production of *Biologics* occurs in a living cell, the process is subject to considerable variability. The 21st century heralds the "biotech revolution" where biologic medicinals promise cures for

some of the most complex diseases. Currently, over 370 innovative biologic products are being tested, targeting more than 200 diseases, including cancers, neurological disorders, heart disease, diabetes, multiple sclerosis, AIDS and arthritis. The biopharmaceutical industry represents one of the fastest growing segments of U.S. healthcare. The *regulation* of follow-on *Biologics* is a rising concern for the biotech industry since many *Biologics* are approaching the end of their patent life, and as a result, will open the market for more affordable generics. Due to the complex processes that are used to produce *Biologics*, creating an exact copy of the original, pioneer biologic is often very difficult. The many sources of variability in the process, from bio-environmental factors such as gene splicing and culture media to physical factors such as temperature and chemical make-up of petri dishes, can lead to variability in the product as well. Biotechnology is used when the desired drug product is a large molecule that is difficult to produce through chemical synthesis. Because of simpler, more straightforward processes used in the production of chemical drugs, exact copies of the original drugs can be produced and marketed as "generics". Brand manufacturers argue that science is not capable of detecting changes in protein structure between the brand biologic and the generic. Furthermore, the brand industry contends that biologics are impossible for generics manufacturers to successfully reverse-engineer without the proprietary good manufacturing practice (GMP) and good laboratory practice (GLP) protocols of the innovator company. The policy issues surrounding the approval of *Biologics* must consider the need to balance the rights of innovator companies with the economic needs of healthcare consumers, while ensuring high quality healthcare. Promoting innovation requires the right combination of incentives, safeguards, and effective regulation to secure maximum benefit from new medical technologies, while assuring mechanisms for equitable access to the treatments.

With the recent developments in clinical research and business process outsourcing it is proposed to develop strategies to regulate the import and export of biological material at this juncture for the social benefit and economic development of our country.

Biobanks

Human tissue is critical for new areas of research that promise to revolutionize medicine like *genomics* and *proteomics*. The samples are important for various types of studies like population genetics, human diversity studies, and even in forensic medicine. The samples reveal the types of genetic changes or protein "signatures" associated with a particular disease and experiments on human tissue are there is enough scope for the findings to be translated into new diagnostic and prognostic tests. Human

tissue has its greatest potential benefit when there is associated clinical data for analysis because genomic and proteomic research may then reveal associations between genetic or protein patterns and response to therapy, or toxicity. Biobank sample collections are used for various purposes, namely for clinical, research, and industrial uses. Council has already prepared a draft guideline on ethical, legal and social issues for National repository of genetic resources and database in the year 2006.

Regulation of Stem Cell Research

The stem cell research hold s great promise of improving human health by control of degenerative diseases and restoration of damage to organs by various injuries; but at the same time it also raises several ethical and social issues such as destruction of human embryos to create human embryonic stem (hES) cell lines, potential for introducing commoditization in human tissues and organs with inherent barriers of access to socio-economically deprived and possible use of technology for germ-line engineering and reproductive cloning. The research in this field, therefore, needs to be regulated to strike a balance. The Council has prepared draft *Guidelines for Stem Cell Research and Therapy in collaboration with DBT. These guidelines emphasis* a separate mechanism of Review and Monitoring is proposed for Research and Therapy in the field of human stem cells, one at the National level called as *National Apex Committee for Stem Cell Research and Therapy (NAC-SCRT)* and the other at the institutional level called *Institutional Committee for Stem Cell Research and Therapy (IC-SCRT).* These guidelines will be debated in different parts of the country before finalization.

Regulation of Devices

India has stunting growth of medical devices industry due to inadequate regulation. Only low technology devices (thermometers, weighing machines etc) are being made because these do not require a pre market certification, and optional QC is provided by agencies like Bureau of Indian Standards. The Drugs and Cosmetics Act was not covering the critical medical devices(pace makers, implants, internal catheters or other critical in vitro testing devices) resulting in near zero indigenous production. Absence of such a regulatory body has resulted in India becoming dumping ground of outdated or third rate western devices which have actually been discarded in the west due to information about their harmful effects. That information is withheld from Indian users who have no other way of knowing the harmful effects because of lack of a regulatory and surveillance body. Formation of such a governing body having regulatory and surveillance responsibility pertaining to the medical devices is, therefore, very essential.

The wide range and huge number of medical devices that are being constantly introduced in comparison to the few drugs every year make the traditional pre market approval approach impossible to implement. As devices are based on a number of advanced technologies having a great diversity in mechanism of their action, they can also fail because of a myriad of mechanical faults, electrical component failure, or biocompatibility problems. An implantable device may fail after many years of its use at an unpredictable time period. Hence, besides product regulation, its correct use must also be ensured to assure safety of device.

There is no doubt about this out country definitely needs a system to ensure that our public is not exposed to poor quality products, especially in this rapidly growing market segment. Also, the advantages of having a device regulation to the various segments of the developmental chain – the R&D groups, the manufacturer, the clinicians and finally the patients have to be clearly elucidated. This medical device regulation will be advantageous to one and all, provided that it is well implemented and administered like in Europe and other developed countries

Recently, the Ministry of Health and FW under Gazette notification S.O. 1468 (E) dated 6.10.05 declared the following sterile devices to be considered as drugs under Section 3 (b) (iv) of the Act : Cardiac stents; Drug Eluting Stents; Catheters; Intra Ocular Lenses; I.V. Cannulae; Bone Cements; Heart Valves; Scalp Vein set; Orthopedic Implants; Internal Prosthetic replacements;

These guidelines have become effective from 1st March 2006. These cover purpose, procedures for Import of Medical Devices, Registration of Medical Devices for Import, Manufacture of Medical Devices in the country and sale of Medical devices in the country

Ethical Issues in Animal Experimentation

The Ministry of Environment and Forests has notified the Breeding of and Experiments on Animals (Control and Supervision) Amendment Rules, 2005 in Jan 2006 in continuation of the Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998 and its amendment in 2001. This amendment emphasizes :

i) personnel using experimental animals shall be responsible for the welfare of animal during their use in experiments;

ii) investigators shall be responsible for the aftercare and rehabilitation of animal after experimentation, and shall not euthanise animals except in defined situation;

iii) costs of aftercare and rehabilitation of animal after experimentation shall be made part of research costs and shall be scaled in positive correlation with the level of costs involved in such aftercare and rehabilitation of the animals;

iv) rehabilitation treatment of animals after experimentation shall extend till the point the animal is able to resume a normal existence by providing a lump-sum amount as costs for rehabilitation and care of such animal to cover its entire statistical expected life span; and

v) the establishment undertaking experiments or duly licensed and authorised animal welfare organization under the control of the Committee may, on payment of lump-sum amount, undertake rehabilitation of animals.

These draft rules if approved will result in extra costing of the research projects aiming at New Drug Developments for which provisions have to be made by all the funding agencies. There is also need for establishing Centres which can develop alternatives to animal experimentation.

Ethical Issues in Drug Development Involving Human Subjects

The Ethical Guidelines For Biomedical Research On Human Subjects, released by ICMR in 2000 have been drafted for Legislation and were forwarded to the Ministry of Health and Family Welfare, and Ministry of Law and suggestions have been incorporated. The Bill entitled "*The Biomedical Research on Human Subjects (Promotion and Regulation) Bill, 2006* is now ready to be placed before the Parliament for notification.

There is a need at the present time for a strong centralized regulatory regime which can guide high quality development of ethical capacity with extra vigilance with an informed understanding of acceptable risk.

Clinical Trial Registry

A number of clinical trials are carried out for which results are not published either because the company decides not to market its product, or because the results are negative or neutral or because the trial was terminated. Information about a drug that does not demonstrate efficacy in a controlled trial or that demonstrates significant hazards that are important for making health care decisions. Failure to publish results of such studies could compromise patient safety. To ensure that systematic reviews are unbiased,

the need for an international trial register of all controlled clinical trials has been highlighted in many scientific fora.

Recognizing the importance of a clinical trial registry, the ICMR is piloting the establishment of a Clinical Trial Register that is web based and designed to be compatible with international clinical trial registry. Once established, a full fledged National Clinical Trial Registry should be established during the Eleventh Plan period.

Research and Development

The India Pharmaceutical industry in the last six decades has grown substantially and has the capabilities to manufacture APIs through different technology like Chemistry, Biotechnology, Biology and also has developed technologies to manufacture various doses forms like parenterals, oral, aerosols etc. This also includes capacity to manufacture immunobiologicals like vaccines for prophylactic and therapeutic use in human and animals. Industry's focus is on Chemistry based, R & D and in the last decades substantial effort are being made for their presence in drug discovery research.

Potential growth in Pharma Sector

Process development still will be a focus area for growth and research in APIs. India has been recognized as a single source for carrying out research in existing molecules as well as molecules under patent. This has huge potentials to encase the opportunity in the 11th Plan. Another important emerging area is to prepare dossiers for submission of R & D application concerning the approval of generic drugs in USA, EU, Japan etc. India has a huge potential of highly qualified post graduates in pharmaceutical chemistry, analytical chemistry, instrumentation etc. This needs support from Government during the 11th Plan to capture the growth opportunities

Pharmaceutical Formulations

In the field of biotechnology, there is a need to focus on the Research & Development, of all cell lines for existing as well as newer vaccine for self-sufficiency. In this area, already a lot of work has been done at the International level for developing therapeutic drug and biotech products for treatment of Cancer, Infectious disease, Heart diseases, inflammatory disorder, allergies etc. India has become a choice for research and clinical trials as the country has all the requirements for carrying out the same. The government should explore the possibilities to support the R & D work that can help local CROs and attract the global pharmaceutical industry. Also

potential scope to create R & D facilities for producing drug products for clinical trials.

Human Resource Development

There is a need to produce highly qualified Doctors/Scientist in this field of science to meet the growing demand in R & D. Institutes of excellence which can liaison with the industry and government must be developed. Focus should also be on continuation of education through training programmes by a well defined training module and also infrastructure.

Indian pharmaceutical companies have been competing for their share in global generic market by creating state of the art manufacturing facilities. It is therefore, imperative to capture the opportunities in contract manufacturing by building large number of units with global standard this would encourage the local industry to manufacture the product as per cGMP norms in order to boost export of their products. This would also generate employment opportunities of technically skilled and unskilled personnel.

In order to meet the global standards, R & D efforts needs to be focused on the various ancillary requirements i.e. primary packaging material, automation in equipments.

Integration of information technology in the field of Pharma and Biotech industry, self-sufficiency in manufacturing of analytical and other ancillary equipments for manufacturing of quality drugs is also an important requirement of the industry.

Intellectual Property Rights (IPR) and Technology Transfer

Closely linked to development of drugs, diagnostics, devices and vaccines are issues of IPR and technology transfer.

Improving public health is one of the most effective means to reduce poverty in developing countries and access to safe, effective and affordable drugs and vaccines is essential to achieving improved health. This has been demonstrated in the battle against such illnesses as tuberculosis, AIDS, malaria and life-threatening diarrhea etc.. Programmes addressing reproductive health and non-communicable diseases also are dependent on modern drugs, too. There is a widening gulf between developed and developing countries with respect to access to advanced health technologies. Primarily either due to inability of developing countries to

generate enough intellectual property for the development of new drugs or there is just not enough money even to buy the generic drugs available. Also, not many pharma companies are willing to invest on R&D on drugs afflicting the poor countries and it is for us to address these issues. There are several strategies being adapted to address this issues both at the global and at the national levels through several mechanisms and public-private partnerships etc.

Besides sufficient and sustained support for research and development (R&D) for the creation of candidate products for the poor, there is also a need to establish policies and systems for improved management of IP to help bring candidate products for the poor to reality, especially since the public sector's experience with handling IP is limited. There is enough evidence to show that better management of IP can be quite powerful in enhancing product development and availability for the poor.

IP is a complex subject which vary by product type, by country, by proposed partner, by the nature of the further development work needed, *etc.* But the following are a few high-priority, highly feasible and complementary tasks.

- Training scientists and officials at universities and research institutes to manage IP.
- Identification and implementation of best practices of IP management to help public sector develop new IP management norms.
- Advising developing and developed country groups concerned with research and product development.
- Promoting coordination and synergy in public sector product R&D through partnerships with the private sector.
- Research on the quantitative relationship between IP and health product availability and cost.
- Collaborate with other countries and other stake holders on issues of TRIPS and other international treaties to facilitate formulation of national policies and strategies for India and other developing countries.

New initiatives

- Centre for Clinical Research including clinical trials research: A Clinical Trial Centre is needed to provide leadership in this field. It should be a facility for human resource development using internationally recognized curriculum related to clinical trials, management of data, designing clinical data base, quality control and assurance. The Centre should help to train clinicians in the concept of scientific and evidence

based medicine. It could also undertake large single or multi centre clinical trial and take part in national and international collaborative trial group and contribute expertise to trials run by others. It could offer advice on trial design or operation, randomize patients or analyze data for groups wanting to run their own trials. The Centre should be committed to promoting the quality and efficiency of clinical trials through ethical considerations, scientific expertise, quality assurance and education.

- Centres for carrying out pharmacokinetic studies in India.
- Toxicology Centre for carrying out regulatory toxicity studies on *Lead* compounds.

Inter agency collaboration and Translating Research into Action

CHAPTER - 4

Terms of Reference

- To review current status of inter-agency, inter-ministry collaboration in priority areas of research and to suggest mechanism of improvement during the 11th Plan period.
- To review the situation regarding research agencies addressing priority areas of research identified by service providers and implementation of major suggestions emerging from research studies and to suggest mechanism for improvement of these during 11th Plan period.

Present status

The Committee reviewed the existing mechanisms and strategies in each of major organizations.

The ICMR has an elaborate peer review system to oversee its research activities. Its Scientific Advisory Board (the highest technical body of the ICMR) includes eminent scientists from different disciplines and Agency/Departmental representatives from DGHS, DBT and DGAFMS. Each Technical Division has its Scientific Advisory Group. Each of the 26 ICMR Institutes has its Scientific Advisory Committee, on which the Programme Managers of Central/State Health Department / Directorates, Representatives of other ICMR Institutes, and non-ICMR scientists are involved. These are intended to provide the ICMR with the directions for research to be pursued without unnecessary duplication, in clearly identified priority areas. Likewise, ICMR is represented in the Scientific Committees of other agencies such as DST, DBT, DSIR, CSIR, Research Councils of CSIR Institutes working in areas related to biomedicine, DGHS, State Councils for S&T, NIHFW etc. The ICMR has been using the following strategies for better utilization of the results of research:

- Involvement of officials of MOH&W, DGHS, National Programme Advisors from the planning stage till the final review meeting.
- Involvement of officials of Government of India in the high-level policy making committees like the SAC/SAG/SAB of ICMR.
- Dissemination of research results to all concerned in MOH&FW and DGHS.
- Holding workshops, symposia, and conferences for dissemination of research results.

- Participation of ICMR officials in the meetings of Health Ministry and DHGS in order to focus its research on the problems and priorities and help the national policies and programmes.

At present, inter-scientific-agency dialogue exists, sometimes on formal basis but mostly on informal basis. For example, ICMR has linkages with the CSIR laboratories and DBT is increasingly trying to forge collaboration with ICMR for efficacy evaluation of products developed by the investigations through the support of DBT, in human subjects. Thus, it was noted a mechanism at informal level exists, through which exchange of information between agencies occurs. However, it was felt that the persons who participate in inter Agency / Institution meetings may very often give personal views and not institutional 'considered opinions'. This result in a lack of true representation in each other's Committees, and the inputs provided by them do not really reflect the Agency's perspective. Therefore such informal `collaboration' leaves much to be desired, in terms of policy directions, identification of research priorities and ensuring the avoidance of duplication of health.

New Initiatives taken in the 10th Plan

Ministry of Health

A Joint Monitoring Group has been set up under the Chairmanship of DGHS to monitor situation of avian flu in the country. This Group meets every fortnight, but in case of an outbreak meets daily. The members of the group include representatives for Animal Husbandry, the NICD, ICMR and WHO country office.

A high level Task Force chaired by Secretary (Health) also meets on avian flu every fortnight. It includes representatives of Department of Animal Husbandry also.

CSIR

The Department of AYUSH, CSIR and ICMR have entered into the Golden Triangle collaboration for research on traditional systems of treatment. The Bhasmas and Rasayanas would be systematically and scientifically studied for their role in management of identified conditions like joint disorders, *bronchial allergy, fertility and infertility, cardiac disorders, irritable formal* syndrome, diabetes, malaria, filarial and kala azar. The CSIR would the QC and predinical studies which the ICMR would assist in clinical evaluation.

DBT

The DBT and ICMR have signed a Memorandum of Understanding to work together on areas of mutual concern. HIV/AIDS and Microbides are examples of two areas where a 'call for proposals' for joint funding has been issued. A Centre for Translational Research is coming up.

Recommendations

Realizing the importance of sociological studies, it is recommended that the ICMR-ICSSR (Indian Council for Social Sciences Research) Joint-Panel be revived. Links with other Institutes like the Indian Institute for Philosophical Research should be established.

It is important to understand the varied type of social phenomenon in medicine, if the health care services are to function better. For example, study the different attitudes and values which various segments of population have towards health, illness, and medical care, social organization of health personnel; social structure and functioning of hospitals; social rates played by patients and health personnel as they interact in different settings; social processes through which health personnel acquire the outlook, standards, and competence for providing satisfactory professional service; social and psychological factors concerning different kinds of disease; studies are also needed on medal students, nurses and doctors; what medical personnel expect of patients, and on types of behaviours that patients expect of medical personnel.

As suggested by PAB of ICMR an overarching National Health Research Management Forum should be put in place wherein all existing and the prospective players in health research will have a space of their own. In this representation of all key stakeholders will be ensured. The ICMR would act as its Secretariat, and would have the following functions:

- To advise on and evolve national health research policies and priorities and to evolve mechanisms and action plans for their implementation;
- To review the output from the National Health research System annually and provide suggestions;
- To promote the development of health research activities in the country;
- To review biomedical & health research management, and suggest strategies to overcome problems in implementation of policies;

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

The National Health Research Management Forum would be chaired by the Minister of Health, Secretary-DG ICMR with Secretaries of Health, DST, DBT, CSIR, AYUSH, DG-DGHS one representative each of private sector and industry, and about three eminent health scientists of the country.

Create a coordination structure with other Ministries, S&T agencies and other partners (like ICSSR) where technologies developed by other organizations are assessed and if found suitable are moved into the system.

Create several public-private platforms analogues to some of the existing ones in other departments (like NIMITLI) in down stream health technologies which are not being addressed currently.

Human Resources Development for Health and Biomedical Research

CHAPTER - 5

Terms of Reference

- To review the manpower position and infrastructure available for research in research institutions, universities, medical college and service institutions and to suggest mechanisms for optimal utilization of these human resources and facilities during the 11th Plan.

Introduction

The human resources capacity for health research is a measure of country's capacity and capability to effectively address to existing and emerging health concerns of the country. Further strengthening of efforts is required to bridge the existing gap in the availability of trained human resource in health research not only within India but also for the South Asia region and beyond. It is important to select appropriate analytical method that would best identify current and future needs. The policy goals should be laid down clearly in the order of priority. The strategies that will support their realizations should be identified.

Human Resource Development

The ICMR should formulate a HRD development plan which should focus on developing policies, procedures, and partnerships to ensure the competitiveness of Indian science in health research. Skilled and talented people are undoubtedly the most important resource for the delivery of high quality science and its translation for the public's health. Current recruitment policies preclude staffing changes that will be conducive to the conduct of research at the cutting edge of science. There should be a recruitment policy to attract and retain the right calibre of staff to meet the country's evolving needs. The aim should be to employ highly qualified staff to deliver outstanding results. While primarily considering qualifications, knowledge, skills and personal qualities it should also evaluate the capacity to adapt and evolve over the longer term. The career opportunities should be made more attractive not only for current employees but also for scientists abroad. It may be necessary to restructure the compensation package offered to scientists to very generous levels by adopting an aggressive approach. At the minimum the pay structure would be on par with those of other S&T organizations in the country such as the CSIR and DBT, including introduction of appropriate number of positions at Scientist G and H levels. All efforts should be taken to retain distinguished scientists and should consider offering a Rs. 26,000 scale also. Similarly the career opportunities and compensation packages of technical staff should also be reexamined.

There should be an organized and focused effort towards formulation of a long term comprehensive human resource development policy and plan to address wide range of related issues. For almost twenty years, many Institutes/Organizations in social sector like the ICMR have had a ban on creation of new positions which is continuing. Only openings available have been on superannuation or resignation of staff. It has not been possible to address cutting-edge areas of modern science adequately. Retraining and re-deployment has helped but not much. Consequently several Institutes of ICMR are sub-critically staffed. There is thus an urgent need for assessing the requirements and creation of adequate number of new positions. For example, the Performance Appraisal Board of ICMR has recommended creations of 500 new scientific positions.

The objective of the Policy should be to ensure the conduct of quality and relevant health research by recruiting, training, managing and retaining a sufficient number of health research personnel based on identified priority areas of research needs and within sustainable resources.

Development of research capacity

The human resource and skills required for meeting the current demands and future challenges is abysmally low. In a billion populations, In a billion populations only a very small number is engaged in health research. The ICMR should liberalize its policy of institutional fellowships like SRFs and RAs. These Fellows could be mentored by senior scientists. As happens in other international research agencies, like the NIH, those who do good work could compete for regular positions as and when advertised.

Examples of some of the ICMR schemes which are currently in operation:

- ICMR Fellowship Programme for Sr.Research Fellow and Research Associate.
- Jr. Research Fellowship Programme in collaboration with PGIMER, Chandigarh.
- MD, Ph.D. programme in collaboration with Sanjay Gandhi Institute of Post-Graduate Institute, Lucknow.
- It provides support for MD thesis in priority area.
- Supports Indian scientists (Jr. and Senior) for training abroad, as well as scientists from developing countries to come to India.

The ICMR also offers some regular training courses:

- Super-Specialization (DM in Haematology)
- Post Graduate Courses
  - Masters in Applied Epidemiology
  - M.Sc.
    - Applied nutrition
    - Virology
    - Entomology
  - Diploma
    - Occupational Health
  - Certificate course
    - Nutrition

In addition, the ICMR provides short term training courses in nutrition, virology, animal sciences, epidemiologic technique, outbreak response, transfusion medicine, vector control, occupational health, genetics, ethics etc.

The NCHM has recommended that along with domestic resources, external aid, WHO assistance etc. be fruitfully utilized for developing such capacity by earmarking fellowships every year to institutes of excellence abroad and within India. Of the total 25% must be at the doctoral level and the rest at the Master's level. It should be our target to have a pool of at least 500 persons with a combination of such critical skills by the end of 2012. Such fellowships should be open for competition and not be confined to central government employees of the Ministry of Health. This will help develop capacity and expertise outside government and be available for policy advice in an objective manner. The working Group supports this recommendations.

Specific disciplines for human resource development

One of the important areas in which there is an acute shortage of human resource is social scientists to work on social determinants of health. Social scientist can bring a social science perspective to practice of medicine, making doctors socially responsible, sensitize them about the role of culture and social relationship in causing and treating disease. Well trained social scientists are needed who can undertake researches in an interdisciplinary perspective to contribute to the social science of medicine and health and assist in improving health people of the community. Very little research has been done in India on sociology of sickness and on medical anthropology, encouragement should be provided for development of human resource in

the field by creating opportunities for training and teaching. A special effort should be made to develop and nurture this expertise.

Some of the other areas in which human resource is needed include:

- Epidemiology, Public Health
- Clinical trials
- Toxicology, animal technologies
- GCP, GLP
- Quality control and Quality assurance
- Genomics and gene therapy
- Bioinformatics
- Health information technology
- Geriatrics
- Health economics
- Socio-behavioural sciences
- Bio-ethics
- Biotechnology
- Molecular Biology
- Stem Cells research and stem cell therapy
- Genetics

Biomedical Research Information Technology

CHAPTER - 6

Terms of Reference

- To study the current status of access to research information from India and abroad to researchers in India, suggest mechanism for research information dissemination and central clearing house for facilities for research information.

Introduction

Information is central to the growth and development of medicine – the practice, teaching or research. In the present times, when new information is growing at an exponential rate, professionals are finding it difficult to cope with the deluge of information. Informatics is also playing a vital role in discovery research. The different kind of data that are required in managing a drug discovery is enormous. The challenge is to make different sets of knowledge bases to complement each other. In the post-genomic era, the research paradigm has shifted towards more rational models. Added to this are the ever growing genomic, proteomic, and transcriptomic databases. Even to find and read the meaningful and relevant content from myriad publications today. There is need for computational text mining. Suitable information tools to churn and extricate useful information need to be developed to complement the explosion of data. The entire spectrum of information ranging from three dimensional protein structures to clinical data is now available. There is an urgent need for an integrated informatics platform which fosters various facets of drug discovery research. With the rapid generation of information, new journals are being started to cater to such needs. The number of scientific journals is growing at a steady 5-7 percent per annum. Despite an occasional discontinuation, the number of journals doubles every ten years. There are an estimated 50,000 in biomedical sciences.

In addition, numerous of reports, status papers and other documents are produced. There are also documents, which give data relating to various parameters such as population, health indicators, mortality and morbidity statistics *etc.*, which are equally important for researchers, policy makers and other decision makers. Availability of such information is also very limited in the existing system of information and communication.

This growth of the literature has made virtually impossible for information-seekers access literature from primary sources such as the printed journals.

Secondary information sources such as abstracting/indexing journals have come into existence to provide ready and rapid access to the content of journals. But to effectively search and retrieve the most relevant information, the use of appropriate technology is essential. This is where the information technology such as computers, computer-readable databases, CD-ROM technology, satellite-based communication systems *etc.* provides the necessary tools to fulfill the requirement.

IT based Information services have thus become an essential infrastructural requirement for supporting medical community whether they are practicing physicians, teachers of health care providers at the community level or researchers in medical colleges. Unfortunately, the existing health science information infrastructure is rather inadequate to meet the complex needs of the health professionals. In order to make health science libraries more responsive to the growing demands of the health team and to meet the challenging needs of information and documentation, it is imperative that the existing resources and services for health science libraries are strengthened.

The new electronic technologies have also come to be regarded as powerful agents for helping the libraries to achieve speedier access to information. They have, in fact, revolutionised every function of the library and information science to the benefit of both the library profession and the users especially in the West. And the advent of computerised databases has largely helped researchers to now easily update their knowledge fast with a variety of tools and technologies of information retrieval. Information highway, info- routes, cyberspace- all of these terms point to the same future: the "information revolution" – a result of progress made in telecommunications and computing, along with the expansion of mass media. More and more medical researchers are now beginning to rely on the World Wide Web and the Internet.

While the new technologies have made the access of information faster and easier, this has benefited only those scientists located in the metropolitan cities and/or those working in well funded Government laboratories. Information access to scientists/teachers in most Medical Colleges/Universities/Research Institutes *etc.* is still poor as they are deprive of these very basic facilities; this may be one of the reasons why quality of science/research from these areas is not really up to the expected standard.

Information Technology is now one of the major components of the technological infrastructure for health management. All sub-sectors dealing with the generation, transmission and utilization of demographic and

epidemiological data such as bio-informatics, bio-statistics, HMIS and the decision support systems (DSS) are finding increasing use in health planning and management. The nationwide network of NICNET provides rapid reporting mechanism for health information, MEDLARS Biomedical Informatics Programmes provides ready access to medical databases to post graduates and research workers as well as practicing physicians. Planning Commission has provided additional central assistance to the UHSs in Karnataka, Andhra Pradesh, Tamil Nadu, Punjab and Maharashtra for strengthening of libraries and networking them through IT. This effort has to be augmented and all medical colleges need to be brought into the network.

Following are the major initiatives taken by of ICMR

- The Indian Journal of Medical Research (IJMR) was made available full-text free on the website www.icmr.nic.in from 2004. New sections such as Editorials, Commentaries, Letter to the Editor have been introduced from January 2004.
- A series of four Lancet-ICMR Workshops on Medical Paper Writing for Publication conducted in February 2005 at Vellore, Kolkata, Mumbai and New Delhi. Junior and middle level scientists from medical colleges participated in these workshops. Received very encouraging feed back.
- ProQuest full text electronic database which contains about 550 + full text medical journals subscribed. The Council has installed only two sites of ProQuest for NICED, Kolkata and NIN, Hyderabad during the year 2002-03 and later, due to increase in demand, four sites more were installed at NJIL & and Other Mycobacterial Diseases, Agra; RMRC, Dibrugarh; ICMR Hqrs, New Delhi; NIMR, Delhi.
- JCCC@ICMR subscribed. JCCC is customized e-journal gateway-cum-database service.
- The ICMR-NIC Centre for Biomedical Information's website has been ranked the top Indian health website by Google since November 2003 and has won several awards for the content as well design. The webpage provides links to the Centre's services in addition it also acts as a portal to National Library of Medicine's (NLM) databases as well as other resources available over the Net. A Meta search tool, MetaMED, was designed to search NLM's PubMED and the Centre's IndMED database in one click.
- medIND database (a full-text version of IndMEd journals) was launched *in August 2003 at www.medind.nic.in.(extramural)*

- A prototype Open Archive, OpenMED@NIC, was launched for Medical and Allied Sciences where authors/owners can self-archive their scientific and technical documents.

Recommended initiatives for the 11th Plan

The 10th Plan *inter-alia* had focused on building up a fully functional accurate health management system, utilizing available IT tools, so as to enable the real time communication link to send data on births, deaths, diseases, requests for drugs, diagnostics and equipment, facilitate decentralized district planning, implementation and monitoring.

A web based, one point interactive health research information system should be developed 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. The Health Research Information System would need to be linked with policy and decision-making

A National Institute of Health Information System, as already recommended by NCMH, should be established. For this purpose, CBHI should be properly upgraded with necessary supports from public health, statistics and national health programmes to play the role effectively. This institute will also be responsible for Human Resource Development and research studies. NIMS, ICMR may be involved in taking up evaluation studies and operation research periodically. The recommendation of National Statistical Commission to upgrade the CBHI as a full fledged Directorate of Health Statistics as a nodal agency to provide sufficient inputs on health statistics should be seriously pursued. The Monitoring and Evaluation division of the Department of Family Welfare which is responsible for collecting and collating all Family Welfare information including RCH should be merged in the proposed National Institute of Health Information System. Keeping in view the recommendations of NRHM, the synergy between the Health and Family Welfare Information System need to be made and this Institute should be responsible for Monitoring and Evaluation of all health related programme including RCH.

Telemedicine

With the area of 3.3 million sq km, population of 1.1 billion, urban-rural divide, inaccessible hilly regions, islands and many tribal areas, India is an ideal setting for telemedicine assisted health care delivery. Growing number of medical, paramedical colleges and schools with lack of adequate infrastructure, learning materials and teachers needs is a matter of grave concern. E health technology has the potential to create a national level GRID which can form the backbone to be shared by healthcare providers, trainers and beneficiaries. A strong fiber backbone and indigenous satellite communication technology in place with large mass of human potential trained in IT and local presence of telepathy industry, e-health application and implementation should not be a problem technically. Further, a number of pilot projects over last five years with successful outcome stand to its testimony. A ground work on telemedicine in the country has already been laid with the efforts of ISRO and Information Technology department partnering with many State Government and specialty Institutes/hospitals. Policy standardization and infrastructural issues have already been researched.

A strong formulation for telemedicine in the country has been laid by ISRO and the Department of Information & Technology partnering with many State governments, hospitals and specialty hospitals. Issues of policy, standardization and infrastructure have been delved into by them. Professional societies on telemedicine/ e-health are actively engaged in its development.

Telemedicine aims at equal access to medical expertise irrespective of the geographical location of the person in need. Recent developments in Information and Communication Technologies (ICT) have enabled the transmission of medical images in sufficiently high quality that allows for a reliable diagnosis to be determined by the expert at the receiving site.

Access too many different sources of medical data, usually geographically distributed, and the availability of computer based tools that can extract the knowledge from that data are key requirements for providing a standard healthcare provision of high quality.

Developments in the integration of bio-medical knowledge, advances in imaging, new computational tools and the use of these technologies in diagnosis and treatment suggest that Grid-based systems can make a significant contribution to this goal. In addition to enhancement of improved

access by integration of information, the benefits are raised to a new level, over a Grid because of multi dimensional access to the information.

It is understood that the *National Task Force* has recommended a National Telemedicine Grid which will contain the following major functions / constituents. The Task Force is already looking into the connectivity, hardware, software requirements for projection under the 11th Five Year Plan which could be incorporated in the Report of the Health Informatics Working Group. Essentially the following is already under consideration of the Task Force:

- A health portal at the Ministry of Health & Family Welfare providing all information related to health informatics, telemedicine, disease surveillance data, medical care details and other educational material or information related to specific Indian healthcare system not available in the internet or hyper link to the internet data repository. This portal will be a constituent of the national grid for repository of information and guidance.
- An All India Medical Institution network connecting the various recognised medical institution, national institutes like PGMER, AIIMS, JIPMER, SGPGI etc., and major super specialty hospitals (Government and Private) in the country for medical education, exchange of knowledge, CME etc.
- An All India Network connecting the various selected district hospitals in the country to be connected to major super specialty hospitals (Govt. /Trust/ Private) for specialist referrals for consultation and treatment and also medical informatics, disease information and health promotion aspects from different states of the country. (super specialty hospital network).
- A national network for medical training connecting various agencies in the country and also establish/integrate similar networks at state levels. (National Medical Training Network).

State Telemedicine/e-Health Grids (STG)

As a part of e-health program and digitalisation of health records, some of the states have been operating Telemedicine Networks initiated by ISRO and other agencies like Department of Information Technology (DIT) under Closed Usage Group (CUG) concept e.g. Chhattisgarh, Karnataka, and Kerala. Many more states are planning to implement such state level networks. There is a need to formalise the state Telemedicine networks into standard State Grids for specific purposes of application and usage like; providing State Health Information, Monitoring and Surveillance of

Disease/Epidemic outbreak, identification and mapping susceptible areas and population etc., as mandated by MoH&FW for health governance.

National Medical Education Institutions Network (NMEIN)

A National Medical Education Institutions Network if created would act as a useful resource base for knowledge sharing for Medical Education, Research and training including CME. The teaching and practical sessions can be configured in live or recorded video, audio and information data broadcast, accessed on the grid, for an effective learning experience.

Association / Society / Health portals Network (ASHPN)

Several associations/agencies are hosting and maintaining diverse health portals like DOCTORYANYWHERE.COM in health care services.

It is necessary to pool the resources available with the various autonomous/government/trust medical associations like Indian Medical Association (IMA), Cardiology Society of India (CSI), Neurological Society of India (NSI), Federation of Gynaecological and Obstetrics Society of India (FoGSI) etc and form an Association/society /health portals Network.

Digital Library & Medical Informatics Network (DLMIN)

It is required to establish a Digital Library & Medical Informatics Network, that will be a network of pooled information in the form of digital library of data bases and Medical/Health Information that can be accessed through Internet / Intranet and used for administrative/research and / or clinical purposes.

Some of databases of immediate value would include, but not limited to:

- Manuals of illness, diseases, symptoms, and diagnostic tools.
- National registry of specialty hospitals and specialists: names, contact information.
- Health education programs and curricular materials.
- Medicines: description, side effects, location, costs.
- Online journals, abstracts, preprints.
- Environmental profiles by state/region
  - Locations of safe water supplies.
  - Location of polluted sources (symptoms and treatment).
  - Location of emergency food supplies.
  - Location and description of health services.

- Location of disease outbreaks.
- Changing environments.

Disaster Management Support Network (DMSN)

It is required that the health care services in times of disaster can be effectively provided through establishment of Disaster Management Support (DMS) Network. This network is required to integrate identified disaster Monitoring Stations (current and proposed) across the country and provide periodic and timely information both statistical and remedial to the central station for necessary advice/action through the power of medical informatics and digital connectivity.

Capacity building: Thrust of health informatics education should be use of health information standards, storage of health information in electronic health records and research and extra collation of health information for better healthcare. Clinicians, healthcare managers, technologists, researchers would all need to specialize in various aspects of healthcare technologies. The course for skill development to include, certificate course in computer application, education framework for general, para-medical and nursing staff. These courses would need to be certified by Medical Council of India.

System of statistical data and collection

In India, health information exists at various levels, forms and systems. There is a wide variety of data that are collected by several agencies, mainly government, both at the Central and the State levels through routine data collection and periodic sample surveys. There is a plethora of information concerning the health sector but in a highly fragmented manner. The health management information system at the ground level especially tends to be duplicated by various agencies.

A major problem of health information is the reliability of data and consequent utilization for decision-making. In some respects, the reliability, relevance, timeliness and quality of the data are questionable. There is therefore a need to review national health information systems at various levels — Central, State, district and block— by various agencies — different ministries and departments in the government — method of data flow, gaps in data, utilization of the data, organisational set up, accessibility of information to various persons at various levels are aspects to be examined. Such a review would help in improving data collection techniques and quality, selectively expanding and examining the data load at various levels,

different types of information sources, biases in data management, reporting of data transmission, vertical, horizontal, utility and use of information, protocols for monitoring and evaluation of health information systems on a routine basis.

These shortcomings are known and have been spelt out by the Statistical Commission of India. It is recommended that action be taken to implement the recommendations made therein with regard to the particular needs of the health sector. Non availability of good quality data and reliable baseline estimations are responsible for lack of clarity in policy design and strategies being adopted.

Other steps to improve information access and flow include i) commitment for sharing information and using electronic media; and ii) standardizing formats for information exchange.

Action Plan for Research Information Dissemination

The current state of library and information network in medical colleges continued to be poor. There is thus a great need to upgrade these facilities to bring them, at least to a level at par with other libraries in sister disciplines using IT. Students and teachers in these disciplines get adequate exposure to the new information technology and are quite comfortable using these new facilities in these libraries some of which are near global level. There is no reason why the same cannot be done in medical colleges.

Policy makers have also shown inclination towards a comprehensive and wholesale upgradation of such facilities and the recognition that without modern information technology there cannot be any real progress in the quality of medical education. It is important to motivate the library personnel to take up the new challenge, as new IT would help them provide better services to their user. A systematic approach is called for to chalk out a strategy for the revamping exercise. As a starter an in depth, evaluation is required to know the existing facilities of these libraries in terms of existing availability of hardware and software and plan means of strengthening the libraries. In fact, the ICMR has just started steps to modernize its network of libraries and upgrade them to modern information centres. In view of the massive exercise involved, it has been proposed to take up this in a phased manner to enable both the information providers and users come to grips with the new developments. A similar exercise is needed for the revamping of these libraries, especially those in medical colleges.

Some Suggested Strategies/recommendations

Some of the action points to help the overall improvement of the medical college libraries including the use of IT in these exercises to provide easy and speedier access to relevant information for all health personnel and other users are given below. Some of these have been suggested in the 10th Plan but could not be implemented.

- As seen, the present IT infrastructure of the medical colleges/ biomedical institutions libraries in terms of user needs and the potential for growth. Undertake this modernization in a phased manner to bring all the libraries of the medical colleges / biomedical institutions to a certain minimum benchmark in terms of infrastructure, databases and services offered in the first phase.
- Create computer-readable indexes of the holdings of these libraries. Automate in a phased manner routine library operations like indexing, issue and return of books, reminder system, inventory control of purchases *etc.* through computerization.
- Switch over as far as possible from printed versions of alerting/journals/reference sources like *Current Contents, Index Medicus, Tropical Diseases Bulletin*, and some core medical journals, to the electronic form as CD-ROMs, to improve the accessibility of literature, save reader's time and save shelf space in the library. Train users to access these facilities themselves.
- Train the library staff on a continuing basis to get familiar with the rapidly changing technological developments in the area of computer-based communications to access/provide these new facilities to users. Involve IT professionals in library activities.
- Plan steps towards national resource sharing and networking of the libraries. To begin with, libraries can network with institutes/universities, which are closer in terms of proximity. They should also be encouraged to join networks of other libraries with the current IT infrastructure in India thus should be possible.

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ANNEXURE

WG 3

No.2(11)/2006-H.&F.W.
Government of India
Planning Commission
(Health, Family Welfare & Nutrition)

Yojana Bhawan
Sansad Marg
New Delhi
25th May, 2006

ORDER

Subject: Working Group on Health Systems Research, Biomedical Research & Development and Regulation of Drugs and Therapeutics for the Eleventh Five-Year Plan (2007-2012)

In the context of formulation of the Eleventh Five Year Plan (2007-12), it has been decided to set up a Working Group on Health Systems Research. Biomedical Research & Development and Regulation of Drugs & Therapeutics under the Chairmanship of Director General, ICMR, New Delhi. The composition of the Working Group will be as follows:

1.	Director General, Indian Council of Medical Research, New Delhi	Chairman
2.	Representative, Deptt. of AYUSH, Ministry of Health & Family Welfare, New Delhi.	Member
3.	Representative, Deptt. of Health and Family Welfare, New Delhi	Member
4.	Representative, Deptt. of Science & Technology, New Delhi.	Member
5.	Representative, Deptt. of Bio-technology, New Delhi	Member
6.	Representative, Directorate General of Health Services, New Delhi	Member
7.	Representative, Council of Scientific and Industrial Research, New Delhi.	Member
8.	Drugs Controller of India, DGHS, Ministry of Health & Family Welfare, New Delhi	Member
9.	Director, Central Drugs Research Institute, Lucknow	Member
10.	Director, Industrial Toxicology Research Centre, Lucknow	Member
11.	Dr. C.K. George, Director, Institute of Health Systems, Hyderabad.	Member
12.	Dr. Y.K. Gupta, Professor of Pharmacology, All India Institute of Medical Sciences, New Delhi	Member
13.	Prof. V.R. Muraleedharan, Indian Institute of Technology, Chennai	Member
14.	Director, Indian Institute of Science, Bangalore	Member
15.	Shri Rajeev Lochan, Director, (Health), Planning Commission, New Delhi	Member

16.	Shri K.M. Gupta, Director, Ministry of Finance, New Delhi	Member
17.	Dr. Ranjit Roy Choudhary, New Delhi	Member
18.	Dr. Somnath Roy, Emeritus Professor, New Delhi	Member
19.	Dr. Y. Atal, Ex-Principal Director, UNESCO, Gurgaon	Member
20.	Dr. Mira Shiva, Voluntary Health Association of India, New Delhi	Member
21.	Dr. Amar Jessani, Centre for Enquiry into Health & Allied Themes, Mumbai	Member
22.	Deputy Director-General, Indian Council of Medical Research, New Delhi	Member-Secretary

2. The terms of reference of the Working Group will be as under:

(i) To review the position/progress/problems in basic, clinical, applied and operational studies during the 10th Plan period and to suggest priority areas for research in these areas, and mechanism to avoid duplication/overlapping and to bring about transparency and social control in research work including ethical issues during the 11th Plan.

(ii) To review the current situation regarding development, testing and quality control of drugs and devices, both in the modern system of medicine and AYUSH and suggest priority areas for research and institutional strengthening during the 11th Plan period.

(iii) To review the manpower position and infrastructure available for research in research institutions, universities, medical college and service institutions and to suggest mechanisms for optimal utilization of these human resources and facilities during the 11th Plan.

(iv) To review current status of inter-agency, inter-ministry collaboration in priority areas of research and to suggest mechanism of improvement during the 11th Plan period.

(v) To review the situation regarding research agencies addressing priority areas of research identified by service providers and implementation of major suggestions emerging from research studies and to suggest mechanism for improvement of these during 11th Plan period.

(vi) To study the current status of access to research information from India and abroad to researchers in India, suggest mechanism for research information dissemination and central clearing house for facilities for research information.

(vii) To review the current investment in bio-medical research and health systems research by various agencies and project requirements to address the identified priorities during the Eleventh Plan period.

(viii) To deliberate and give recommendations on any other matter relevant to the topic.

3. The Chairman may form sub-groups and co-opt official or non-offical members as needed. The Working Group will submit its report by 31st August, 2006.

4. Shri Rajeev Lochan, Director (Health), Room No.463, Planning Commission, Yojana Bhawan, New Delhi will be the Nodal Officer for all further communications.

5. The expenditure on TA/DA in connection with the meetings of the Working Group in respect of the official members will be borne by the parent Department/Ministry to which the official belongs as per the rules of entitlement applicable to them. the non-official members of the Working Group will be entitled to TA/DA as permissible to Grade-1 officers of the Government of India under SR 190 (a) and this expenditure will be borne by the Planning Commission.

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To : The Chairman and all Members of the Working Group.

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2. All Pr. Advisers/Advisers/HODs in Planning Commission
3. Prime Minister's Office, South, Block, New Delhi
4. Cabinet Secretariat, Rashtrapati Bhawan, New Delhi
5. US (Admin.I) / Pay & Accounts Officer/Accounts-I Section, Planning Commission/DDO, Planning Commission
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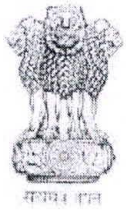
October 2006

REPORT OF THE WORKING GROUP ON HEALTH CARE FINANCING INCLUDING HEALTH INSURANCE FOR THE 11TH FIVE YEAR PLAN



Ministry of Health & Family Welfare

Nirman Bhawan, New Delhi - 110011

Ministry of Health & Family Welfare

Subject: Report of the Working Group on Health Care Financing including Health Insurance for the 11th Five Year Plan

* * * * *

The Planning Commission constituted a Working Group on the above mentioned subject with the following Terms of Reference:

(i) To review the present position of health financing at state, centre and individual levels. Keeping in view identified problems and constraints of existing system, make suggestions for improvement in quality and efficiency with reduction in the cost of health care to the poor in the Eleventh Plan;

(ii) To suggest management strategies for community based health insurance as well as process and impact assessment parameters for these initiatives during the Eleventh Plan;

(iii) To assess disease burden and cost of ill health in the country and project figures for 2012 and 2017;

(iv) To give cost estimates for health care-public, NGO and private-current and for the Eleventh Plan period;

(v) To suggest alternative sources / strategies for health financing during the 11th Plan to meet the cost of health care;

(vi) To deliberate and give recommendations on any other matter relevant to the topic.

The membership of the Committee was as follows:

1	Secretary (Health & FW) Ministry of Health & Family Welfare, GOI	Chairman
2	Joint Secretary (In-charge of Insurance), Ministry of Finance	Member
3	Joint Secretary, Ministry of Finance	Member
4	Director General, NSSO, New Delhi	Member
5	Director General, NCAER, New Delhi	Member
6	Secretary (Health), Government of Andhra Pradesh	Member
7	Secretary (Health), Government of Madhya Pradesh	Member
8	Secretary (Health), Government of Karnataka	Member
9	Secretary (Health), Government of Gujarat	Member
10	Shri A. Kumar, Director (H&FW), Planning Commission, New Delhi	Member
11	Shri K.M. Gupta, Director, Ministry of Finance, New Delhi	Member
12	Director, Centre for Development Studies, Thiruvananthapuram	Member
13	President, IMA, New Delhi	Member
14	Shri Ashok Sahni, Hon. Executive Director, Indian Society for Health Administrators, Bangalore	Member
15	Dr. Ravi Duggal, CEHAT, Mumbai	Member
16	Shri B.B.L. Sharma, Health Economist, New Delhi	Member
17	Prof. Ramtesh Bhatt, IIM, Ahmedabad	Member
18	Dr. A.S. Dua, Former Member, Sub-Commission, NCMH, New Delhi	Member
19	Dr. Moneer Alam, Health Economist, IEG, New Delhi	Member
20	Dr. K.S. Nair, Faculty, NIHFW, New Delhi	Member
21	Dr. P. Mohapatra, Ex-Director, Institute of Health Systems, Hyderabad	Member
22	Joint Secretary, Ministry of Health & Family Welfare	Member Secretary

The Secretary (H&FW) authorized Ms. K. Sujatha Rao, AS & DG (NACO) to be the Chairperson on his behalf and Shri Amarjeet Sinha, Joint Secretary, Ministry of Health and Family Welfare, to be the Member Secretary. The group met on 18th July, 2006. The minutes of the meeting are placed at Annex – I.

Introduction : The context

India is one of the few countries that has a public health spending of less than 1% of GDP resulting in nearly three quarters of the money being met from out of pocket by households. Of the Rs. 148727 crores spent on health during the year 2004 – 2005 accounting to 5.2% - of 5DP at the factor cost Government spent is about 22% (Annexure II) Almost 73% was met by households making it a very regressive system of health financing. Of this, about 50% was spent on primary care. Estimates show that Government in 2004-2005 met barely 50% of the total required to implement the six National Health Programs aimed at controlling communicable diseases such as malaria, TB, leprosy, HIV/AIDS and RCH. Besides, data also shows that over time, revenue outlays for health in proportion to total budgets have been steadily falling in almost all states. **Annexure II, III, IV.** Data also showed that besides chronic underfunding, the sector was plagued with instances of inefficiencies at several levels resulting in waste, duplication and suboptimal use of scarce resources. All these factors combined have had an adverse impact on the functioning of the public health sector's ability to provide health care services to the people, resulting in an estimated 3.3 % of the population getting impoverished on account of high health expenditures incurred in private sector hospitals. Health spending averaged 11% of non food expenditures and almost 5% of the total annual expenditures of households. Almost 40% were reported to have taken loans to incur such expenditures and nearly 10% sold assets resulting in intergenerational poverty.

It is in the above context that the Working Group on Health Financing deliberated the specific TOR's in two meetings as under :

Terms of Reference – I

To review the present position of health financing at state, centre and individual levels. Keeping in view identified problems and constraints of existing system, make suggestions for improvement in quality and efficiency with reduction in the cost of health care to the poor in the Eleventh Plan;

The Working Group on Health Financing initiated the deliberations keeping in mind the need to ensure an equitable and efficient health system through the rational use of resources. In reviewing the present position of health financing and the existing system of health financing in the country, note was taken of the recently published report of the National Commission on Macro Economics and Health (NCMH August 2005) which had undertaken a detailed exercise on financing of health care. The Report had made certain projections of investments required to be made in the health sector for reducing inequities and inefficiencies that characterize the health sector. The WG also reviewed the health spending estimates as provided under the National Health Accounts framework for the year 2001-02 and later reiterated by the Ministry of Health- **Annexure V.** It also noted three subsequent developments having implications for health financing:

a) The NSSO 60th Round Report (January – June 2004) on Morbidity Health Care and the condition of the aged (March 2006) showing two worrying developments : an increase by nearly 50% in health expenditures in urban and rural areas as compared to the last survey conducted in 1994-5;and a near stagnation in the utilization of public facilities with a sharp fall in Bihar - **Annexure VI .**

b) The Report of the Task Force on Innovative Health Financing Mechanisms under the NRHM (December 2005). The Report recommended the need to develop systems for risk pooling for obtaining access to medical services from the public and private facilities in accordance with commonly agreed standards and prices. Based on this the Ministry of Health & Family Welfare has developed a framework for Community Health Insurance advocating a policy of different approaches being adopted as far as risk pooling and community health insurance is concerned.

c) Approval of the detailed Framework for Implementation of the National Rural Health Mission (July 2006). The approval includes in principle agreement on financial resources for the NRHM 2005-2012 in line with the commitment made in the Common Minimum Programme and the recommendations of the NCMH, providing for an annual increase of 30-40% Central Government allocation and 10% by States'.

Apart from the NSSO surveys that have shown the steady decline in the utilization of public facilities except in a few states, evidence from several other reports have also conclusively brought out the increasing dependence of the private households on the private sector, often paying huge amounts often for substandard quality of care. While at the periphery, primary health care facilities lack drugs, well trained personnel, diagnostic facilities, poor access due to inconvenient location and mismanagement, the higher level facilities provide low quality of care due to patient overload and exhausted staff. It is clear that with the mere correction of these shortcomings and by bringing in better management, utilization of the existing facilities can be improved. This alone will substantially reduce out of pocket expenditures, particularly among the poor, and also get better returns on the investments made in the establishment of the public health infrastructure.

The dysfunctional nature of the health was also perceived to be the result of a centralized disease control approach that provided little scope for inclusive strategies where the beneficiaries of the system also had a role to play; inflexible financial systems and procedures; and poor human resource management. The financing system is equally dysfunctional as funds are released in five years cycles, divided under different and complex budget heads- revenue, capital etc providing for little flexibility to respond to any health emergency. To address such technical and allocative inefficiencies in resource utilization, Government has in the last one year initiated several interventions under the National Rural Health Mission (NRHM) in 5 key areas that when implemented will have a significant impact on reducing current inequities in health care financing and access.

- Decentralized planning under which every district is expected to prepare a perspective and an Annual District Health Action Plan 2005-2012, projecting the basic health care needs of local communities, integrating also the wider determinants of health and combining promotive, preventive and curative care in a common referral link that operates from the village to the District Hospital. This process is based on the principle of decentralization of funds and functions to Panchayat Raj institutions and locally elected bodies, hospital committees in partnership with community organizations and Village Health and Sanitation Committees and broader civil society. This measure will bring in both accountability and generate demand for services as well;
- Strengthening of management capacity at all levels, with equal emphasis on skill development and development of the required human resources for coping future health challenges;

- Improved financial management by providing flexibility and making it performance and outcome based;
- Improved delivery of services based on the recognition of the need to guarantee a minimum package of services to every citizen at all the levels of care; and
- Close monitoring based on baseline surveys and a list of critical health indicators.

The practice, constrains and action needed to overcome taken may be seen at **Annexure- VII**.

It is believed that the implementation of the above initiatives will increase utilization of the health facilities and provide the poor a measure of protection from risk and reduce out of pocket expenditures. The implementation of the policy framework indicated above will however require a quantum increase in resources. Such an increase is expected to be provided under the NRHM during the XIth Plan period as per norms described below :

NORMS AND BROAD FINANCIAL FRAMEWORK OF THE NRHM:

The NRHM derives its cost norms from three sources: (i) existing norms of schemes brought under the umbrella of NRHM; (ii) norms and (iii) standards developed by the National Commission on Macro Economics and Health; norms suggested in the EFC. A diverse set of norms are expected to provide flexibility to States in planning and to accommodate interventions/innovations as required for meeting local needs.

For achieving program efficiencies ,the National Disease Control Programmes related to control of TB, Malaria, Blindness , Iodine Deficiency, Kalazar. the Integrated Disease Surveillance Programme, and all the Family

Welfare Programmes of the Ministry of Health and Family Welfare have been integrated under the NRHM. Financial integration is proposed by creating a single Budget head for NRHM, while other disease control programs such as Cancer, non - communicable diseases, HIV/AIDS prevention etc. will converge their programs with the NRHM interventions. Such integration is expected to bring down duplication of services and make better use of existing resources. Optimizing existing resources and infrastructure will alone release an estimated 30% of existing budgetary outlays for alternative use.

13. The National Commission on Macro Economics and Health has provided the cost of a package of services to be provided at the primary and secondary levels of health care facilities. The core and basic package include childhood diseases/health conditions, maternal diseases/health conditions, blindness, leprosy, TB, Vector borne diseases, RTI/STI, preventive and promotive activities, minor injuries, other minor ailments, and snake bite. The NCMH also provides standard costs for non-recurring and recurring costs of Sub Health Centres, PHCs, CHCs. The Ministry of Health and Family Welfare has developed IPHS for SHC/PHC/CHC and is in the process of developing IPHS for Sub Divisional and District Hospitals. The NCMH assessments, read with the IPHS and the actual Facility Survey of each health facility, will determine the actual resource need. The over all resource envelope for NRHM has been projected as per assessment of NCMH, which is in line with the CMP promise of raising public expenditure on health to 2-3 % of the GDP.

Specific norms have been proposed for untied grants at al levels of health action. These include - (i) grants to Panchayats/Rogi Kalyan Samitis; (ii) capacity building in community organizations; (iii) skill needs of doctors/para medics/educated RMPs; (iv) local criteria and need based selection of resident health workers/Nurses/Doctors/Specialists as per IPHS; (v) partnerships with

the Non Governmental sector; (vi) nurturing and development of ASHAs; (vii) strengthening of Block and district level management; (viii) improving physical infrastructure for health; (ix) MIS/monitoring-evaluation of programme; (x) behaviour change and communication/IEC; (xi) support to mobile medical units in each district of the country; (xii) grants to Rogi Kalyan Samitis at PHC, CHC, Sub Divisional, District Hospital in all States and to Government Medical College Hospitals in special focus States; (xiii) grants - in-aid to NGOs at district, state and national levels; (xiv) support for school health programmes/ ICDS health component, nutrition and health education programmes for women, resources for surveys, public reports on health, etc.; (xv) Social health insurance as per local models with subsidies only for Below Poverty Line Families at par with the current limits under the Universal Health Insurance Scheme; (xvi) strengthening nursing institutions/Medical Colleges in capacity development; (xvii) Ambulances and phones at al levels; (xviii) National and State level Health System Resource Centres and District and Block level resource Groups; (xix) strengthening procurement and logistics in States; (xx) meeting diversity of northeastern States.

RESOURCE ASSESSMENT AND CENTRE - STATE SHARING

As regards costing of additional resource needs, the National Commission on Macro Economics and Health has made a detailed assessment of investment requirements, based on disease burden estimations, bare minimum standards and treatment protocols, and unit cost estimations of providing such services at government prices that are 30-50% lower than the private sector. The Commission has recommended additional non-recurring investment of Rs. 33,811 crores and a recurring investment of Rs. 41,006 crores for health promotion, regulatory systems, enforcement of regulations, human resources for

health, training, research and development, delivery of health care services, and social health insurance as under :

Table 1: Estimated Additional Resources as Estimated by NCMH

Activity	Non - recurring additional investment	Recurring additional investment
1. Health Promotion including publicity and dissemination and community involvement for preventive activities.		**Rupees 4000 crores**
2. Training - of Village Health Committees, unqualified RMPs, village level workers, in service health personnel, fellowships, rural allowance for health personnel, etc.	**Rs. 853 crores**	Rs. 765 crores
3. Delivery of health care services (Bare minimum requirements)	**Rs. 23968.92 crores**	**Rs. 20,958.86 crores**
4.Social Healt insurance including premium - subsidy for BPL families.		**Rs. 9000 crores**
5. Human resource for health - opening, upgrading and strengthening Nursing Colleges	**Rs. 3923 crores**	**Rs. 526.50 crores**
TOTAL	**Rs. 28744.92 crores**	**Rs. 35250.26 crores**

The resource projections indicated above have been found to be realistic and adopted for purpose of estimating additional allocations under NRHM for the XIth Plan period. However, there is need to bear in mind two caveats: 1. The cost of construction and other unit costs in the North Eastern States, the hilly regions, need to be estimated by 1.5 times; and 2. Given the current absorptive capacities in the States and weak management structures at various levels, it is likely that the demand for resources may be lower than anticipated. Therefore, while adopting the resource envelope suggested by NCMH in principle, the actual need year on year requirement of resources will depend on the pace at

which States push reforms in order to remove the clogs that are currently constraining their e ability to absorb and effectively utilize additional resources.

A substantial share of the additionality indicated above will have to come from Central funds. It is proposed that NRHM provide 100% grants to States on a 75-25 sharing basis between the Center and States during the XIth Plan. The long term additional funding by the Central Government will significantly improve the central share in overall public expenditure on health. While doing so, the Central Government will constantly monitor the state expenditures on health to ensure that they increase in proportion to central spending in real terms.

Given the absorptive capacity in the States and the time it may take to improve the implementation capacity, it should be fair to assume an annual 30% increase in health sector allocations up to 2007-08 and an annual increase of 40% from 2009-201o to 2011-12. Following this broad assessment, the Central Government resource needs are likely to be as follows:

Table 2 : Projected Resource need for NRHM 2005-2012

Rupees in crores

Year	Central Government NRHM allocation	Recurring	Non-Recurring	State Contribution	Total
2005-06	6500			-	6500
2006-07	9500	9000	500	-	9500
2007-08	12350	11000	1350	2179	14529
2008-09	17290	13000	4290	3051	20341
2009-10	24206	16206	8000	4272	28478
2010-11	33884	23884	10000	5980	39864

2011-12	47439	42439	5000	8372	55811

The resources indicated above relate to communicable disease control programmes, RCH, Family Planning, IDSP, etc. programs that come under the NRHM. There is need to, however, also provide an estimate of resources required for the non-communicable disease control programmes (mental health, vascular diseases, cancer, etc.), HIV/AIDS, medical education, etc. Since the non-communicable diseases do not entail any externalities, normally public funding is not provided in a significant manner. However, with evidence suggesting increasing prevalence of hypertension, mental health, accidents & injuries affecting a large number of poor and the treatment under all these conditions being exorbitant, public health financing has to take into account provisioning of free treatment in all public health facilities for these diseases/conditions. It is accordingly recommended that 20 per cent of the total amount projected in the table 2 above may be provided additionally for tertiary care which may also include medical education and research.

Regarding HIV/AIDS, the importance of containing this disease needs to be under-scored since treatment of AIDS is extremely expensive besides the fact that this infectious disease has the capacity to devastate the socio-economic fabric as witnessed in South Africa. Adequate resources have to be provided to stabilize and reverse the epidemic. For the Phase-III of the National AIDS Control Programme to be implemented during the 11th Five Year Plan, an estimated amount of Rs. 11,285 crores has been projected. Of this an amount of Rs. 8,000 crores is required to be provided in the budget. 25 per cent of this is under domestic budget (NRHM) and 75 per cent under the EAP component. Therefore, the additional budgetary provision over and above Rs. 55,811 crores projected in Table-2 above is Rs. 5,814 crores for the HIV/AIDS programme.

Thus the additional total resource requirement for health during the 11th Plan is estimated to be Rs. 72,788 crores.

Terms of Reference - II

To suggest management strategies for community based health insurance as well as process and impact assessment parameters for these initiatives during the Eleventh Plan;

Need for new avenues of health financing

The Group expressed its desire to explore new health financing mechanisms in order to reduce the burden of health expenditures among the poor households. The National Commission on Macroeconomics & Health has pointed out that 3.3% of India's population is impoverished every year on account of health distress. There is also evidence to suggest that the poorest 10% of the population rely on sale of assets to meet their health care needs. A study in some of the poorest districts by Jha & Jhingran 2002 had revealed that illness of a family member is the most common reason among poor households leading to a financial crisis and causing a sense of insecurity. Nearly 40% of the Below Poverty Line families reported having faced a financial crisis during the last two years and about 69% of these was on account of illness and 11% on account of a death of a family member. Clearly poor people in rural areas are spending significant amounts on health care leading to their impoverishment.

Vulnerability and risk among informal sector workers

Work and social security are the central concerns of the poor in our country. Most of our nation's poor or almost 400 million workers are engaged in

the informal economy, also called the informal or unorganized sector. There are a large number of agricultural labour who fall in the below poverty line category. Among these workers, women are the poorest and most vulnerable of all facing varied risks. Risk pooling could be one way of reducing such risk.

The poor have devised their own systems to cope with the many risks in their lives. The most well-known of these is savings for a variety of purposes, including coping with risk - paying for medical expenses, funeral costs, or a leaking roof. The system of "Vishi", or contributing to a central pool of money which is then drawn upon by a few of the contributors in times of need, is thus a kind of risk management. The several examples of micro credit organizations and the Self- Help Group movement are based upon and built on these practices.

Current Status of Health Insurance in India:

The ESIS and CGHS are the oldest schemes for social health insurance in India. ESI Hospitals provide services to an estimated 35 million beneficiary across the country, while the CGHS serves an estimated 4 million cardholdres. CGHS uses a subscription but the actual expenditure incurred is many times more than the premium collected. The experience with health insurance so far has been mixed. Some policies like Mediclaim covers more than 75 lakh persons with a range of premium varying from Rs. 175 to Rs. 5770 per annum, the claims ratio being 84%. The Yeshasvini Cooperative Farmers Health Care System, the work of Karuna Trust, the Vimo SEWA, etc. are some recent examples of community health insurance providing protection against catastrophic health expenditure. Similarly, State Governments and some central ministeries have also been exploring the possibilities of risk pooling for Health Care. Government of Assam started a Health Insurance Scheme which covers major surgeries but

excludes essential maternity care etc. Government of Jharkhand is trying to design a Health Financing Product without exclusions in one block of each District with the partnership of industrial houses and Insurance Management Organization. Government of Kerala has recently initiated a programme of health insurance for 25 lakh below poverty line families called Kudumbshree Scheme which tries to rectify some of the exclusions in the earlier UHIS Scheme. The National Commission on Enterprises in the unorganized sector has also been examining the feasibility of Health Insurance for informal sector workers. The Ministry of Textiles has started a Health Insurance Scheme for co-operatives of weavers.

One of the impressive models of CBHI aimed at the poor is SEWA in Gujarat. SEWA's experience over 14 years based on insuring over 140,000 workers and their families suggests that for health insurance to be viable, it has to be controlled and run by the users themselves - negotiating fees, treatment regimens etc. with providers, both public and private. Those providers that adopt poor quality of care or fraudulent practices are black-listed. This has already had the effect of providers improving the quality of their care and revising some of their prices. It has also resulted in the public health system gearing itself up to provide the care required, with the public charitable trust hospitals serving as a back-up or alternative to the public and private-for-profit health providers. Finally, the experience of SEWA with health insurance has encouraged the development of a "cashless" system with providers, both public and private, enabling women and their families to seek quality care of their choice without having to pay upfront immediately. This new system is being tested out in eight talukas in Gujarat, as well as two working class neighbourhoods of Ahmedabad city.

SEWA experience points to the need for a comprehensive insurance package covering both life and non-life risks. This is advisable both because a holistic approach to risks and shocks faced by the poor is required, and also because this will lead to overall viability of insurance for the poor.

The Government of India's Universal Health Insurance Scheme (UHIS) was launched in the Budget of 2003-04 and is the first broad-based health security scheme having an element of financial contribution from the State. In 2004-05 budget the UHIS was revised to restrict it to Below Poverty Line families; increase the subsidy element to Rs.200 against the Rs.365 annual premium paid for individual coverage; Rs.300 for the Rs.547.50 premium for a family of five and Rs.400 for those paying a premium of Rs.730 for covering a family of seven persons. The coverage under UHIS is unsatisfactory (barely 1.3 lakh persons till 31 July 2005). Maternity benefit is not covered under UHIS. Exclusion of essential health care needs are likely to make any policy unattractive. Perhaps a range of health insurance products developed as per local needs, improved social marketing of such products, simpler procedures for claims, and accredited facilities for hospitalization in rural areas could have helped a larger coverage under UHIS.

The perception of Insurance Companies about UHIS

The General Insurers' (Public Sector) Association of India (GIPSA) have identified the following constraints in the UHIS programme: inability of BPL families to pay even the subsidized premium; low premium structure being cost prohibitive for effective canvassing and service; perception of government sponsored scheme as a free scheme; health insurance for poor as state responsibility and not commercially viable; and inadequate public health facilities, standards and system of Third Party Administrators.

The perspective for improving coverage for Risk Pooling

The experiences from across the world show that health insurance is neither a substitute for a well - functioning, effective and efficient public health care system, nor, an argument for undermining higher public investments as the success of risk pooling is dependent on the provision of health care services in the public and private sectors. Health insurance is an effective mechanism for reducing risk against lumpy and unpredictable expenditures that characterize health spending. Given the inability of households, more particularly the poor to raise such resources in a short time, cashless and simple procedures for claim settlement seem to be the ideal ways of ensuring access to health services to the poor and creating confidence among them regarding the system of health insurance as a way of health financing.

NRHM - An opportunity

The National Rural Health Mission (NRHM) aims to bring about fundamental reforms in the system of health care delivery as well as exploring new health care financing mechanisms and developing credible community based health insurance schemes. The NRHM envisages an empowered District Health Mission with adequate technical, managerial and accounting support in managing risk pooling and health security. With schemes to have Accredited Social Health Activists (ASHAs) for every 1000 population; strengthened 3222 Community Health Centres and a 24 hour round the clock hospital facilities in every Block; subsidizing indirect costs under the Janani Suraksha Yojana for promoting institutional deliveries among Below Poverty Line pregnant woman.

All these initiatives will contribute to providing opportunities to improve risk pooling through community based health insurance.

Need for diversity of approaches - letting a hundred flowers bloom

A critical issue in the context of India's health insurance is the rapid growth of an unregulated private health sector following no standards and with no control on the prices to be charged or use of technology. The 60th Round of NSSO shows a doubling of the costs of inpatient hospitalization in urban areas since the past decade. Combined with long waits and poor quality of care in the public health facilities, this escalation is leading to the greater indebtedness of people.

In the above context and in order to provide choice and expand access, international experience shows that insurance coverage for the poor is indeed possible, if certain critical issues are taken into account. The most important of these issues is developing a mechanism of implementation that is specially tailored to the reality of the poor, and organized according to their convenience.

Need for participation of government funded public health institutions

The Group deliberated on the participation of Government Health Care facilities in any innovative risk pooling arrangement. The Group felt that the participation of Government Hospitals and Health Centres was very critical for any risk pooling arrangement as otherwise it becomes a system of subsidizing private health care. It was also felt that the challenge of risk pooling for remote rural households can only be met when public health systems are also a part of such innovative health financing mechanisms. The example of Karuna Trust's work in Karnataka showed how by compensating poor households for loss of

wages and other indirect expenses and reimbursing hospitals a certain amount for drugs and medicines in every case of hospitalization, result in increasing access to medical care, optimal utilization of the public facilities and reduction in households expenditures. One possibility therefore is to have a number of pilots undertaken on risk pooling for poor households through NGOs, Self Help Groups, other community organizations covering the indirect expenditures that are incurred in seeking health care.

Any kind of Health Insurance Scheme, which does not involve the public medical facilities, would not succeed because, in majority of states, these are the only facilities available in rural areas. The involvement of the States could be worked out by designing a Plan Scheme by the Ministry of Health and Family Welfare with subsidy being passed on to the hospitals through the State Governments. In such a situation, the State Governments can invite bids on 'premium to the charged' at their level from all the insurance companies, both public and private. For availing of the subsidy from the Central Government, the minimum features of the Scheme could be decided a priori and informed to the State Governments. The State Government may add some more features to the scheme and may also provide financial assistance to the policyholders by contributing whole or part of the premium. In this scenario, the modalities of administering the scheme at different levels may be described in detail by the Central Government or may be left to the State Governments.

Innovative financing for efficiency

Innovative mechanisms of health financing can be used to improve accountability of the health system, be it in the public or private sector. For example if a CHC were to receive resources directly on the basis of their case load, it would contribute to a more effective service delivery. Similar would be

the case of the private sector. For involving the private sector as a provider of care paid for by a public financing system, there is need to establish effective standards, capacity to monitor their enforcement, and a regulatory framework for ensuring that providers did not exploit the market imperfections so inherent in the health sector. The work of the National Commission on Macroeconomics and Health on unit costs for core, basic and secondary health care package alongside the facility survey of the public and private sectors in 8 districts could be a useful starting point for developing standard costs and treatment protocols and a basis for public private partnerships in health service delivery.

Difficulty with formal insurance organizations

There was an apprehension feeling that the formal organization of Health Insurance Companies do not have the capacity to address the needs of the poor on account of the complex procedures involved in reimbursing the amounts and setting claims. Even the current arrangement of a few Third Party Administrators [TPA] to facilitate health care reimbursements does not seem to be effective in enabling the poor participate in health insurance. The Group felt that there was a need for a district level body to play the role of TPA. The Group felt that the District Level Board for Innovative Health Financing could mobilize finances from a varied set of sources such as user fees from those with ability to pay, household contributions, government subsidy etc. In such a system the role of the NGOs, Community Based Organizations is vital for articulating peoples needs, ensuring access without hassles and motivating communities to contribute and save for health care. For discharging these functions, the District Health Financing Boards as well as the NGO's need capacity building in management and financing. In this context it was noted with satisfaction the IRDA notification issued on 10th November, 2005 on micro-insurance,

formalizing the involvement of NGOs, cooperatives and other community based organizations in health insurance.

Role of Panchayati Raj Institutions

Panchayati Raj Institutions have the mandate to manage the Primary Health system. The various tiers of Panchayati Raj Institutions ought to exercise control and supervision over health facilities, functionaries and functions. Communitization through ownership by Panchyati Raj Institutions adequately prepared to undertake the management role is necessary for an efficient and effective health system. The experience with Hospital Development Committees in Kerala and Rogi Kalyan Samitis in Madhya Pradesh has prompted the Central Government to mandatorily seek the establishment of such community organizations in health institutions. Innovative health financing would require active ownership of the public health system by Panchayati Raj Institutions.

Amendments needed in the regulations on health insurance

The single most important determinant for the success of any health insurance scheme is the confidence and trust that it generates among the contributory households, as in this case, they are sanctioning current use for a future benefit, year after year. While the regulations for insurance are enforced by the Insurance Regulatory and Development Authority (IRDA), a structure and rules framed for their operations, licenses for Third Party Administrators systematized etc.for addressing the concerns of the model of financing proposed, two major changes would be required: (i) allowing NGOs and local district health financing boards to manage health insurance; and (ii) widen the network of the Third Party Administrators in order to provide such scope and possibility

at the district level, so as to allow entry to NGOs and district health financing boards. Monopolies of the few insurance companies and a handful of Third Party Administrators will have to give way to several players at the local level district based organizations working through an equally large network of Third Party Administrators. For effectively regulating such diverse systems of health financing models and to cope with the complexities of the health sector it would be adviseable to establish a Health Insurance Regulatory Authority as an independent authority or under the aegis of the existing IRDA.

In conclusion, it is recommended that to initiate establishing risk pools for the poor based on the concepts of community based health insurance the following steps may be considered:

- Appoint a body that will take the responsibility of organising the health insurance programme - could be an independent Health Insurance Corporation, or a cell in the Dept. of H & FW, a separate trust, or a NGO.

- Examine the feasibility of organizing large risk pools by combining the organized sector with the organized elements in the informal sector such as cooperatives, self help groups etc. This is essential as size of risk pools determine the extent to which the cross subsidization between the rich and poor, the old and the young and the sick and healthy can take place. Such cross subsidization is essential for long term sustainability of the insurance scheme.

- Arrive at a basic package that would address the medical, surgical and other health needs of the poor to be provided as inpatient or outpatient. For the BPL families, transport and wage loss compensation need to also be factored.

- The premium for a reasonable package of basic services is estimated to cost about Rs 250 for a family of five. The proportionate share between the three key stake holders will need to be finalized : the Central Governemnt, the State Governemtn and the individual households. It is necessary to note that the poor cannot sustain contributing to a scheme which is not subsidized.

- An independent body should be appointed to administer the scheme having the requisite technical and managerial capacity.

- A cell should be established to closely monitor specific indicators to ensure that the programme is on track.

Terms of Reference - III

To assess disease burden and cost of ill health in the country and project figures for 2012 and 2017;

The NCMH recently carried out disease burden estimations based on an exhaustive review of available research and data and extrapolated to 2015. These estimations were also peer reviewed by experts. For each disease/ health condition, experts also provided a minimum standard and treatment protocol. Costs of treating a condition as per the given protocol was then computed using market prices for drugs, medicines and other goods. For services and the capital infrastructure required, government rates were adopted and unit costs derived by arriving at average utilization rates currently observed. It is for this reason stated that the cost of delivering a similar service in a private facility would be 30-50 % more. As there is no new research or evidence emerging, the WG felt

that there was no purpose served in undertaking a review of these estimations. Accordingly, the disease burden for 2015 and the cost of treatment as arrived at by the NCMH is adopted.

Terms of Reference - IV

To give cost estimates for health care-public, NGO and private-current and for the Eleventh Plan period;

The only source of data available for providing an estimate of the proportional share of health expenditures by NGO's, the public and the private sector and for the XIth. Plan period is the 60th. Round NSSO which is a large household survey recently conducted. As per this survey, the average medical expenditures incurred at different health facilities for inpatient care is given below. As can be seen from the table, there has been an overall increase in the expenditures incurred in all facilities, in rural as well as urban areas. Most worrying is the near doubling of expenses incurred in the private hospitals located in urban areas. It is recommended that to get better insights into how adverse has been the impact of these increases, an analysis fractile goup wise needs to be undertaken.

Table -3 :Average Medical Expenditure (Rs.) per Hospitalization Case

Type of Hospital	Rural		Urban	
	2004	1995-96	2004	1995-96
Government Hospitals	3,238	2,080	3,877	2,195
Private Hospitals	7,408	4,300	11,553	5,344
Any Hospital	5,695	3,202	8,851	3,921

Source : 60th Round NSSO 2004

Terms of Reference - V

To suggest alternative sources / strategies for health financing during the 11th Plan to meet the cost of health care;

Currently India's health financing mechanism as mentioned earlier is largely out-of-pocket and a declining trend in public finance. Some recommendations for resource mobilization to meet the enhanced investment levels for health care are given below:

First, within the existing public finance of healthcare, macro policy changes in the way funds are allocated can bring about substantial equity in reducing geographical inequities between rural and urban areas. Presently, the central and state governments together spend Rs.250 per capita at the national level, but this is inequitably allocated between urban and rural areas. The rural healthcare system gets only Rs.120 per capita and urban areas get Rs.560 per capita, a difference of over 4 ½ times. If allocations are made using the mechanism of global budgeting, as is done in Canada for instance, that is on a per capita basis then rural and urban areas will both get Rs.250 per capita. This will be a major gain, over two times, for rural healthcare and this can help fill gaps in both human and material resources in the rural healthcare system. The urban areas in addition have municipal resources, and of course will have to generate more resources to maintain their health care systems which at least in terms of numbers (like hospital bed : population ratios and doctor : population ratios) are adequately provided for. Global budgeting also means autonomy in how resources are used at the local level. The highly centralized planning and programming in the public health sector will have to be done away with and greater faith will have to be placed in local capacities.

Second, shortage of human resources and skills is a major constraint for the public health system to realize its goal of universal access to health services. In this context it is pertinent to consider the fact that since the public exchequer contributes substantially to medical education, to the extent that nearly 80% of medical graduates are from public medical schools, there is need to utilize this resource for public good. Since medical education is virtually free in public medical schools the state must demand compulsory public service for at least three years from those who graduate from public medical schools as a return for the social investment. Today only about 15% of such medical graduates are absorbed in the public health system. In fact, public service should be made mandatory also for those who want to do post-graduate studies (as many as 55% of MBBS doctors opt for post-graduate studies). Such a measure will be the least costly way of assuring availability of the required medical skills a the point of delivery in the public health system. Such assured availability of quality care is necessary for enforcing the concept of guaranteed care, a cornerstone of the NRHM policy.

Third, the governments can raise additional resources through levying "sin taxes" - compulsory cesses and levies on products such as cigarettes, beedis, alcohol, pann masalas and guthka, personal vehicles etc. that directly contribute to enhancing health risks, that are also extremely expensive to treat. For instance tobacco, which kills 670,000 people in India each year, is a Rs.350 billion industry and a 2% health cess would generate Rs.7 billion annually for the public health budget. Similarly alcohol, which presently generates Rs.250 billion in revenues, can also bring in substantial resources if a 2% health cess is levied. With 10% of morbidity and mortality, particularly among the young is on account of accidents and injuries, the same logic can be applied to personal transportation vehicles both at point of purchase as well as each year through a

health cess on road tax and insurance paid owners. Land revenues and property taxes can also attract a health cess which is earmarked for public health.

Fourth, social insurance can be strengthened by making contributions similar to ESIS compulsory across the entire organized sector and integrating ESIS, CGHS etc. with the general public health system. Also social insurance must be gradually extended to the other employment sectors using models from a number of experiments in collective financing like sugar-cane farmers in south Maharashtra paid Re 1 per tonne of cane as a health cess and their entire family was assured healthcare through the sugar cooperative. There are many NGO experiments in using micro-credit as a tool to factor in health financing for the members and their family. Large collectives, whether self-help groups facilitated by NGOs, or self-employed groups like headload workers in Kerala, can buy insurance cover as a collective and provide health protection to its members. At least 60% of the workforce in India has the potential to contribute to a social insurance programme.

Fifth, other options to raise additional resources could be various forms of innovative direct taxes like a health tax similar to profession tax (which funds employment guarantee) deducted at source of income for employed and in trading transactions for self-employed. Using the Tobin tax route is a highly progressive form of taxation which in an increasingly service sector based economy can generate huge resources without being taxing on the individual as it is a very small amount of deduction at the point of transaction. What this basically means is that for every financial transaction, whether cheque, credit card, cash, stock market, forex etc. a very small proportion is deducted as tax and transferred to a fund earmarked for social sector. For example if 0.025% is the transaction tax then for every Rs.100,000 the transaction tax would be a mere Rs.25 or one paise per Rs.40 transacted. This would not hurt anyone if it were

made clear that it would be used for social sectors like health, education, public housing, social welfare etc.

The Group felt that over time, attention should shift from incremental change to a structural overhaul of the health system in order to assure universal access based on a rights-based approach. This requires a multi-pronged strategy of building awareness and consensus in civil society, advocating right to healthcare at the political level, demanding legislative and constitutional changes, and regulating and reorganizing the entire healthcare system, especially the private health sector, alongside making the required level of problem investment in health care.

Likewise to reduce out - of-pocket financing of the healthcare system, policies need to be quickly put in place for a system of health financing that will be a combination of public finance and private contribution by establishing various collective financing options such as social insurance, collectives/common interest groups etc. At another level the healthcare system needs to be organized into a regulated system that is ethical and accountable and is governed by a statutory mandate, which pools together the various sources of financing and manages it for ensuring all the members access to comprehensive healthcare. This will happen only if the entire healthcare system, public and private, is organized under a common umbrella, ideally through a single-payer mechanism that operates in a decentralized way.

Terms of Reference - VI

To deliberate and give recommendations on any other matter relevant to the topic.

Strategies for health financing during the 11th plan

Hospital Development Committees/Rogi Kalyan Samitis

Hospital Committees should be established in every public health facilities with elected representatives, health care providers, representatives of consumer groups etc. For instance, in Rajasthan Medical Relief Societies, RKS in Madhya Pradesh and SKS in Haryana have been set up in all the government hospitals at district sub- division and below levels for the purpose of better maintenance and improvement of hospital services.

Availability of Drugs through PPPs

In order to provide cheaper medicines to the common man, MRS in Rajasthan has established outlets known as life-line fluid stores opened within the hospital premises, providing medicines free of cost to BPL families. PPP initiatives can be started in collaboration with pharmaceutical companies, private pharmacies and govt. hospitals

Through these initiatives several critical medicines, injections, antibiotics, IV Fluids etc. can be purchased in bulk through open tender from the manufacturing companies and sold through the outlets in the hospital premises. This will result in to reduction of prices considerably

All states may be advised to replicate similar models which would help make available critical drugs at affordable prices to the common man and to provide medicines free of cost to BPL families.

Levying of User charges

A nominal user charges may be levied for all outpatient services provided in public health facilities. Available studies show that there is a willingness to pay for services provided in government hospitals. The poorest of the poor may be exempted from paying for services. For in-patient care, a modest user charges may be levied (based on cost of recurrent items). The funds collected should be kept at the disposal of hospital committee and should be utilized for the improvement of service delivery. Government may provide matching grants linked to user charges collected to those facilities located in rural remote areas. More over the exemption mechanism needs to be properly implemented. Graded user charges can be levied. Awareness should be generated among the segment of the population who are exempted from paying user charges (as the poor in some cases do not know that they have been exempted from paying charges).

Facilities should hold periodic and timely Audit and regular utilization reviews to identify whether user fee policy has had an adverse impact. Community may be given responsibility to identify the families, which have no means to pay (eg. Tanzania). Issuing card should be made less bureaucratic.

Encourage maternal health insurance scheme

Encourage maternity health insurance scheme under the NRHM (pooling JSY incentives), to increase institutional deliveries, achieve reductions in maternal and infant mortality, stimulate the development of accreditation

systems across rural and urban India, institutionalize multiple partnerships and contribute to the development of sound, inclusive referral systems.

Encourage Small risk pools

The cost of hospitalization (both direct & indirect costs) is huge among the poor in rural areas. Currently, there is no financial protection available to this vast majority of the population. Initially, small risk pools led by a consortium of self-help groups, may be encouraged to administer financial help to needy households at village levels, in the event of hospitalization and death. Government can encourage consortium of such self -help groups by proving an initial grant for its operation.

Encourage Co-operative health insurance

Promote health insurance schemes by Involving network of co-operatives as in Karnataka. Constitute risk pools around professional or occupational groups like self help groups or micro credit groups, weavers, fishermen, farmers, agricultural laborers and other informal groups (as in Kozhikod, Kerala)

Creation of separate budget head for all donor grants

In India, foreign grant is received for combating specific diseases like HIV/AIDS, TB, leprosy, malaria etc. Such grants are disease specific which often do not take into account the disease burden or the priority of the Government. The funds from donor agencies should therefore be pooled under a single budget head so that government may prioritize the spending according to the disease burden of the population. This may well make all the difference.

Other Recommendations

- Govt should enable need based bottom up programme planning and budget should be in consonance with the extent of the disease burden

- A separate provision should be made in the budget for meeting all emergencies. Certain discretion should be allowed to reallocate available funds in meeting emergencies at least up to the District level

- Institute an internal audit system at state and district level (as done in srilanka)

Annex- I

MINUTES OF THE MEETING OF WORKING GROUP ON HEALTH CARE FINANCING INCLUDING HEALTH INSURANCE FOR THE ELEVENTH PLAN HELD ON 18th JULY, 2006 AT NIRMAN BHAVAN, NEW DELHI.

Following were present:

1. Ms. Sujata Rao, Additional Secretary (NACO), MOH&FW, GOI. - Chairperson
2. Shri I. V. Subba Rao, Pr. Secretary (Health), Govt. of AP
3. Ms. Usha Ganesh, Pr. Secretary (Health) Govt. of Karnataka
4. Shri M.M. Upadhyay, Pr. Secretary (Health) Govt. of MP
5. Dr. Amarjit Singh, Commissioner (Health) Govt. of Gujarat
6. Sh. GC Chaturvedi, Joint Secretary, Insurance Division, Ministry of Finance, GOI
7. Dr. D. Narayana, Fellow, CDS, Trivendrum
8. Dr. Ravi Duggal, CEHAT, MUMBAI
9. Dr. Moneer Alam, Health Economist, Professor, IEG, New Delhi
10. Dr. N. Devadasan, Institute of Public Health, Bangalore
11. Dr. Ravendra Singh, Director(Policy),MOHFW, GOI
12. Dr. S.P. Goswamy, National Consultant (Health Insurance), MOHFW, GOI
13. Ms. Radha Ashrit, SRO(Health), Planning Commission, New Delhi
14. Sh. Amarjeet Sinha, Joint Secretary, MOHFW, GOI- Member Secretary

The Planning Commission, New Delhi, vide their letter No. 2(15) /06-H&FW Dated 25-05-06 constituted a Working Group on Health Care Financing including Health Insurance for the Eleventh Plan, defining the Terms of Reference for deliberations. The first meeting of the Group was held on 18/07/06 under the Chairpersonship of Ms Sujata Rao, Additional Secretary (NACO), MOH&FW, GOI, New Delhi. In her welcome address, Ms. Rao requested the members to provide suggestions for low cost health care to the poor people.

Shri Amarjeet Sinha, Joint Secretary, MOHFW explained the various aspects of NRHM 2007-2012 to the participants. He also highlighted various points relating to Health Financing and Health Insurance which are under active consideration of MOHFW, GOI. He further deliberated on the factors increasing high out of pocket health expenditure and ways of reducing health expenditure. He also highlighted the various health insurance schemes being run by NGOs in various States. He gave a broad framework of Terms of References which were as follows:

i. To review the present position of health financing at state, centre and individual levels. Keeping in view, identified problems and constraints of existing system, make suggestions for improvement in quality and efficiency with reduction in the cost of health care to the poor in the Eleventh plan.

ii. To suggest management strategies for community based health insurance as well as process and impact assessment parameters for these initiatives during the 11th plan.

iii. To assess disease burden and cost of ill health in the country and project figures for 2012 and 2017.

iv. To give cost estimates for health care public, NGO and private - current and for the 11th Plan period.

v. To suggest alternative sources/strategies for health financing during the 11th Plan to meet the cost of health care.

vi. To deliberate and give recommendations on any other matter relevant to the topic.

Dr. Amarjeet Singh, Commissioner (Health), Gujarat, explained the success story of Chiranjeevee Scheme launched by the Gujarat in 5 selected districts with the help of Public-Private Partnership, providing Maternity benefit to the women. Out of 215 Gynecologists in the State, 163 got themselves empanelled under the scheme and earning substantial amount. Based on the success of the scheme, State Government would be considering introducing this scheme in whole of the State.

Shri Upadhaya, Pr. Secretary (Health), MP, explained the insurance scheme launched by the State to provide the Maternity benefit to 45 lacs BPL women. He informed that due to this scheme, the number of institutional deliveries has doubled in just 5 months. District Committee are processing the claim and releasing the money to the beneficiaries and taking the re-imbursement from the Insurance Company.

Dr. Narayana, CDS, Trivendrum mentioned that the utilisation of public services had been going down while the use of private sector health care facilities had increased. Dr. Ravi Duggal, CHEHAT, Mumbai highlighted the need for improving the utilisation of existing Government health facilities. He advocated that the funds should be provided to PHCs, CHCs etc. on the basis of utilisation of these facilities like beds, OPD, Indoor patients, deliveries etc.

Shri Chaturvedi, Joint Secretary (Insurance) suggested that private sector should be provided more funds for making available health services in the rural areas. He also advocated more public-private partnership in this regard.

Ms. Usha Ganesh, Pr. Secretary (Health) mentioned that there should be incentive for Government hospital staff also. They should be allowed to get 30% of the funds generated through the health insurance.

Some of the participants have mentioned the issues about the availability of specialist doctors for posting at rural areas, management of hospitals and the payment system to the doctors. The need for more utilisation of private health facilities was also mentioned as and where the government health facilities could not able to function properly. There was also a suggestion for taxing health hazardous items, which could be utilized for provision of health care to poor patients.

As the representative from NSSO was not present in the meeting, Ms. Rao asked Shri Amarjeet Sinha, Joint Secretary, MOHFW to request NSSO to send a representative during the next meeting apart from making a presentation on the findings from various NSSO surveys about the cost of treatment at rural areas as well as on utilisation of Government health facilities in availing various health services.

Summing up the discussions, Ms. Rao requested all the participants to send their suggestions/material on various items of Terms of Reference to Shri Amarjeet Sinha (email: **amarjeet_sinha@hotmail.com**) latest by 31/07/06, which shall be exchanged amongst the members for their final views. The next meeting would be held in the 2nd week of August 06 after the receipt of the suggestion from the members.

The meeting was ended with vote of thanks.

ANNEXURE II

HOUSEHOLD, PUBLIC AND TOTAL HEALTH EXPENDITURE IN INDIA (2004-2005)

States	Household Exp. (Rs.Crores)	Govt. Exp. (Rs. Crores)	Other Exp. (Rs.Crores)	Aggregate Exp. (Rs.Crores)	PC HH Exp. (Rs.)	PC G Exp. (Rs.)	PC Other Exp. (Rs.)	PC Exp (Rs.)	HH as % of THE (%)	PE as % of THE (%)	OE as % of THE (%)
Central Govt.	0	14819	730	15549	0	137	7	144	0	95.3	4.7
A.P.	6441	1696	640	8777	820	216	82	1118	73.38	19.39	7.29
Arun. Pradesh	430	67	0	497	3776	589	0	4365	86.51	13.49	0
Assam	3054	672	52	3778	1089	239	19	1347	80.84	17.78	1.38
Bihar	11854	1091	202	13147	1021	124	23	1497	90.17	8.3	1.53
Delhi	1004	721	55	1780	664	476	37	1177	56.41	40.48	3.11
Goa	524	116	22	662	3613	798	153	4564	79.17	17.48	3.53
Gujarat	4893	996	424	6313	920	187	80	1187	77.51	15.78	6.71
Haryana	3385	421	175	3981	1518	189	79	1786	85.03	10.56	4.4
H.P.	2126	306	40	2472	3377	486	64	3927	85.99	12.38	1.63
J & K	1759	471	47	2277	1609	431	43	2082	77.26	20.69	2.05
Karnataka	3847	1267	353	5467	702	231	64	997	70.36	23.18	6.46
Kerala	8373	1048	281	9702	2548	319	86	2952	86.3	10.84	2.9
M.P.	6432	1051	228	7711	746	164	35	1200	83.41	13.63	2.96
Maharashtra	11703	3527	726	15957	1156	348	72	1576	73.34	22.1	4.55
Manipur	420	89	8	517	1680	356	32	2068	81.24	17.2	1.56
Meghalaya	58	94	8	160	242	388	34	664	36.45	58.37	5.18
Mizoram	38	58	0	96	405	623	0	1027	39.39	60.61	0
Nagaland	1024	84	7	1116	4897	404	37	5338	91.74	7.57	0.7
Orissa	2999	684	111	3795	786	179	29	995	79.04	18.02	2.93
Punjab	3493	827	273	4593	1379	326	108	1813	76.05	18	5.95
Rajasthan	3399	1190	267	4855	565	198	44	808	70	24.5	5.5
Sikkim	72	55	0	127	1274	965	0	2240	56.89	43.11	0
Tamil Nadu	3624	1590	760	5974	566	248	119	933	60.67	26.61	12.72
Tripura	253	100	13	366	760	301	40	1101	68.99	27.35	3.66
Uttar Pradesh	17158	2650	550	20359	924	150	31	1152	84.28	13.02	2.7
West Bengal	7782	1715	433	9929	931	205	52	1188	78.38	17.27	4.36
U.Ts.	3160	325	227	3712	11168	52	37	598	85.13	8.74	6.12
State Totals	**109308**	**17965**	**5906**	**133178**	**1012**	**167**	**54**	**1233**			
GT[GOI+State]	109308	32784	6636	148727	1012	304	61	1377	73.5	22	4.46

Notes:

i) Household Expenditure Based on NHA for the year 2001-02 and extrapolated for 2004-05

ii) Central Govt. expenditure includes transfer to states, other central ministries and central PSUs; and data obtained from Demand for Grants (Provisional), Govt. of India

iii) Govt. Expenditure includes Central, States, Local Govt. and PSUs: data obtained from States Finances (Provisional), RBI, Various issues

iv) Other include foreign agencies, private firms and NGOs; data relates to 2001-02, which is subsequently extrapolated for 2004-05

v) PC HH Exp. – Per Capita Household Expenditure; PC G Exp. – Per Capita Govt. Expenditure; PC Other Exp. – Per Capita Other Expenditure; HH as % of THE – Household as % of Total Health Expenditure; PE as % THE – Public Expenditure as % of Total Health Expenditure; OE as % of THE – Other Expenditure as % of Total Health Expenditure; C. Govt. – Central Govt; U.Ts – Union Territories.

Source: Report of the National Commission on Macro Economics & Health. 2005

Annexure III

TRENDS IN HEALTH EXPENDITURE IN INDIA

Year	Health Expenditure as % of the GDP			Per-Capita Public Expenditure on Health (Rs.).
	Revenue	Capital	Aggregate	
1950-51	0.22	NA	0.22	0.61
1955-56	0.49	NA	0.49	1.36
1960-61	0.63	NA	0.63	2.48
1965-66	0.61	NA	0.61	3.47
1970-71	0.74	NA	0.74	6.22
1975-76	0.73	0.08	0.81	11.15
1980-81	0.83	0.09	0.91	19.37
1985-86	0.96	0.09	1.05	38.63
1990-91	0.89	0.06	0.96	64.83
1995-96	0.82	0.06	0.88	112.21
2000-01	0.86	0.04	0.90	184.56
2001-02	0.79	0.04	0.83	183.56
2002-03	0.82	0.04	0.86	202.22
2003-04	0.86	0.06	0.91	214.62

Note:

i) GDP is at market price, with 1993-94 as the base year
ii) Includes only Central and State government expenditure

Source: Report of the National Commission on Macro Economics & Health, 2005

Annexure IV

SHARE OF HEALTH IN REVENUE BUDGET OF MAJOR STATES (IN %)

States	1985-86	1991-92	1995-96	1999-00	2003-04(R.E.)	2004-05 (B.E.)
Andhra Pradesh	6.41	5.77	5.7	6.09	5.21	4.8
Assam	6.75	6.61	6.08	5.25	4.39	4.36
Bihar	5.68	5.65	7.8	6.3	4.84	6.47
Gujarat	7.45	5.42	5.34	5.21	3.68	3.76
Haryana	6.24	4.19	2.99	4.08	3.63	3.35
Karnataka	6.55	5.94	5.85	5.7	4.85	4.18
Kerala	7.69	6.92	6.81	5.95	5.42	5.2
Maharashtra	6.05	5.25	5.18	4.59	4.39	3.89
Madhya Pradesh	6.63	5.66	5.07	5.18	4.89	5.08
Orissa	7.38	5.94	5.42	5.03	4.47	4.58
Punjab	7.19	4.32	4.56	5.34	4.27	4.05
Rajasthan	8.1	6.85	6.18	6.39	5.75	5.73
Tamil Nadu	7.47	4.82	6.4	5.51	5.26	4.91
Uttar Pradesh	7.67	6	5.73	4.42	5.13	5.75
West Bengal	8.9	7.31	7.16	6.3	5.23	5.04
All States	7.02	5.72	5.7	5.48	4.97	4.71

Source : Report of the National Commission on Macro Economics & Health, 2005.

Annexure V

STATEMENT ON FUNDS FOR HEALTH CARE IN INDIA, 2001-02

Source of funds	Exp. In Rs.000S	% Distribution
(a) Public funds		
1. Central Government	67,185,399	6.4
2. State Government	132,709,065	12.6
3. Urban Local Bodies and Panchayat Raj Institutions #	14,496,554	1.3
Total (a)	214,391,018	20.3
(b) Private funds		
1. Households	760,939,107	72.0
2. Firms $	55,365,142	5.3
3. Non Governments Institutions Serving Households (NGOs) *	799,783	0.1
Total (b)	818,104,032	77.4
(c) External Support		
1. Grants to Central Government	16,483,158	1.5
2. Material Aid to Central Government	825,937	0.1
3. Grants to State Government	2,389,555	0.2
4. To NGOs	5,147,996	0.5
Total (c)	24,846,646	2.3
Total funds	1,057,341,696	100.0

Source : National Health Accounts, India 2001-02, Ministry of Health & Family Welfare

Annexure VI

% OF TREATED AILMENTS RECEIVING NON-HOSPITALIZED TREATMENT FROM GOVERNMENT SOURCES

Major State	Rural			Urban		
	2004 *60th Rd*	1995-96 *52nd Rd*	1986-87 *42nd Rd*	2004 *60th Rd*	1995-96 *52nd Rd*	1986-87 *42nd Rd*
Andhra Pradesh	21	22	12	20	19	16
Assam	27	29	40	24	22	26
Bihar	5	13	14	11	33	17
Chhattisgarh	15	*	*	20	*	*
Delhi	@	*	*	23	*	*
Gujarat	21	25	28	18	22	18
Haryana	12	13	15	20	11	19
Himachal Pradesh	68	*	*	86	*	*
Jammu & Kashmir	52	*	*	51	*	*
Jharkhand	13	*	*	24	*	*
Karnataka	34	26	32	16	17	30
Kerala	37	28	32	22	28	33
Madhya Pradesh	23	23	24	23	19	28
Maharashtra	16	16	21	11	17	15
Orissa	51	38	37	54	34	43
Punjab	16	7	12	18	6	11
Rajasthan	44	36	46	53	41	52
Tamil Nadu	29	25	28	22	28	31
Uttaranchal	18	*	*	35	*	*
Uttar Pradesh	10	8	*	13	9	14
West Bengal	19	15	16	20	19	20
India	22	19	21	19	20	24

Note: 1. The estimates of the 52nd round are based only on the treatments with reported source of treatment

2. * denotes estimate not available and @ denotes estimate not presented

Source : Morbidity, Health Care and the condition of the aged NSS 60th Round, Ministry of Statistics & Programme Implementation, 2006.

Report on the

Working Group on

Clinical Establishments, Professional Services Regulation and Accreditation of Health Care Infrastructure

For
the 11th Five-Year Plan

Government of India
Planning Commission

Report on the Working Group on Clinical Establishments, Professional Services Regulation and Accreditation of Health Care Infrastructure For the 11th Five-Year Plan

Composition of the Working Group

1. The Planning Commission constituted a Working Group on Clinical Establishments, Professional Services Regulation and Accreditation of Health Care Infrastructure for the Eleventh Five -Year Plan (2007-2012) under the Chairmanship of Secretary, Department of Health & Family Welfare, Government of India with the following members:

1.	Secretary, Department of Health & Family Welfare, New Delhi	Chairman
2.	Secretary (Health), Govt. of Assam	Member
3.	Secretary (Health), Govt. of Rajasthan	Member
4.	Secretary (Health), Govt. of Uttar Pradesh	Member
5.	Secretary (Health), Govt. of Kerala	Member
6.	Secretary (Health), Govt. of Tamil Nadu	Member
7.	Director General of Health Services, Directorate General of Health Services, New Delhi	Member
8.	Chief, Bureau of Indian Standards, New Delhi	Member
9.	Shri Rajeev Lochan, Director (Health), Planning Commission, New Delhi	Member
10.	Shri K.M. Gupta, Director, Ministry of Finance, New Delhi	Member
11.	Dr Antia, Foundation for Research in Community Health, Pune	Member
12.	Dr. Naresh Trehan, Escorts Hospital, New Delhi	Member
13.	Dr. Akhil Sangal, Chief Executive Officer, Indian Confederation for Health Care Accreditation	Member
14.	Dr. Shakti Gupta, Medical Superintendent, All India Institute of Medical Sciences, New Delhi	Member
15.	Head, Medical Care & Hospital Administration, National Institute of Health & Family Welfare, New Delhi	Member
16.	Dr. I.H. David, Health Management Consultant, Hyderabad	Member
17.	Dr. Prakasamma, Director, School of Nurses, Hyderabad	Member
18.	Joint Secretary, Ministry of Health & Family Welfare, New Delhi	Member Secretary

Terms of Reference:

2. The Terms of reference of the Working Group were as under:

i) To review the existing system of Clinical Establishments, Professional Services Regulation and Accreditation of Health Care Infrastructure (Public, Private, NGO) in urban and rural areas with a view to provide universal access to equitable, affordable and quality health care which is accountable at the same time responsive to the needs of the people, reduction of child and maternal deaths as well as population stabilization, and also achieve goals set under the National Health Policy and the Millennium Development Goals.

ii) To identify the potential areas/infrastructure/ institutions involved in providing accreditation with a view to ensure cost effective and standardized delivery of health services to people in rural & urban areas.

iii) To suggest a practical and cost efficient system of Accreditation of Health Care Infrastructure.

iv) To deliberate and give recommendations on any other matter relevant to the topic.

It was decided by Secretary (Health & FW) that Dr R.K. Srivastava, Director General of Health Services will chair the meetings of the Working Group and Shri Vineet Chawdhry, Joint Secretary would function as Secretary.

Setting up of a Core Group

3. Director General Health Services set up a core group comprising of the following to prepare the background material as per the TORs: -

1. Shri Vineet Chawdhry, Joint Secretary, Ministry of Health & Family Welfare, Nirman Bhavan, New Delhi.

2. Shri Giridhar Gyani, Secretary General, Quality Council of India, New Delhi.

3. Shri Sunil Nandraj, WR Office, WHO, Nirman Bhavan, New Delhi.

4. Dr. A.N. Sinha, CMO, Dte. General of Health Services, Nirman Bhavan, New Delhi.

Meetings of the Core Group & Working Group

4. Two meetings of the Core Group were held on 24.7.2006 and 18.9.2006 to finalise the background papers on Clinical Establishment Registration & Regulation Legislation and Accreditation of Clinical Establishment and the same were circulated to all the members of the Working Group.

5. A meeting of the Working Group was held on 25.9.06 in Nirman Bhawan, New Delhi. List of participants is enclosed (Annexure- I).

Regulation of Clinical Establishments

Introduction and background

6. In majority of the countries, quality of care provided by the health care delivery system has come into sharp focus. Since quality is a crucial factor in health care, initiatives to address quality of health care have become worldwide phenomena. Many countries are exploring various means and methods to improve the quality of health care services. In India the quality of services provided to the population by both public and private sectors remains largely an unaddressed issue. The current structure of the health care delivery system does not provide enough incentives for improvement in efficiency. Mechanisms used in other countries to produce grater efficiency, accountability, and more responsible governance in hospitals are not yet deployed in India. The for-profit private sector accounts for a substantial proportion of health care in India (50% of inpatient care and 60-70% of outpatient care), but has received relatively less attention from the policy makers as compared to the public sector. Thus the private sector health care delivery system in India has remained largely fragmented and uncontrolled, and there is a clear evidence of serious quality of care deficiencies in many practices. Problems range from inadequate and inappropriate treatments, excessive use of higher technologies, and wasting of scarce resources, to serious problems of medical malpractice and negligence. Current policies and processes for health care are inadequate or not responsive to ensure health care services of acceptable quality and prevent negligence.

7. In the present situation there is a need to establish bodies and systems to monitor clinical and non-clinical effectiveness of the services offered in the public and private facilities. In India concerns about how to improve health care quality have been frequently raised by the general public and a wide variety of stakeholders, including government, professional associations, private providers and agencies financing health care. There also have been attempts to establish systems and process that would ensure quality of care by the health providers.

Defining Regulation

8. Regulation can be thought of as occurring when a Government/State exerts control over the activities of individuals and firms (Roemer, 1993). More specifically, regulation has been defined as government " action to manipulate prices, quantities (and distribution), and quality of products" (Maynard, 1982). Regulation seeks to ensure quality, accountability, protect the consumers and control costs as well as the distortions created by market forces.

Regulation of Clinical Establishments

9. There are several actors involved in the regulatory process namely, the health care professionals, managers, ministry of health, commercial interests, NGOs, community and consumer groups amongst others.

Global Experience

10. Review of global experiences show that regulatory frameworks in the health sector assume a variety of forms. One of the first challenges countries have faced in planning for regulation and accreditation systems is to gain consensus on the definitions of various forms of regulation and evaluation, Licensure, certification and accreditation of healthcare organizations have been used in many countries as tools for defining the required characteristics of acceptable healthcare services. Their voluntary or mandatory nature varies as a function of system objectives. The following definitions are based on technical support experiences in a variety of countries:

- Licensure — a government administered mandatory process that requires healthcare institutions to meet established minimum standards in order to operate.

- Certification — a voluntary governmental or non-governmental process that grants recognition to healthcare institutions that meet certain standards and qualifies them to advertise services or to receive payment or funding for services provided.

- Accreditation — a process by which a government or non-government agency grants recognition to healthcare institutions that meet certain standards that require continuous improvement in structures, procedures or outcomes. It is usually voluntary, time-limited and based on periodic assessments by the accrediting body, and may, like certification, be used to achieve other desirable ends such as payment or funding.

Determination of the mechanism(s) a country will adopt is essential in order to differentiate the evaluation functions to be used, the purposes of each and the entity (ies) that will employ each mechanism.

Broad concept of Regulation of Clinical Establishments

11. The foremost amongst these mechanisms is legislation or imposition of legal restrictions or controls where participants must conform to legislated requirements. In addition to these formal rules, more informal codes of conduct, standards, guidelines or recommendations may exist. Essentially, the elements of any regulatory process include establishment of rules, its application to specific cases, detection or monitoring violations and imposition of penalties on violators.

The scenario in India

Constitutional Provisions

12. The preamble to the Constitution of India coupled with the Directive Principles of State Policy strives to provide a welfare State with socialist patterns of society. It enjoins the State to make the "improvement of public health" a primary responsibility. Furthermore, Articles 38,42,43 and 47 of the Constitution provide for promotion of health of individuals as well as health care. The Constitution of India also enumerates the separate and shared legislative powers of Parliament and State Legislatures in three separate lists: the Union List, the State List and the Concurrent List. The Parliament and State legislatures share authority over matters on the Concurrent List, which include criminal law and procedure; marriage, divorce and all other personal law matters; economic and social planning; population control and family planning; social security and social insurance; employment; education; legal and medical professions; and prevention of transmission of infectious or contagious diseases. Laws passed by Parliament with respect to matters on the Concurrent List supersede laws passed by state legislatures. The Parliament generally has no power to legislate on items from the State List, including public health, hospitals and sanitation. However, two-thirds of the Rajya Sabha may vote to allow parliament to pass binding legislation on any state issue if "necessary or expedient in the national interest". In addition, two or more States may ask parliament to legislate on an issue that is otherwise reserved for the state. Other states may them choose to adopt the resulting legislation.

Issues in regulation of Health matters in India

13. Health regulation in India encompasses a variety of actors and issues. These include promulgation of legislation for health facilities & services, disease control & medical care, human power (Education, Licensing & Professional Responsibility), Ethics & Patients Rights, Pharmaceuticals & Medical Devices, Radiation Protection, Poisons & Hazardous Substances, Occupational Health and Accident Prevention, Elderly, Disabled & Rehabilitation Family, Women & child Health, Mental Health, Smoking/Tobacco Control, Social Security & Health Insurance, Environmental Protection, Nutrition &

Food Safety, Health Information & Statistics and Custody, Civil & Human Rights to enumerate a few.

Regulation relating to the Medical Profession

14. There exists legislation with respect to licensing of medical professionals such as doctors, nurses, dentists and pharmacists with a view to control their entry into the market. Statutory regulatory councils have been established to monitor the standards of medical education, promote medical training and research activities, and oversee the qualifications, registration, and professional conduct of doctors, dentists, nurses, pharmacists, and practitioners of other systems of Medicine such as Ayurveda, Yoga, Unani, Siddha and Homeopathy. Important of these laws are: the Indian Medical Council Act, 1956, the Indian Nursing Council Act, 1947; the Indian Medicine Central Council Act, 1970; the Homeopathy Central Council Act, 1973; and the Pharmacy Act, 1948. Almost all of these laws establish councils that set forth uniform educational and qualification standards. In addition, each statute establishes a central registry for individuals certified to practice the field of medicine regulated. Finally, councils often prescribe standards of professional conduct and determine which actions amount to professional misconduct.

15. There also exist few institution specific regulations such as the All India Institute of Medical Sciences Act 1956, the Post Graduate Institute of Medical Education and Research, Chandigarh Act, 1966, the National Institute of Pharmaceutical Education & Research Act, 1998 and the Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum Act, 1980 enables the establishment of institutes of national importance. The Bureau of Indian Standards Act, 1986 made possible the establishment of a Bureau for the harmonious development of activities of standardization, marketing and quality certification of goods.

Regulations relating to Disease Control & Medical Care

16. Under the realm of disease control and medical care, various laws were enacted. The oldest laws pre-date to the days of the British Rule. Some of these include, the Epidemic Disease Act of 1897, which provides for prevention of dangerous epidemic diseases, the Lepers Act of 1898 and the Indian Aircraft Act of 1934. Thereafter, various other legislations such as the Medical Termination of Pregnancy Act, 1971 and its subsequent amendment. Which permits MTP by a registered medical practitioner in a variety of specified circumstances. Similarly, the use of pre-natal diagnostic techniques is also regulated through the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994 and its subsequent amendment in 2002. This Act prohibits the use of prenatal diagnostic tests for the purpose of determining fetal sex and the practice of "sex selection". Such tests may only be conducted at registered facilities and for limited purposes, including the detection of chromosomal abnormalities, genetic metabolic diseases, sex-linked genetic disorders, and congenital anomalies. There also exists separate legislation, namely, the Transplantation of Human Organs Act, 1994 that

provides for the regulation of removal, storage and transplantation of human organs and for the prevention of commercial dealings in human organs.

Regulations relating to Drugs & Pharmaceuticals

17. The key central statute governing the import, manufacture, distribution and sale of drugs and cosmetics is the Drugs and Cosmetics Act, 1940. In empowering the Central Government to regulate the import, manufacture, distribution, and sale of drugs in India, the Drugs Act establishes institutions – such as the Drugs Technical Advisory Board and the Central Drugs Laboratory – to execute certain provisions of the Act. The Ministry of Health and Family Welfare mainly administers the provisions in this Act through the Central Drugs Standard Control Organization. This organization performs a variety of functions such as approving new drugs and establishing uniform drug standards. In addition to the elaborate rules formulated under this Act, the various lists of schedules regulate various aspects related to vaccines (Schedule G), prescription drugs (Schedule H), standards of disinfectant fluids (Schedule O), life period of drugs (Schedule P), standards of condoms (Schedule R), standards of cosmetics (Schedule S), GMP for Ayurvedic drugs (Schedule T) and requirement and guidelines on clinical trials for import and manufacture of new drugs (Schedule Y) to enumerate a few.

18. There also exist several legal standards that address blood safety and transfusion services. In 1993, amendments to the Drugs and Cosmetics Act and accompanying rules required the screening of blood for five transmissible infections, including HIV/AIDS. Blood banks are required to obtain a license from the relevant authority, and these licenses must be renewed at regular intervals. A 1996 Supreme Court decision also generated key changes in the regulation of the country's blood supply. In *Common Cause v. Union of India and others,* the court set forth mandatory licensing of blood banks, a ban on professional blood donations and strict guidelines for holding blood donation camps.

Regulations of the private institutional providers of health care

19. Studies on utilization and household health expenditures reveal that 50 percent of people seeking indoor care and around 60 to 70 per cent of those seeking ambulatory care (or out-patient care) go to private health facilities in the country. The private health sector comprises of the 'not-for-profit' and the 'for-profit' health sectors. Despite their considerable presence in the country, information about the number, role, nature, structure, functioning, type and quality of care in private hospitals remains grossly inadequate. Quality of care provided by the private health care services in India has also come under scrutiny. This exists in a set up where there exist few systems for quality assurance, with majority of the population utilizing the services of the formal health sector but having no control on the quality of care.

20. Furthermore, regulations and accountability mechanisms for private establishments are far and few in between. In vast majority of the States in India, clinical

establishments are not regulated or monitored. Only few States have requirements for registration of private facilities such as hospitals and nursing homes.

Regulation of Clinical Establishments in India

21. As ' health' is a state subject, some State legislation had been brought out by UTs/States quite early such as:

i. The Bombay Nursing Homes Registration Act, 1949;
ii. Delhi Nursing Homes Registration Act, 1953;
iii. Tamilnadu Private Clinical Establishments Act, 1997.

A comparison of the various provisions of the three above named Acts is at Annexure II. While the Tamilnadu Act did not perhaps get implemented, the other two statutes named above were also felt to have become outdated. The general impression derived is that these laws have never been implemented in the right spirit. Even in these States/UTs, there has been haphazard growth of private clinical establishments. The High Courts of Delhi and Mumbai have also intervened through their various orders for effective implementation of these statutes.

Directive from the National Human Rights Commission – 1996

22. Much later, in 1996 the death of one Ina Raja in a private hospital due to medical negligence was reported to the NHRC. The Commission directed the Govt. of India, MCI and the Delhi Govt. to examine:

Registration of private hospitals after ensuring availability of minimum facilities

Monitoring to ensure availability of facilities,

Framing of regulations,

Violation to be made a cognizable offence,

Shifting of non-conforming hospitals that are health hazards from non-conforming areas.

Resolutions of the Central Council of Health & Family Welfare

23. The Central Council of Health and Family Welfare in its 5th Conference held in January 1997 had resolved that: -

(a) States may enact laws to provide for registration of only those private hospitals that have minimum facilities for different forms of treatment.

(b) Monitoring mechanisms should be developed by the State to ensure that the facilities and services created in private and voluntary sector hospitals continue to be available and are maintained at the desired level; and

(c) Private Hospitals in non-confirming areas that are posing health hazards may be considered for shifting to other areas.

(d) The accreditation system would however, require to be studied.

Consequently, the National Institute of Health & Family Welfare was assigned the responsibility of drafting model legislation. The same was circulated to all State governments in February 1999. (Annexure-III).

24. Again the Council in its 6th Conference held in 1998 examined the matter afresh and resolved that the Central Government may frame norms and standards for ensuring proper health care for different categories of institutions in consultation with the State Governments for private hospital/Nursing Homes/Clinical Establishments to be followed by all the State Governments. These norms shall prescribe the minimum standards of staff and infrastructure for all such institutions. The Council further resolved that the State Government may enact laws to provide for compulsory registration of private hospitals, nursing homes and clinical establishments in order to ensure minimum facilities for different forms of treatment. It would also be necessary to regulate fees charged by the private health institutions. The laws could provide for compulsory exhibitions of fees, qualification of doctors, equipment available, etc.

25. To carry out the above mandate a National Workshop was organized by the Government of India, with assistance of WHO and the Medical Council of India on 18th and 19th August, 1999 at New Delhi to provide for a discussion among the service providers of nursing homes and hospitals for the purpose of presenting the minimum standards for registration of nursing homes and hospitals. A copy of the proceedings of this workshop is enclosed (Annexure- IV).

26. It was however felt that uniform enforcement of minimum standards would require a central legislation. Therefore, to vest in Parliament the authority to legislate on this subject, Ministry of Health & Family Welfare wrote to all States for getting appropriate resolutions passed from the State Legislatures. Only three states viz. Himachal Pradesh, Mizoram and Arunachal Pradesh have passed such resolutions. However, this does vests in Parliament to legislate on regulation of Clinical Establishments. Therefore, in the year 2000, another draft Bill under the nomenclature Clinical Establishments Regulation and Accreditation Bill was prepared.

Legislation by States

27. During this entire period, various states have also enacted their own legislations for regulating Clinical Establishments. As per available information the following States have enacted laws for regulation of clinical establishments:

i. Bombay Nursing Homes Registration Act, 1949 (Annexure V)

ii. The AP Private Medical Care Establishments Act, (Annexure VI)

iii. Delhi Nursing Homes Registration Act, 1953 (Annexure VII)

iv. Orissa Clinical Establishment (Control and Regulation) Act, 1991 (Annexure VIII)

v. Punjab State Nursing Home Registration Act, 1991 (Annexure IX)

vi. Manipur Nursing Home and Clinics Registration Act, 1992 (Annexure X)

vii. Sikkim Clinical Establishments, Act 1995 (Annexure XI)

viii. Nagaland Health Care Establishments Act, 1997 (Annexure XII)

ix. MP Clinical Establishments Regulation Act. (Annexure XII-A)

It is also gathered that some more States such as Rajasthan, Karnataka and Haryana have drafted the regulatory legislations but have not been able to get them tabled and considered by their respective legislative assemblies.

Issues relating to enforcement, effectiveness and implementation

28. Despite the plethora of legislation for regulating clinical establishments, the common perception continues to be that such establishments are by and large not subject to any regulation and are, therefore, not accountable. A critical analysis of existing clinical establishment Acts suggests the following deficiencies and weaknesses:

Out datedness of existing legislations:

29. Until recently, there are only few examples of regulations promulgated by the State sat local government levels e.g., Nursing Home Acts of Delhi and Bombay. Furthermore, most of the legislations affecting the health sector are old, inherited from pre independence days, cumbersome and irrelevant to the concerns of today's health sector. Many regulations have not been updated and, therefore, have lost their relevance.

Ineffective implementation:

30. Despite the existence of basic legislation, the degree to which regulations are enforced and effective is low. It has been found that the enforcement of regulatory controls is often weak or lacking. A PIL had to be filed in Maharashtra to force the state to implement the BNHRA 1949. States have limited capacity and resources to effectively implement the existing regulations.

Absence of rules:

31. Even in States that have enacted the clinical establishment Act, rules have not been framed for its implementation.

Ineffective content of rules:

32. Even in case the local governments have promulgated the rules, these merely cover registration of nursing homes/private hospitals. Minimum standards have not been developed, nor are issues relating to accountability of quality and price been addressed.

Non-coverage of other private institutional providers:

33. There is absence of legislation to regulate functioning of laboratories and diagnostic centers private service providers, despite the emergence of a considerable number of such facilities in India.

No uniformity in standards:

34.Standards framed by different States have nothing in common. Thus what may be a minimum standard in one State might be considered too harsh in another. While it has to be acknowledged that State specific variations would certainly exist, the need of the hour is for uniform standards.

Options for future action

35. From the preceding discussion, it is evident that despite enactment of legislations by various States, health care providers in India continue to be fairly unregulated. Some factors responsible for the wishy-washy implementation of existing laws have been enumerated in the preceding paragraph. Protracted discussions have been held in this Ministry with various stakeholders for almost a decade now, with no concrete results. On account of this, however, there is an increased awareness about the general mistrust and apprehension on the part of various service providers that such regulatory laws are prone to be mis-used and would unleash licensing and Inspector Raj into a sector that has hitherto remained by and large self-regulating. Hence, there is resistance to the implementation of the laws already enacted.

36. The fact that most of these State laws keep the government clinical establishments out of the requirements of registration and adherence to minimum norms further fuels this suspicion. Private sector players are quick to accuse the govt. of observing double standards in prescribing minimum standards for private establishments and doing nothing to improve the pathetic conditions in public health institutions. This issue would need to be addressed in the right spirit by the government. No exemptions have been provided for government institutions in laws framed for management of bio medical waste, setting up of blood banks and pre-natal diagnostic tests etc. All these laws have had salutary impact on their specific areas. All the more reason that government establishments should also be required to register and comply with prescribed standards. As a matter of fact MOH&FW has already started developing the Indian Public Health Standards (Annexure XIII) and compliance to these ought to be made mandatory especially when funds are also being provided out of the National Rural Health Mission for up gradation of public Health Institutes.

37. Another roadblock is the lack of clarity about standards. The variety of health service provides is so vast that it would be well neigh impossible to have uniform minimum standards to cover each and very possible clinical establishment. It is the understanding of this Group that this is one significant reason that has held back most States from formulating any minimum standards to regulate clinical establishments. Most States particularly the Health Departments are so bogged down with multifarious responsibilities that they have hardly any free time for innovative thinking. A lead role is, therefore, necessary for the Central Government in this area.

Centre to enact Central legislation

38. Historically, all laws pertaining to registration of medical professional have been central statutes as the Indian Medical Council Act, The Dentists Act and the Nursing Council Act. No similar central legislation exists for paramedics and paramedical education and practice continues to be unregulated despite enactment of laws by States for regulating para medical education. Moreover, experience suggests that as the private sector develops or as resources become available, it is much harder to implement regulatory legislation. Second, the existence of central legislation also means that as the judicial system is strengthened, or consumers become more aware of their rights, there is legal recourse through which to pursue the implementation of regulations. In the context of the NRHM, when the Centre is exploring options for public private partnerships, regulation of private institutional providers of health assumes greater significance.

Implementation at the district level

39. In terms of implementation, two aspects are of prime importance – firstly there is a need to empower Panchayti Raj Institutions to undertake registration and monitor the minimum standards for clinical establishments. This is already mandated by the 73rd and 74th amendments to the Constitution of India. Secondly there exists a need for provision of resources and developing capacities to undertake the task of implementing standards that may get to be prescribed.

STEPS INVOLVED

40. In the light of the above discussion, the following steps are recommended for implementation: -

(i) The Central Government should enact legislation for registration and regulation of clinical establishments.

(ii) Registration should be compulsory for all clinical establishments including diagnostic centres etc. under any recognized system of medicines.

(iii) Public Health Clinical Establishments (government owned) should also be brought under the purview of such legislation.

(iv) Even if the clinical establishment is already registered under any State Act, it should be required to re-register under the Central Act. This is necessary to have a reliable database of functional clinical establishments in the country. This would also help inventorize availability of manpower and infrastructure in clinical establishments, which could form the basis for developing uniform minimum standards. To instill confidence in these service providers, the Central Law should be simple and client friendly.

(v) It should encourage use of IT and web based technology so that data mining and updating of records become completely digitalize.

(vi) As far as possible, registration should be done on the basis of documents certified by licensed professionals such as Chartered Accountants, approved valuators, assessors etc. The setting up of administrative paraphernalia for inspection is to be discouraged.

(vii) To the maximum extent possible, the responsibility of actual registration should be entrusted to Panchayati Raj Institutions (PRIs). There is already a multiplicity of licensing/inspector authorities under various health related legislations. These are, therefore, required to be consolidated.

(viii) There need not be any direct role of the Central Government in the registration process except for maintaining a National Register of Clinical Establishments and for determining uniform minimum standards. Such a pattern already exists in the registration of medical, dental and nursing professional.

(ix) A corpus should be set up for supporting research in the development of standards. It would be necessary to engage specialists and experts to suggest justifiable standards.

(x) Minimum standards should be determined through a consultative process that would foster greater responsibility. The National Advisory Board should be set up for overseeing this exercise. Such Boards could draw upon various professional bodies and individuals for assistance in development of standards. It has to be encouraged that this will be a long drawn process and in all probability would have to be preceded by classification and categorization of various clinical establishments. It is for this reason that it is not proposed to link registration with determination of minimum standards.

(xi) Due care would have to be taken to avoid over emphasis on standards for infrastructure. Otherwise investments required to comply with standards might have a spiraling effect on service costs in the health sector. Greater focus would, therefore, be required on standards for service delivery.

41. It is understood that the Ministry of Health and Family Welfare has already prepared draft legislation on the above lines. A copy of the same is placed at Annexure XIV. The Group has examined the draft and recommends that the Ministry should carry this forward.

Regulation of Professionals

42. In so far as medical professionals are concerned, legislative framework for their registration and regulation already exist in forms of the Indian Medical Council Act, the Dentist Act and the Nursing Councils Act. All these legislations set up regulatory councils at the National and State levels. While the National Councils prescribe norms and standards of education, the State Councils primarily deal with registration and enforcement of standards. Despite this, not much data is available at the national level about the availability and quality of medical and para-medical personnel. The registration of an individual is currently a one-time exercise in most States. Acquisition of additional and higher qualifications by the individuals is not required to be registered. Similarly, the shifting out from a particular State, change of address or the demise of the registered professional does not necessarily gets updated. All State Councils must, therefore, shift to a system of periodical renewal of registration, say every three to five years. Acquisition of qualification of a specialist or a super specialist must also be required to be registered. These details should also get transferred to a National Register to be maintained and updated by each apex council. When such data is available, proper planning of human resource requirement could be possible. There is also need to move forward towards a system of accreditation of various courses offered by Medical, Dental and Nursing educational institutions. The Human Resource Ministry has already established system for accreditation and rating of universities. Such a system is also needed in the sector of medical education. The proposed Medical Education Grants Commission could have appropriately handled this task. Till such by time a Commission

is set up, this task could be entrusted to premier institutions like the AIIMS, New Delhi, PGIMER, Chandigarh.

43. In the field of Para Medical Education, the situation is not comfortable. This sub sector continues to be primary unregulated. Few States have set up Para Medical Councils. However, lack of uniformity of norms and standards has not given any creditability to set up councils outside the States these have been set up in. The need, therefore, is to set up National Para Medical Council as an apex body to determine standards for para medical education, and to ensure uniform enforcement throughout the country.

Accreditation

International Scenario on Accreditation in Healthcare Services

44. A critical issue facing the health sector today is quality, with growing urgency amongst health care providers as well as consumers. Among the various approaches gaining momentum, 'accreditation of health facilities' has gained acceptance and prominence globally.

Introduction:

45. Accreditation is defined as public recognition of achievement of accreditation standards by a healthcare organization, demonstrated through an independent external assessment of that organization's level of performance in relation to the standard. Accreditation assessment relies on establishing technical competence of an organization in terms of accreditation standards in delivering services with respect to its scope. It goes beyond compliance. It calls for excellence on continued basis. It is this feature which makes it market driven involving all stakeholders; be it consumers, empanelling agencies, regulators and other third parties. Accreditation is also one of the established mechanism world over, as means to promote acceptance conformity assessment results, nationally as well as internationally.

46. In other words, the basis for accreditation is the existence or absence of such standards measured through qualitative indicators (evidence of performance) observed by a body of experts.

47. Accreditation is voluntary. It focuses on learning, self-development, improved performance and reducing risk. Accreditation is based on optimum standards, professional accountability and encourages healthcare organization to pursue continual excellence.

The concept of Hospital Accreditation

48. Accreditation in healthcare services refer to the evaluation process in which an accrediting body examines a healthcare organization to ensure that it is meeting certain

standards established by experts in the field. Accreditation is usually performed by a multidisciplinary team of health professionals and is assessed against the published standards for the environment in which clinical care is delivered. The standards adopted nationally usually derive from an amalgamation of national statutes, governmental guidance, independent reports, overseas accreditation standards and biomedical and health services research.

49. The process of quality assessment through accreditation features the need of establishing standards for all services of a general hospital for example according to universally/nationally accepted quality standards. The best country specific approach is however, dependant upon the desired outcomes of the accreditation system. The basic expectations for an accreditation system are that it provides for:

an independent, objective evaluation process;

be highly credible and unbiased;

represent the broadest possible consensus among users and stake holders;

encourage improvement in the delivery of healthcare;

and be relied upon by key users and stakeholders.

50. Cardinal principles of accreditation evaluation are;

i) Hospital operation are based on sound principles of system based organization; transparent and objective.
ii) Accreditation standards are implemented and institutionalized into hospital functioning.
iii) Patient safety and quality of core, as core values are established and owned by management and staff in all functions and at all levels.
iv) There is structured quality improvement program based on continuous monitoring including feedback on patient care services.

51. The evaluation process incorporates interview with patients, residents and staff. It calls for on-site visit to patient care areas and to departments, addressing issues related to physical assessment of infrastructure, medical equipment, security, infection control etc., as required in the accreditation standards. In short accreditation is comprehensive review of not only facility but also of clinical competence of hospital to deliver services within its scope.

52. With rapid growth of state of art private sector in the healthcare, the accreditation program in moving closer to regulatory agenda. In most developed economies there are very strong financial incentives to seek accreditation. Governments acknowledge that independent assessment program by way of accreditation should be encouraged with

incentives, more so for secondary/tertiary level of hospitals to bring in thee best in terms of Patient Safety and Quality of Care.

53. The accreditation body, while operating in regulatory areas i.e. Healthcare, Food Safety, will have some kind of linkages, may be with the regulator. For example, regulation may provide that a healthcare organization will automatically be deemed to have been registered, if accredited by the recognized national accreditation body. Similarly accreditation body will take cognizance of applicable regulatory requirements at the time of granting accreditation.

Global Scenario

54. The accreditation of health services originated in the U.S. during the early ninety's and today is the main instrument used by the U.S. Government for the distribution of financial resources to health institutions. The Government only contracts those health institutions that have been accredited. Other regions have also applied this method, such as Canada. Australia and the Province of Catalonia, in Spain. In the Australian system, a star rating is given to hospitals like the star ratings of hotels. The rating is given according to the facilities provided. The form of accreditation, however, would vary from country to country. The United Kingdom has self-accreditation program. In Latin America, after the II Accreditation Conference (1992), the process began to be implemented through national meetings in practically all countries. In Argentina, Chile and Uruguay initiatives have been observed at the central or state levels. In the Andean sub-region the success in Bolivia, Colombia and Peru has been significant. Guatemala stands out the most in Central America; and in the Caribbean, the Dominican Republic has fully embarked on the process of accrediting its private hospitals. Cuba, until the end of 1997, intended to have 60 hospitals accredited. In Southeast Asia significant progress in accreditation has been accomplished in Indonesia and Thailand.

Country specific status of hospital accreditation

USA:
The accreditation of hospitals began way back in 1910 in the United States, when Ernest Codman, M.D., proposed the "end result system of hospital standardization". The proposal became the stated objective of American College of Surgeons (ACS) that developed the first minimum standards for the hospitals in the year 1917. In the year 1951, the American College of Physicians (ACP), and the Canadian Medical Association (CMA) joined with the ACS to create the Joint Commission on Accreditation of Hospitals (JCAHO) and independent, not-for-profit organization whose primary purpose is to provide voluntary accreditation. It has accredited about 15000 healthcare organizations.

Australia:
The Australian Council on Healthcare Standards (ACHS) is the pioneer in accreditation in Australia. It had accredited around 700 healthcare organizations by 15th October 2001. It began as collaboration between doctors and administrators in adjacent states, based on

Canadian model. It an independent, not for profit organization, dedicated to improving the quality of healthcare in Australia through continually reviewing of performance, assessment and accreditation.

The organization is governed by a board of Directors elected by council members and supported by a corporate management structure, which oversees the process of evaluation and assessment by professionally qualified surveyors. The body has formal links with the government through representation on council and governing board. The programme focuses on the primary, secondary and tertiary care service providers. ACHS was accredited by ISO against their international standards for national healthcare accreditation bodies in the year 2001.

Canada:
The Canadian Council on Health Services Accreditation (CCHSA) is a national, non-profit, independent organization whose role is to help health services organization, across Canada and internationally examine and improve the quality of care and service they provide to their clients. It has accredited around 3500-4000 healthcare organization in the country and around 5-6 healthcare organizations internationally. It was setup following the separation of the United States and Canadian accrediting bodies in 1958. It is the second longest established programme in the world. It is totally independent of government, but in some provinces the government gives a financial incentive for accreditation and is sole accrediting body in Canada. The programme focuses on the primary, secondary and tertiary care service providers. CCHSA underwent accreditation survey by ISQua in the year 2002.

Ireland:
The Irish Health Services Accreditation Board (IHSAB) is an independent organization established under a statutory instrument (SI), whose prime purpose is to continuously review and operate an accreditation scheme for the Irish health system within a quality improvement framework using an approach of self-assessment and peer review survey.
The board mainly focuses on acute health services. It is on the process of getting ISQua accreditation. The process of accreditation is voluntary. The board has accredited around 35 hospitals to date.

Malaysia:
The Malaysian Society for Quality in Health (MSQH) was formed through the initiatives of both the Ministry of Health Malaysia and the Association of Private Hospitals of Malaysia. The society is an independent, not profit organization working actively in participation with healthcare professionals to ensure continuous quality improvement in health in the services provided by healthcare services and facilities in the country. It is strongly supported by the Ministry of Health. The accreditation process in the country is voluntary. The society has accredited 66 hospitals as of 6th May 2006.

New Zealand:
Quality Health New Zealand is an independent non-profit organization and is constituted as an incorporated society. It was set up as the New Zealand Council on Healthcare

Standards (NZCHS) to provide a voluntary accreditation programme for hospitals and other health services with the technical support of ACHS. The government, the Health Boards Association and the private Hospitals Association, initially funded it. Today it is financially independent mainly funded from the fees paid by participants in its Accreditation Programme and clients of its other assessment services.
It mainly focused on aged care facilities and private and public acute hospitals and services but also have programmes for primary care, hospices, disability support and no-for-profit voluntary organizations. Since 1990 Quality Health New Zealand has worked with a wide range of health and disability services thought New Zealand, undertaking well over 500 surveys and numerous audits.

South Africa:
The Council on Health Service Accreditation for South Africa (COHSASA) is structured as a national collaborative effort between the state, private sector consumers and health professionals. In terms of the memorandum and articles of association, the structure of the council includes a board of directors, an executive team and several member organizations. It is a total independent programme and focuses on all the primary, secondary and tertiary care. It includes hospital based and district base services and was developed with technical support from the HAP United Kingdom.
COHSASA is the only body in this country recognized as an impartial accreditation agency for healthcare facilities and is the only healthcare accrediting organization in South Africa accredited by ISQua. Since the start of the operation, 400 healthcare facilities have entered the COHSASA programme and some of the facilities are in the process of accreditation.

United Kingdom:
The Health Quality Services (HQS) is the longest established health accreditation service in the UK and the rest of Europe. It was launched by the King's fund; a London based charity and developed into HQS providing accreditation across the spectrum of public and private services.
HQS is accredited by the ISQua. Around 114 organizations were accredited by the HQS as on 8th March 2006.

From the above scenario of accreditation of different countries, it can be said that the accreditation systems over a period of time have shifted from a single system focusing on entire hospital to a more complex pattern with specialized agencies undertaking for several compartments of the health delivery system.

Hospital Accreditation in India

55. In the Indian context it can be said that the rising demand for quality care, the limited healthcare investment by the government, the growing number of private players in healthcare and insurance sector, the opening-up of the health sector to global patients makes the search for quality an imminent reality.

56. The demand for Hospital accreditation in India was raised in the early nineties. The extension of the Consumer Protection Act to medical practitioners stimulated the demand for Hospital Accreditation. It was viewed as a device to protect medical practitioners by fixing standards of subordinate and ancillary services that could largely affect a doctor's performance and also to eliminate substandard establishments. Many Non resident Indian doctors sent in suggestions for the establishment of an Autonomous Council to lay down standards for Hospitals. This Council could also be responsible for classification of Hospitals/Nursing Homes/ Laboratories/ Clinics and would include representatives from:

- Hospital Association of India
- Voluntary Health Association of India
- Indian Medical Association
- Medical Council of India
- Dental Council of India
- Nursing Council of India
- National Academy of Medical Sciences
- Director General of Health Services or his Nominee
- Association of Surgeons of India
- Association of Physicians of India
- Association of Obstt. And Gynaecology
- Four Independent Medical Experts
- The model of the Australian Council for Hospital Standards was also suggested for the Indian Context.

Initiatives taken by the Ministry of Health & Family Welfare

57. An initiative at the national level, undertaken by the MOHFW, GOI in the year 2001 was the development of a draft organizational framework for developing a hospital accreditation system in India. This document provides organizational options for envisioned national and state accrediting organizations and considers important issues in operational sing the proposed system.

58. Another initiatives was a workshop, organized by the WTO cell, MOHFW on 9th February 2005 under the GOI-WHO biennium (2004-2005) to bring together stakeholders to discuss issues related to accreditation of health facilities.

59. The World Health Organization, India country office organized a one and half day workshop, 'Accreditation of Health Facilities in India- A Way Forward' on October 7-8, 2005 at Taj Malabar, Kochi, Kerala. Other development partners who supported this initiative included the World Bank amongst others. The Workshop sought to:

- Share key concepts & experiences relating to accreditation of Health care facilities and review the current scenario in India & draw lessons.
- Engage in a constructive dialogue with key stakeholders to explore options to develop an accreditation system that would have multiple benefits, including notably the improvement in quality of care in both public and private sectors in India.
- Develop a roadmap for establishing an accreditation system in the participating States.

60. This workshop brought together representatives from the States of Andhra Pradesh, Karanataka, Kerala, Maharashtra and Tamil Nadu. The participants included policy makers from the Central and State Governments, representatives from the private medical sector as well as civil society from the State of Andhra Pradesh, Karnataka, Kerala, Maharashtra and Tamil Nadu. Development partners including the World Bank, USAID, ECTA, DFID and GTZ also participated in the workshop.

Possible Options

61. Option 1
MOHFW Role: Confined to overall policy decisions and development of standards for health care facilities.
Role of States: Design, operationalization and implementation of an accreditation system

Option 2
MOHFW Role: Preparation of blueprint for states to implement an accreditation system, including development of standards.
States: To operationalize and implement an accreditation system

Option 3
MOHFW Role

- Policy making in consultation with stakeholders
- The national quality framework and accreditation process, in consultation with stakeholders
- Development of standards across types and level of services
- Training, information dissemination, conducting relevant, problem based research
- Developing implementation plans and monitoring
- Co-ordination and supervision of regional offices
- Facilitate sharing of experiences and skills transfer.
- Mobilizing the human, physical and financial resources to strengthen state implementation plans.
- Making recommendations to the GOI concerning quality aspects and related.

Role of States

- Implementation of Accreditation as designed by the national body.
- Support services to participants at regional level including training
- Regional monitoring of implementation of accreditation
- Review of the decisions and reports generated by the body to determine their robustness and
- Usefulness to the providers and consumers
- Redress: participating hospitals, consumer

Progress made so far

National Accreditation Board for Hospitals and Healthcare Providers

62. National Accreditation Board for Hospitals and Healthcare Providers (NABH) has come up with a uniform standard for the hospitals throughout the country. NABH is a constituent Board of Quality Council of India (QCI). It has reportedly adopted its standards and accreditation process in line with worldwide accreditation practices. The formal launch of accreditation was announced in February 2006. About 20 major hospitals were reported to be undergoing accreditation evaluation. It is institutional member of ISQua.

63. Other organizations like Indian Confederation for Health Care Accreditation (ICHA) have also starting the process of accreditation of health institutions. Financial rating organizations like ICRA have also started rating hospitals.

Empanelment by CGHS

64. For the empanelment of hospitals and diagnostic centres by the Central Government health Scheme, it has now been made mandatory that all diagnostic labs must be certified by the National Accreditation Board for Testing and Calibration Laboratories (NABL). Similarly, physical inspections of hospital that have applied for empanelment have been entrusted by Ministry of Health and Family Welfare to the Quality Council of India. Similar procedures could be adopted by the Employees State Insurance Corporation of the Labour Ministry and Ex-Servicemen's Contributory Health Scheme of the Ministry of Defence for empanelment of hospitals and diagnostic centres. It is expected that such demands/requirements shall generate further demand for accreditation and for accrediting agencies. MOHFW has, therefore, taken the position that no legislation may be necessary for accreditation of health institutions per se. This would be purely a voluntary exercise. There should therefore be an independent body that should oversee the functioning of accrediting agency to ensure that institutions of doubtful competence are not allowed to take the advantage of the lack of well-established accreditation frame. This body would also liaise with regulatory of clinical establishments for ensuring that only such establishments get accreditation that have complied with the minimum standards. It is, however, to be encouraged that setting up of such a body would be a complex and contentious exercise. It would therefore not be prudent to make the establishment of such a Supervisory of Body as a pre-condition for

introduction of accreditation in the health sector. The process of setting up a Supervisory Body can be initiated in the 11th Plan period and the financial provision should be made for facilitating the functioning of such a Body as and when it comes into being.

Recommendations

65. i) Accreditation would be purely voluntary

ii.) There can be several accrediting agencies like NABH under the Quality Council of India, Indian Confederation for Health Care Accreditation and even the Bureau of Indian Standards can take up this task.

iii.) There would be no funding from Central Government. All the organizations will have work on a self-sustaining process. However, Government of Indian would promote accreditation.

iv.) Accrediting agencies will have to take into consideration the requirements of Medical Tourism for which international standards will recognized by developed countries need to be adopted for accreditation.

v.) Accrediting agencies will also have to take into view the requirements of Insurance Companies.

vi.) Accreditation standards should be based not only on physical infrastructure, but also on standard operating procedures (SOPs) for various kinds of identifiable medical Instruments.

vii) The focus of accreditation should be on continuous improvement in the organizational and clinical performance of health services, not just the achievement of a certificate or award or merely assuring compliance with minimum acceptable standards.

66. Taken as a whole, the process will assess the extent to which health care organizations are delivering safe health care effectively. It would indicate areas of strength and weakness, including aspects requiring attention; involve an evaluation of the validity and reliability of an institution's internal review procedures, and provide reassurance that each institution has in place effective arrangements for assuring optimal standards in the organisation and has procedures securely in place that will enable it to continue to do so.

SUMMING UP

67. i.) There is need for a central legislation for registration of clinical establishments in the country. The draft legislation prepared by Ministry of Health and Family Welfare needs to be carried forward.

ii.) Registration of clinical establishments should not be linked to compliance of standards in the initial years.

iii.) Uniform standards need to be developed for the entire country. These standards should not focus on infrastructure alone, but also on service delivery.

iv.) The registration of medical professionals needs to be periodically updated. Additionally acquisition of higher qualifications should require re-registration. National Registers of all medical and para-medical personnel need to be created.

v.) National Paramedical Council should be set up for regulating paramedical education and service delivery.

vi.) Accreditation of health institutions should be voluntary, but encouraged by the Central and State governments.

vii.) There is a need for setting up of National level body to oversee the functioning of various accreditation agencies that might come into being.

viii.) Provisions need to be made in the 11th Plan for facilitating development of minimum standards and also for setting up an oversight body for accrediting agencies in the health sector.

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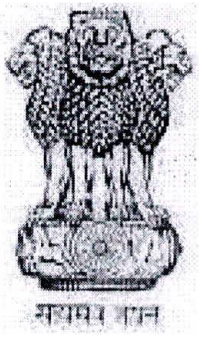
REPORT OF THE WORKING GROUP ON

POPULATION STABILIZATION

FOR THE

ELEVENTH FIVE YEAR PLAN

(2007-2012)



GOVERNMENT OF INDIA
PLANNING COMMISSION

NEW DELHI

Chapter 1

Introduction

India's successive five-year plans have provided the policy framework and funding for the development of nationwide health care infrastructure and manpower. In 1951, India became the first country in the world to launch a family planning programme to check the population growth. Since then, the family planning programme in India has undergone variety of forms. The passive, clinic-based approach of the 1950s, gave way to a more proactive, extension approach in the early 1960s. The late 1960s saw the emergence of a "time-bound", "target-oriented" approach with a massive effort to promote the use of IUDs and condoms. This was followed by even more forceful "camp approach" to promote male sterilization in the 1970s. The excesses of these campaigns lead to a severe backlash from which it took years for the programme to recover. After re-christened as Family Welfare Programme in 1978, maternal and child health services began to receive greater attention under the programme's plan of action. The centrally funded programme has been providing the states additional infrastructure, manpower and consumables needed for the delivery of services.

In the 1990s, Government of India began to reorient the programme in the light of recommendations made by a subcommittee of the National Development Council, an expert group headed by Dr. M. S. Swaminathan, and more specifically to address the concerns expressed at the International Conference on Population and Development held at Cairo in 1994. Following a major review undertaken with the support of the World Bank and other agencies in 1994-95, method-specific contraceptives targets were abolished and the emphasis shifted to decentralized planning at district level based on community needs assessment, and implementation of programmes aimed at fulfilling unmet needs. The first phase of the Reproductive and Child Health Programme was launched in 1997 as a flagship programme that covered the entire gamut of safe motherhood, child health and RTI/STI diagnosis and care. The National Population Policy (NPP) articulated the new broad-based approach towards population stabilization, and set long-term policy goals. A National Population Commission was also set up under the chairmanship of the Prime Minster of India to review, monitor and give directions for the implementation of the NPP, and to promote inter-sectoral coordination.

Goals under National Population Policy, 2000

The two important demographic goals of the National Population Policy (2000) are: achieving the population replacement level (TFR 2.1) by 2010 and a stable population by 2045. The National Population Policy envisages the following socio-demographic goals to be achieved by 2010.

1. Address the unmet needs for basic reproductive and child health services, supplies and infrastructure.
2. Make school education up to age 14 free and compulsory, and reduce dropouts at primary and secondary school levels to below 20 percent for both boys and girls.

3. Reduce infant mortality rate to below 30 per 1000 live births.
4. Reduce maternal mortality ratio to below 100 per 100,000 live births.
5. Achieve universal immunization of children against all vaccine preventable diseases.
6. Promote delayed marriage for girls, not earlier than age 18 and preferably after 20 years of age.
7. Achieve 80 percent institutional deliveries and 100 percent deliveries by trained persons.
8. Achieve universal access to information/counseling, and services for fertility regulation and contraception with a wide basket of choices.
9. Achieve 100 percent registration of births, deaths, marriage and pregnancy.
10. Contain the spread of Acquired Immunodeficiency Syndrome (AIDS), and promote greater integration between the management of reproductive tract infections (RTIs) and sexually transmitted infections (STIs) and the National AIDS Control Organization.
11. Prevent and control communicable diseases.
12. Integrate Indian Systems of Medicine (ISM) in the provision of reproductive and child health services, and in reaching out to households.
13. Promote vigorously the small family norm to achieve replacement levels of TFR.
14. Bring about convergence in implementation of related social sector programmes so that family welfare becomes a people-centered programme.

Working Group on Population Stabilization

In this context, the Working Group on Population Stabilization for the Eleventh Plan (2007-2012) was constituted by Planning Commission with the following terms of reference (TORs) under the chairmanship of Secretary (Health & FW) (**Annexure 1A**). The meeting of the Working Group was chaired by Smt. S. Jalaja, Additional Secretary (Health & FW)

a) Review the current demographic projections for the 11th Plan and beyond: the time by which the country's population is likely to stabilize; and to review the goals indicated in the National Population Policy (NPP), 2000.
b) Suggest strategy for achieving population stabilization as early as possible keeping in view the current mortality, fertility & couple protection rates in different states; fixation of state wise goals for the 11th Plan & individual years for birth rate, IMR, couple protection rates, immunization, antenatal, intra-partum, neonatal & child health care, etc.
c) Assess the current status and future requirements (short, medium & long-term) of demographic, bio-medical, social and behavioural research aimed at meeting the felt needs for health care of women and children, adolescents and aged during the 11th Plan.
d) Project financial implications for implementation of family welfare programme during 11th Plan including the plan and non-plan requirements; and the Centre-State participation in the funding.
e) To deliberate and give recommendations on any other matter relevant to the topic.

As part of this Working Group, two sub-groups were formed. One sub-group would prepare the report keeping in view the terms of references while the second

sub-group would provide inputs based on the suggestions of various expert committees constituted under the National Commission for Population.

Chapter 2

Demographic Scenario and Projections for Eleventh Plan Period

Current Demographic Scenario

India, currently the second most populous country in the world, has 17 percent of world's population in less than three percent of earth's land area. India began the 20th century with the population about 238 million and by 2000 it ended up with 1 billion. According to estimates, India added another 100 million by 2006 when its population reached 1.1 billion. The country added 16 million people annually in the1980s and 18 million annually in the 1990s until the present. While the global population has increased threefold during the last century, from 2 billion to 6 billion, India has increased its population nearly five times during the same period (Table-1). India's population is expected exceed that of China before 2030 to become the most populous country in the world.

India is in the middle of demographic transition. Both fertility and mortality have started declining throughout the country, though the pace and magnitude of the decline varies considerably across the states. Like many countries of the world, the onset of mortality decline preceded the onset of fertility decline by few decades. The country has witnessed significant improvements in demographic and health indicators since Independence. But an accurate assessment of India's demographic achievements is hampered by data deficiencies, particularly for the period before the 1970s. The official estimates of fertility and mortality levels at the time of independence are believed to be gross underestimates. Nonetheless, even they suggest significant achievements in this field. The crude birth rate, which was officially put at 42 per 1,000 in 1951-61, has declined to 24 in 2004, as per the estimates available from the sample registration system (SRS). The life expectancy at birth, which was about 32 years at the time of independence, has doubled. Infant mortality rate has come down from about 150 in 1951 to 58 by 2004.

Considering the size and diversity of India's population, the decline in both fertility and mortality is a significant achievement. Nearly one-third of India's population has lowered its fertility to replacement level. Fertility in India has come down under a wide range of socio-economic and cultural conditions. Despite this achievement, many are concerned with the pace of fertility decline, particularly in the large, north Indian states. To overcome this, the northern region of India will need much more focused programmes and more investment not only in the provision of family welfare services but also for the overall socio-economic development.

Table 1: Population Size and Growth, India, 1901-2001

Census year	Population (000s)	Growth over decade		Multiple of 1901 population
		Number (000s)	Percent	
1901	238,396	-	-	1.0
1911	252,093	1,3697	5.7	1.1
1921	251,321	-772	-0.3	1.1
1931	278,977	27,656	11.0	1.2
1941	318,661	39,683	14.2	1.3
1951	361,088	42,428	13.3	1.5
1961	439,235	78,147	21.6	1.8
1971	548,160	108,925	24.8	2.3
1981	683,329	135,169	24.7	2.9
1991	846,421	163,092	23.9	3.6
2001	1,028,737	182,316	21.5	4.3

Source: Registrar General and Census Commissioner, India, Census of India 2001: Series-1: India, General Population Tables (2006).

Achievements of Family Welfare Programme

Although India's success in fertility reduction is not comparable to that of some other Asian countries (See **Annexure A**), its achievements are by no means modest. The total fertility rate (TFR), which used to be over 6 births per woman at the beginning of 1960s, has declined to 3.0 in 2003, as per the data from the Sample Registration System. Thus essentially, India has crossed two-thirds of the way towards its goal of replacement-level fertility of 2.1. Several states in the south, with populations as large as some other Asian countries, have either already reached replacement fertility or about to reach it in a few years (see Table 2).

Table 2. Total Fertility Rate around 2000 and the Expected Number of Years It Would Take to Reach Replacement-Level Fertility, Major Indian states

Year	TFR 2000	Mean fall During last 10 years@	Years required for TFR=2.1	Expected TFR 2010
Andhra Pradesh	2.5	0.81	4	1.8
Assam	3.2	0.61	18	2.6
Bihar *	4.3	1.08	20	3.2
Gujarat	3.0	0.41	22	2.6
Haryana	3.3	0.86	14	2.4
Himachal Pradesh	2.4	1.35	2	1.8
Karnataka	2.4	1.03	3	1.8
Kerala	1.9	0.17	0	1.8
Madhya Pradesh *	3.9	0.86	20	3.0
Maharashtra	2.7	0.79	7	1.9
Orissa *	2.9	0.89	9	2.0
Punjab	2.6	0.82	6	1.8
Rajasthan *	4.1	0.45	45	3.7
Tamil Nadu	2.0	0.49	0	1.8
Uttar Pradesh *	4.6	0.75	34	3.9

West Bengal	2.4	1.02	3	1.8
All India	3.3	0.74	16	2.5
			(18)**	(2.6) **
Mean for EAG	4.2	0.82	26	3.4

* EAG states.
** State-weighted average.
@ As per the SRS data.

The percentage of married women using contraception has increased from a level just over 10 percent in the early 1970s to 48 percent in 1998-99, and to 53 percent by 2004 (Table 3). Considering the logistical problems of supplying information and services to more than 250 million women of reproductive age, this increase is a remarkable achievement. Surveys have repeatedly shown that women's knowledge about contraception is nearly universal. Female sterilization remains the most common method of family planning. For the first time in recent decades, the 2001 Census has registered a fall in the growth rate of population below two percent, indicating that the decline in the birth rate has begun to overtake the decline in the death rate.

Table 3: Use of Contraceptive Methods in India, 1992-93 to 2002-04

	Percent of married women ages 15-49 using contraception		
	1992-93	**1998-99**	**2002-04**
Any method	40.6	48.2	53.0
Any modern method	36.3	42.8	45.7
Pill	1.2	2.1	3.5
IUD	1.9	1.6	1.9
Condom	2.4	3.1	4.8
Female sterilization	27.3	34.2	34.3
Male sterilization	3.4	1.9	0.9
Any traditional method	4.3	5.0	7.3
Periodic abstinence	2.6	3.0	4.1
Withdrawal	1.4	2.0	2.7
Other	0.2	0.4	0.5
Not using a method	59.4	51.8	47.0

Sources: International Institute for Population Sciences (IIPS), National Family Health Survey 1992-93 (1995); IIPS and ORC Macro, National Family Health Survey (NFHS-2) (2000); and IIPS, Reproductive and Child Health; District Level Household Survey 2002-04 (2006).

In the early 1970s, less than 15 percent of the deliveries were occurring in institutions. It has increased to 34 percent in 1998-99 and to 41 percent by 2002-04. Thirty percent of women had institutional delivery in rural areas as against 70 percent for their urban counterparts. Before the expanded programme of immunization was lunched in 1978, the percentage of children immunized against the six preventable diseases was negligible. As per DLHS, the percentage of fully immunised children has reached 48 percent in 2002-04 at the all-India level. The same source shows that nearly three-forth of pregnant women receive antenatal check-up.

However, there are also indications of slackening in the progress towards better health. During the 1990s, the SRS data suggest deceleration in the decline of

infant mortality rate. In particular, neonatal mortality rate has hardly shown any sign of fall. The level of child immunization is also not increasing at the rate observed in the 1980s. During the six-year interval between NFHS-1 and NFHS-2, the proportion of fully immunized children increased by only one percentage point per annum. At this rate, India could hope to reach the goal of universal immunization only after 50 years! The surveys also indicate that the decline in maternal mortality rate may have also been stalled. The decline in the birth rate is yet to pick up speed in some northern states.

Regional Variations

The five Empowered Action Group states of Bihar, Madhya Pradesh, Orissa, Rajasthan and Uttar Pradesh (together with the three new states formed in this region, Jharkhand, Chhattisgarh and Uttaranchal) had a combined TFR of 4.2 around 2000. For this region as whole it would take another 26 years to reach replacement fertility under the current rate of decline (see Table 2). Thus, without acceleration of fertility decline in EAG states, India cannot hope to achieve replacement fertility by 2010. Assuming the prevalence of below-replacement fertility in some southern states, at best, India could hope to achieve a TFR of 2.6 by this date.

What are the hopes for a faster reduction in fertility in the EAG states? Table 4 shows the position of EAG states with respect to some important determinants of fertility around 2000, the average change in the determinants during the last 10 years, and the number of years it may take the region as whole to reach the levels required to attain a TFR of 2.1. The current levels of the indicators in some southern states that have achieved, or close to achieve the mark have been taken as the required levels to reach replacement-level fertility. Under the current trends, it would take the EAG states at least 25 years for the use of contraception, female age at marriage, unmet need for contraception, ideal family size and regular exposure to mass media to reach their respective levels required to attain replacement-level fertility. Only the trends in infant mortality and female literacy suggest that they would be reaching the required levels earlier. But an important caveat with respect to their trends must be noted. Although the average decline in IMR during the last 10-years has been quite rapid, there has been substantial deceleration in the decline in recent years, and further decline could be more difficult. With respect to female literacy, the 2001 Census has recorded a substantial increase probably because of adult literacy campaigns. It is doubtful whether an increase in literacy by such means would have the same effect on fertility as through formal channels. Thus the prospects for India achieving replacement fertility by 2010 seem bleak, considering the demographic challenges posed by EAG states. The demographic key indicators for states, based on DLHS (2002-04) and Facility Survey (2003) of Reproductive and Child Health Project, have been presented in **Annexure B**. The time lag between Kerala and other states in selected demographic parameters is presented in **Annexure C**.

Table 4: Levels of Some Important Determinants of Fertility in EAG States and the Numbers of Years it May Take for Them to Reach the Level Required for Replacement-Level Fertility

Indicators	Level around 2000	Change during last 10-years	Required level for TFR = 2.1	Required no. of Years
Percent using contraception	34	10	65	31
Median age at marriage	15	0.5	18	60
Unmet need for contraception	21	5	5	32
Ideal family size	3	0.3	2	33
Female literacy rate, age 7+	45	15	80	23
Infant mortality rate	85	28	40	16
Empowerment of women	Low	?	High	?
Exposure to mass media	41	12	75	28
Home visit by ANM (%)	5	?	20	?

Population Projection

The Technical Group on Population Projections set up by the National Commission on Population has recently come out with population projections for India and states. As per this report, India's population is expected to reach 1.2 billion by 2011 and 1.4 billion by 2006 (see Table 5). According to this projection, population would grow by 1.4 percent during the Eleventh Five-Year Plan period (more precisely during 2006-11). Even by 2021-26, the population is expected to have a growth rate of 0.9 percent (see Table 6). An important assumption underlying this projection is that the total fertility rate would reach replacement level (approximately 2.1) only by 2021. The reason behind this gloomy expectation is the slow pace of fertility transition in several large, north Indian states. In fact, according the Technical Group, TFR would not reach the replacement level in some of these states even by 2031. Although the Technical Group did not carry forward the projection till the date of stabilization, the projected delay in reaching the replacement-level fertility would imply that India's population would not stabilize before 2060, and until population size nears 1.7 billion.

Table 5. Projected Population of India (in millions) by Broad Age Groups, 2001-2026

Year	2001	2006	2011	2016	2021	2026
Under Age 15	365	357	347	340	337	327
15-59	593	672	747	811	860	900
60+	71	84	98	118	143	173
Total	**1029**	**1112**	**1193**	**1269**	**1340**	**1400**
Source : Office of Registrar General, India						

One of the most chilling results of this exercise is the wide geographical disparity in the projected population growth. If the total population of the country is expected to grow by 36 percent between 2001 and 2026, in southern states, the growth is expected to be around 15-25 percent only, whereas in northern parts of the country, the growth is expected to be in the range of 40-50 percent (see Table 7). Of the expected addition of 370 million to India's population during 2001-26, Uttar

Pradesh alone would account for a whopping 22 percent, and the other three northern states - Bihar, Madhya Pradesh and Rajasthan – would account for another 22 percent. The population growth in these regions is also expected to cause population pressure in major migration destinations, chiefly Delhi and Maharashtra. Clearly, something urgent needs to be done to check population growth in these states.

Table 6. Projected Levels of Some Key Demographic Indicators, India, 2001-26

Indicator	2001-06	2006-11	2011-16	2016-21	2021-26
Population growth rate (%)	1.6	1.4	1.3	1.1	0.9
Crude birth rate	23.2	21.3	19.6	18.0	16.0
Crude death rate	7.5	7.3	7.2	7.1	7.2
Infant mortality rate	61	54	49	44	40
Total fertility rate	2.9	2.6	2.3	2.2	2.0
Life expectancy at birth for males	63.8	65.8	67.3	68.8	69.8
Life expectancy at birth for females	66.1	68.1	69.6	71.1	72.3
Source : Office of Registrar General, India					

Table 7. Some Key Results of Population Projection for States, 2001-26

State	Projected growth rate	Projected population growth 2001-26			Total fertility rate	
	2006-11 (%)	% growth	(000's)	% share	2011	2021
Andhra Pradesh	1.0	23.4	17,863	4.8	1.9	1.8
Assam	1.3	33.6	8,946	2.4	2.5	2.1
Bihar	1.5	37.2	30,848	8.3	3.0	2.2
Chhattisgarh	1.4	37.2	7,757	2.1	2.8	2.2
Delhi	2.8	102.0	14,131	3.8	1.8	1.8
Gujarat	1.4	36.7	18,587	5.0	2.2	1.9
Haryana	1.7	47.0	9,942	2.7	2.3	1.9
Himachal Pradesh	1.0	24.6	1,497	0.4	1.9	1.8
Jammu & Kashmir	1.4	32.4	3,290	0.9	2.3	1.9
Jharkhand	1.4	38.6	10,410	2.8	2.7	2.1
Karnataka	1.1	26.6	14,082	3.8	2.0	1.8
Kerala	0.8	17.0	5,413	1.5	1.8	1.8
Madhya Pradesh	1.7	45.4	27,381	7.4	3.0	2.4
Maharashtra	1.4	37.6	36,454	9.8	2.1	1.9
Orissa	0.9	23.1	8,519	2.3	2.1	1.9
Punjab	1.2	28.7	6,986	1.9	2.0	1.8
Rajasthan	1.7	44.2	24,994	6.7	2.9	2.2
Tamil Nadu	0.7	15.1	9,451	2.5	1.8	1.8
Uttar Pradesh	1.8	49.7	82,565	22.2	3.7	2.8
Uttaranchal	1.5	38.4	3,257	0.9	2.7	2.2
West Bengal	1.0	25.4	20,358	5.5	1.9	1.8
North-eastern states	1.2	31.0	3,782	1.0	2.0	1.8
India	1.4	36.1	371,228	100.0	2.5	2.1

Chapter 3

Strategies to Achieve Population Stabilization

Fertility decline in India has been the effect of various socio-economic developments as well as government sponsored family welfare programme. Rising levels of education, increase in female age at marriage, influence of mass media, economic development, gender empowerment and measures for equality, continuing urbanization, diffusion of new idea, and declines in infant and child mortality have all contributed in lowering the levels of fertility. These factors, along with strong health infrastructure and focused family welfare programme, will continue to be driving the fertility transition. Even at the national level, the views regarding the ideal number of children are fast approaching the two child norm. But at the same time, preference for sons is clearly evident in many parts of India. The regional difference in fertility level is also likely to continue for many more years. Given this context, what are the strategies that can be adopted to achieve the population stabilization within a reasonable time period?

National Rural Health Mission (NRHM)

Recognizing the importance of health for social and economic development and for improving the quality of life, the Govt. of India launched the National Rural Health Mission (NRHM) in 2005 to carry out the necessary correction and strengthening of basic health care delivery system. The Plan of Action of NRHM envisages increasing public expenditure on health, reducing regional imbalances in health infrastructure, pooling resources, integration of organizational structures, optimization of health manpower, decentralization and district management of health programmes, community participation and ownership of assets and providing public-private partnership. The goal of the mission is to improve the availability of and access to quality health care of the people, especially for those residing in rural areas, the poor, woman and children.

The expected outcomes from the Mission as reflected in statistical data are:

- IMR reduced to 30/1000 live births by 2012.
- Maternal Mortality reduced to 100/100,000 live births by 2012.
- TFR reduced to 2.1 by 2012.
- Malaria Mortality Reduction Rate – 50% up to 2010, additional 10% by 2012.
- Kala Azar Mortality Reduction Rate – 100% by 2010 and sustaining elimination until 2012.
- Filarial/Microfilaria Reduction Rate – 70% by 2010, 80% by 2012 and elimination by 2015.
- Dengue Mortality Reduction Rate – 50% by 2010 and sustaining at that level until 2012.
- Cataract operations-increasing to 46 lakhs until 2012.
- Leprosy Prevalence Rate – reduce from 1.8 per 10,000 in 2005 to less than 1 per 10,000 thereafter.
- Tuberculosis DOTS series – maintain 85% cure rate through entire Mission Period and also sustain planned case detection rate.

- Upgrading all Community Health Centers to Indian Public Health Standards.
- Increase utilization of First Referral Units from bed occupancy by referred cases of less than 20% to over 75%.
- Engaging 4,00,000 female Accredited Social Health Activists (ASHAs).

The NRHM (2005-12) seeks to provide effective health care to rural population throughout the country with specific focus on 18 states that have weak public health indicators and poor health infrastructure.

Meeting the unmet demand for contraception

The NPP document lays great stress on meeting the unmet need for contraception as an instrument to achieve population stabilization. The presence of high level of unmet need for contraception in EAG states is not a myth, as it is supported by data from both NFHS and DLHS. But it would be a mistake to assume that inadequate access to services should be the dominant, or even a major, explanatory factor for its presence. As a carefully conducted in depth investigation in the Philippines had shown, unmet need for contraception could arise from several reasons, such as weak motivation, low female autonomy, perceived health risks, and moral objection to the use of contraception. The elimination of these factors, and thus the unmet need, could prove to be as difficult as generating fresh demand for contraception.

According to the DLHS Round 2 (2002-2004) 21 percent of women in India have an unmet need for family planning. The unmet need for limiting is higher (13 percent) as compared to unmet need for spacing (9 percent). Total unmet need is highest among the younger women and women of lower parity, particularly for spacing. If all the women who say that they want to space or limit their births were to use family planning, the contraceptive prevalence rate could increase from 53 percent to 74 percent. It is important to address the unmet need for contraception, particularly for spacing by providing access to safe, effective and reversible methods. To do so it may be necessary to expand the basket of contraceptive choices. Social marketing of contraceptives and availability of the range of methods would help to meet the needs of couples who are not ready to accept sterilization. In their annual surveys of eligible couples, ANMs should be asked to identify women with unmet need for contraception and address their concerns so that unwanted pregnancies could be avoided. Even if unmet need cannot be entirely eliminated, elimination of about half the unmet need would be sufficient to have the desired effect on birth rate.

Expanding the Basket of Contraceptive Choices

Female sterilization has been the mainstay of Indian family planning programme. The users of reversible methods form less than 15 percent of the users of all methods. A high level of infant and child mortality, and strong preference for sons, deter women from accepting a terminal method of contraception early. The data from the NFHS show that about half of the unmet need for contraception is for spacing. The Hindu-Muslim difference in fertility and use of contraception has become major political issue in India. Partly the difference stems from the religious objections for the use of sterilization among Muslims. Under these circumstances, there is an urgent need to expand the basket of reversible methods of contraception offered under the

programme. Research indicates that addition of a method to the basket of choices has an independent effect on the overall use. Injectibles and implants, which are not currently offered under the programme, must be introduced as early as possible by taking necessary safe guards. Female condoms would also be a welcome addition to the programme.

Increasing Male involvement

Male methods account for only 6 percent of current contraceptive use. Vasectomy, which used to be a popular method, went out of favour after the excesses committed in the 1970s. Vasectomy is safer and easier to perform in primary health centres than tubectomy. In recent years, the introduction of no scalpel vasectomy (NSV) has shown some signs of success in some states. Vigorous efforts should be made to promote this method, and train more doctors in performing this task. As males are the main decision makers in Indian households, IEC activities also need to focus on men for imparting knowledge on reproductive health of both men and women and about the advantages of small family.

Diffusion through Satisfied Users

It has become increasingly clear that fertility decline in India is the result of horizontal and vertical diffusion of a new reproductive idea and information about various methods of contraception. Strong spatial patterns in fertility decline, and systematic changes in fertility differentials by socio-economic status, support the innovation-diffusion hypothesis. The satisfied adopters of the method play a key role in this ideational change. By recruiting such couples for working in liaison with grassroots health workers, it may be possible to increase the rate of diffusion.

Research has shown that contraceptive use increases in closely-knit communities through diffusion of information and the idea of small family norm. Inter-personal communication plays a key role in the ideational change. Thus satisfied users can serve as active agent in this process. The Janmangal programme in Rajasthan is based on this idea. Janani also uses "Women Health Partners" for IEC. As the family planning programme has been there for half a century, there are already some users of contraception in every community. The scheme intends to use them to rapid transmission of small family norm.

ANMs would identify a 'satisfied' acceptor couple (SAC) of each method from caste and communities among whom the acceptance of the method is low. They would be requested to spread information about the method, and motivate others in their community. They would work in coordination with health workers at grassroots such ASHA, ANM and Anganwadi worker. For their services, a fixed honorarium could be provided. The performance of these SACs would be reviewed each year by the ANM to decide whether they could be retained for this work in the following year.

The Role of Mass Media

An instrument that has become increasingly important these days is the use of mass media in promotion of small family norm and providing information on reproductive and child health services. The rapidly increasing exposure to electronic media has made this an important channel of behavioural change communication. The

analyses of NFHS data have shown that the exposure to mass media, and family planning messages through these sources have strong independent effects on the current use of contraception, and future intention to use among non-users. It used to be contended that interpersonal communication is a more effective agent of behavioural change than the mass media. But recent research shows that messages though media stimulate discussion between husband and wife, among friends and neighbours and with health workers. Thus mass media and inter-personal channels should be seen as complementary rather than substitutes in the process of developmental communication.

Research shows that exposure to mass media has a strong independent effect on the use of family planning methods. Mass media has a wide reach, and would help to raise curiosity and create grounds for interpersonal communication to occur. However, surveys show that in EAG states, regular exposure to mass media has not yet reached desirable levels to have a wider impact. It is therefore required to raise exposure to mass media in EAG states by providing DVD/CD player and Television set to PHCs, FRUs and Mahila Mandals. As a part of this scheme, imaginatively produced DVD/CDs on reproductive and child health, including information on various methods of contraception, could be distributed.

Facility surveys show that less than 20 percent of the PHCs have telephone connections. For efficient referral services and monitoring of the programmes, telephone connections are essential. It is therefore important to provide telephone connections to every PHCs, FRUs and CHCs. PHCs and FRUs receiving at least 10 outpatients/maternity cases in a day in EAG states could be identified for the supply of DVD/CD Players and TV sets. For moving the TV set between OPD and inpatient ward, a trolley could also be provided. During fixed hours in a day, DVD/CDs on RCH and family planning could be played for viewing by the outpatients/women coming for delivery. DVD/CD players and TVs could also be supplied to Mahila Mandals on the condition that they would arrange DVD/CD viewing sessions (along with TV shows) at fixed hours in a day. ANMs during their field visits should check whether these are effectively used. The production of DVD/CDs could be out-sourced. Telephone connections should be supplied to all PHC/FRU/CHCs. There should be a fixed budget line to cover monthly telephone bills and maintenance, as in other government offices.

Arranging Group Meetings of Newly Wedded Couples and Pregnant and Nursing Mothers

In India, about 10 marriages occur for every 1,000 population. Many women marry at young age. It is therefore extremely necessary to impart knowledge on the responsibilities of parenthood to newly weds as early as possible. Similarly, group meetings of pregnant and nursing mothers can be arranged to provide them information about maternal and child heath care and contraception. It is not sufficient to just ask the ANMs to make home visits for IEC as it is difficult to monitor such activities. Surveys show that heath workers visit less than10 percent of eligible women during a whole year. To give a formal platform for such communication strategies, ANMs with the help of SACs, and ASHAs should be asked to arrange group meetings of newly weds in a village every year. Such formal meetings will also give the required visibility to the programme.

In villages with population more than one 1,000 the ANMs with the help of ASHAs and SACs will organise group meetings of newly weds, and pregnant and nursing mothers at least twice in a year. In villages with less than 1,000 populations, such meetings may be held once in a year. In these meetings, ANMs should provide information and knowledge on prenatal, natal and post natal care of women, new-born care, child immunization, virtues of small family size, interval between births, methods of contraception and abortion, STI/RTI and HIV/AIDS, with the aid of illustrative pamphlets and booklets. The active cooperation of Panchayat members should be sought to arrange these meetings.

Social Marketing

In spite of longstanding social marketing programme for condoms and oral pills, the use of these methods has not picked up. The growing epidemic of HIV/AIDS provides an opportunity to promote the use of condoms. The experience of our neighbouring countries suggests that substantial potential for greater use of pills by younger couples, if supported by counselling and IEC activities. The social marketing programme has suffered from (i) strong urban bias in the distribution network; (ii) low incentive to commercial participants; (iii) limited product range and (iv) simultaneous presence of wasteful, free distribution system.

Surveys have disclosed large unmet need for contraceptives, particularly in EAG states. Apparently, the government delivery system is not reaching the needy. As per the NFHS data, less than 10 percent of rural women report that they are visited by the ANMs during a year. This implies that ANMs are able to visit less than 100 households in a whole year. On the other hand, there is a large pool of formally or informally qualified Rural Health Practitioners (RHPs) who meet the day-to-day health care needs of rural folks. It is proposed to use them in the delivery of non-clinical methods of contraception and referring the clinical cases to the PHCs or FRUs, for a nominal fee. The successful experimentation of this approach by Janani in Bihar gives hope that this scheme could work if implemented with care and imagination.

Involvement of Private Sector

There is an urgent need to increase the involvement of private sector in the delivery of family planning services, especially in areas where the pubic sector is weak. This includes inner-city slum areas and large parts of EAG states. It is estimated that private medical practitioners provide more than two-thirds of all health care in India (see **Annexure**: **D**). In rural areas, they are more respected and accessible than government grassroots heath workers. As experience of Janani in Bihar has shown, rural heath practitioners could be recruited for social marketing of non-clinical methods and for referring clinical methods to public/private health institutions.

Increasing the Visibility of the Population Stabilization Programme

The inverted red triangle, the eye-catching logo of the Indian family planning programme of yesteryears, has slowly fading from the public memory. There is an urgent need to bring back the visibility to the population stabilization programme. The paradigm shift in the programme calls for a new but simple logo. An award may be announced for developing a simple but effective logo. A private agency could be hired

at the national level to publicise the logo and the programme. The strong presence of electronic media, particularly television, can be used for popularising small family norm and population stabilization programmes, both in rural and urban areas.

Strengthening Family Welfare Infrastructure

The sub-centre, manned by an auxiliary nurse midwife (ANM), is the most peripheral health institution available to the rural population. As per the norms established under the Basic Minimum Services programme in 1997, there should be one sub-centre for every 5,000 population in plain areas, and for every 3,000 population in hilly/tribal areas. In 2002, there were 1,37,271 sub-centres, or one sub-centre for 4,579 rural population.

The primary health centre (PHC) is a first referral unit for six sub-centres. In 2002, there were 22,975 PHCs , one for every 27,364 rural population. PHCs provide outpatient services and have 4-6 inpatient beds. According to the norm they should have one medical officer and 14 paramedical and other supporting staff. But in many remote areas there are no functional PHCs .

Community Heath Centres (CHC) are planned as first referral units (FRUs) for four PHCs for offering specialized care. According to the norm they should have at least 30 beds, one operation there, X-ray machine, labour room and laboratory facilities. The staff should consist of at least four specialists, a surgeon, a physician, a gynaecologist and a paediatrician who should be supported by 21 paramedical and other staff. Currently there are 2,935 community heath centres, or one for 2,14,000 population. But majority of CHCs do not function as FRUs as they either do not have the required number of specialists or the facilities.

The facility survey undertaken as a part of RCH project has brought out the serious shortfalls in physical infrastructure, staff and supplies at pubic heath institutions. The survey considered a heath institution as adequately equipped if it had 60 percent of the critical inputs. According to this criterion, at the all India level, only 36 percent of the PHCs had adequate physical infrastructure such as building, water and electricity supply, laboratory and labour room, vehicle etc., 38 percent had adequate staff in position, 31 percent had adequate supplies of kits, drugs, vaccines and contraceptives, and 56 percent had the adequate equipments in function, such as weighing machine, vaccine carrier, BP instruments, autoclave, etc. The position of CHCs, FRUs, and district hospitals were somewhat better, but they too had severe shortage of supplies. Only 10-15 percent of them had adequate supplies. The staff in position in CHCs (25 %) and FRUs (46%) was also far from adequate. In EAG states, the position of PHCs was far worse than the all India average. Only15-20 percent of them had adequate infrastructure, staff and supplies. It was also observed that only 12 percent of medical and paramedical staff (only 4 percent in EAG states) had received adequate in-service training. The FRUs/CHC and district hospitals attended only about 10 referred cases of delivery in a month.

Involvement of Local Self-Governments

The 73rd and 74th Constitutional Amendments made health and family welfare a responsibility of local bodies. Being closer to the people, a decentralized institution is

expected to meet their needs and preferences. The whole idea of decentralized governance is based on some key factors like people's participation, accountability, transparency and fiscal transfers. How far decentralization of services helps in improving the quality and coverage of healthcare delivery? Experiences from across the country indicate a precondition for enhancing the effectiveness in delivery of public health services is community participation in decision-making and programme implementation. This can be facilitated through the intervention of the PRIs by making health services responsive to local needs, more accountable to the local population, focusing on local problems, prioritizing the requirements, generating public demand for the services, and efficient use of available resources. The National Population Policy (NPP-200) reiterates the crucial role of panchayats in planning and implementation of health and family welfare programmes. Decentralization is expected to bridge the existing gap between the service providers and the clients to a great extent. However, for the PRIs to be effective in health service delivery, more responsibilities need to be given in the sector-specific budget allocations, revenue-raising powers and training. In reality, the functions and powers devolved to the Panchayats vary considerably across the states. Since one-third of elected members at the local bodies are women, this is a good opportunity to promote a gender sensitive, multi-sectoral agenda for population stabilization with the help of village level health committees. Under the National Rural Health Mission (NRHM), ASHAs would be selected by and be accountable to the village panchayats (the coverage under NRHM for various health facilities/functionaries is presented in **Annexure E**).

Expected Level of Achievement

Although the actual impact of the forgoing strategies to reach population stabilization is difficult to predict, if effectively perused, they should able to bring down the birth rate faster than what is projected by the Technical Group on Population Projections. Through these measures, it is anticipated that TFR would reach replacement if not by 2010, by 2015 - roughly by five years earlier than that projected by the Technical Group. By the end of the eleventh plan, at the all-India level, crude birth rate (CBR) is expected decline from 24 in 2004 to 19, and couple protection rate (CPR) to increase from 53 percent in 2002-04 to 64 percent. It is expected that the increase in CPR would result from reducing the unmet need for contraception by half, i.e., from 21 percent to 11 percent. The expected levels of achievement for the states are shown in Table 8.

Table 8. Expected Level of Achievement for CBR and CPR by the End of 11th Plan

State	Crude birth rate		Contraceptive use		Unmet need	
	SRS 2004	ELA 2012	DLHS 2002-04	ELA 2012	DLHS 2002-04	ELA 2012
Andhra Pradesh	19.0	16	62.8	68.7	11.7	5.9
Assam	25.1	20	57.5	68.8	22.5	11.3
Bihar	30.2	21	31.0	49.4	36.7	18.4
Chhattisgarh	27.4	21	46.6	57.5	21.7	10.9
Delhi *	18.4	16	64.1	72.3	16.4	8.2
Gujarat	24.3	16	59.2	67.4	16.3	8.2
Haryana	25.1	17	60.3	67.7	14.7	7.4
Himachal Pradesh	19.2	15	70.1	76.0	11.8	5.9
Jammu & Kashmir	18.7	18	54.8	67.2	24.8	12.4
Jharkhand	26.2	20	37.9	54.4	32.9	16.5
Karnataka	20.9	16	59.3	66.9	15.1	7.6
Kerala	15.2	14	68.5	76.1	15.2	7.6
Madhya Pradesh	29.8	22	50.5	61.0	21.0	10.5
Maharashtra	19.1	16	63.3	69.6	12.6	6.3
Orissa	22.1	17	54.7	64.3	19.1	9.6
Punjab	18.7	15	68.2	73.4	10.4	5.2
Rajasthan	29.0	21	46.9	57.8	21.8	10.9
Tamil Nadu	17.1	14	57.7	66.8	18.1	9.1
Uttar Pradesh	30.8	25	35.6	52.4	33.6	16.8
Uttaranchal	20.5	16	48.7	62.2	26.9	13.5
West Bengal	19.3	16	74.1	79.6	11.0	5.5
North-eastern states	17.6	17	40.2	58.1	35.7	17.9
India	24.1	19	53.0	63.6	21.1	10.6

Chapter 4

Research and Financial Requirements

Research Needs

Research studies on family planning and population stabilization are being undertaken by various governmental and private agencies. The International Institute for Population Sciences (IIPS) is the nodal agency for conducting the National Family Health Surveys (NFHS) and the District Level Household Surveys (DLHS-RCH) for the country as a whole. These surveys provided very valuable information on issues related to antenatal care, immunization, safe delivery, contraceptive prevalence, unmet need for family planning, awareness about RTIs and STIs, and utilization of government health services and user's satisfaction. The DLHS Round II survey is completed during 2002-04 in 593 districts. The second phase of facility survey was carried out in 307 districts in 2003 to assess the availability of healthcare facilities and their utilization in SCs, PHCs, CHCs and other hospitals. At the state level, the Population Research Centres (PRCs) are in a position to conduct studies related to the changing demographic and health requirements. The data collected periodically through Census, Sample Registration System and other governmental agencies are also helpful in assessing various demographic and health indicators.

Over the decades, though many micro-level research studies and large-scale demographic surveys have helped in strengthening India's family welfare programmes, more focused research may be required to address emerging issues and dimensions of demographic, epidemiological and health transitions in India. Though the fertility has declined throughout the country, the factors responsible for reduction in fertility considerably vary across the states. Well-organized and executed demographic surveys can highlight the reasons behind the declines in fertility and mortality and the changing attitudes of couples towards contraception.

1. The demographic research should focus on testing and validating of relationship between acceptance of family planning and socio-economic conditions of population. In recent decades there is a significant shift in the process from provision of family planning to quality of services. The research should highlight the current status and future requirements to understand the needs of women and children.

2. Research studies should be undertaken to document the successful family planning interventions in both pubic and private sectors, within India and abroad, and analyze the reasons for their success so that they could be implemented elsewhere.

3. The cost effectiveness and financial requirements of various health and family welfare programmes are yet to be studied in detail. This is a pre-requisite for future planning and programme implementation.

4. Rapidly demographic changes in the country call for more research in areas such as demographic dividend, labour migration and outsourcing of jobs, population ageing, and imbalances in population sex ratio.

5. With the introduction of new contraceptive methods and RCH services, it is necessary to find out the acceptability of contraceptive methods for men and women belonged to various socio-economic strata. This will help in understanding the misconceptions as well as side effects of various birth control methods. Based on the findings of these studies, the programme can be fine-tuned to meet the requirements.

6. The demographic surveys should also address factors responsible for changing value of children, gender preferences, and the attitude towards small family norms.

7. Demographic and behavioural surveys should also address issues related to reproductive rights, male involvement in family planning, adolescent reproductive health, and women's health status and autonomy.

8. Bio-medical research needs to be strengthened to develop appropriate contraceptive technologies. Institutions such as Indian Council of Medical Research (ICMR), National Institute of Health and Family Welfare (NIHFW) and Central Drugs Research Institute (CDRI) can play an important role in this regard.

9. Specific studies are required to find out the acceptability of emergency contraception in the Indian context.

Monitoring and Evaluation:

Regular procedures should be developed to evaluate and monitor various RCH programmes both at the district and state levels. This will also help in popularizing successful experiments and to draw lessons for better programme implementation. Regular monitoring will also help in identifying area specific problems and will facilitate the programme mangers to chalk out remedial measures. The DLHS surveys provided valuable inputs for evaluating the impact RCH programmes at district level. However, it should be noted that such surveys are not substitutes for monitoring the programmes through a regular management feedback system. If effective mechanisms were developed to fill and analyze the data in the forms devised under the Community Needs Assessment Approach, (CNAA), much of the current problems in monitoring the programmes could be solved. The dependency on annual surveys for evaluation could be reduced, and better informed planning by local bodies would be possible, if the civil registration system is streamlined and strengthened. Unfortunately, such long-term measures to improve the statistical system do not receive the attention they deserve.

Financial Implications

The National Rural Health Mission (NRHM) has envisaged increasing the share of central and state governments on healthcare from the current 20-80 to 40-60 sharing

in the long run. During the 11th Plan period the states would be expected to contribute 15 percent to make the share of the central government 85 percent. Regarding the additional resource needs, the National Commission on Macro Economics and Health (NCMH) had made a detailed assessment of investment requirements. The Commission has recommended additional non-recurring investment of Rs. 33,811 crores and a recurring investment of Rs. 41,006 crores, the expenditure to be made over a period of five to seven years. If we broadly agree with the overall calculation of the NCMH and allow for local variations within the overall resource envelope, the broad resource need for NRHM will be an additional Rs. 30,000 crores of non-recurring resources and a recurring need of Rs. 36,000 crores, over and above the current allocations for NRHM in 2005-2006.

11th Plan – Requirements

Table 9: Annual Resource needs for NRHM

	Central Govt. NRHM Allocation	Recurring	Non-Recurring	State Contribution	Total
2005-06	6,500			-	6,500
2006-07	9,500	9000	500	-	9,500
2007-08	12,350	11000	1350	2,179	14,529
2008-09	17,290	13000	4290	3,051	20,341
2009-10	24,206	16206	8000	4,272	28,478
2010-11	33,884	23884	10000	5,980	39,864
2011-12	47,439	42439	5000	8,372	55,811

Source: National Rural Health Mission, Framework for Implementation

Chapter 5

Recommendations

There are different ways of improving the responsiveness of health and family welfare system. Just increasing the budgetary provision will not yield the desired results unless it is accompanied by strategic reforms and programmes to involve communities in population stabilization. Health outcomes can be improved if local communities have a greater say in the provision of basic healthcare. To improve efficiency, based on the experiences so far, the following recommendations have been made:

1. Despite five decades of effort to promote the use of family planning methods, a large percentage of couples report unmet need for contraception. If this unmet need could be met, population stabilization goal would be achieved. Even meeting half of the unmet need could make significant dent on the birth rate. ANMs and ASHAs could be asked to identify the couples with unmet need in their area, and address their concerns. As more than half of the unmet need is for limiting family size, meeting the unmet need would call for significant expansion of sterilization services, especially in the large north Indian states, although the NHRM launched by the Government of India acknowledged this issue.

2. India's Family Welfare programme placed heavy emphasize on sterilization as the major method of family planning. Many other Asian countries started their family planning programmes with spacing methods and then gradually introduced sterilization. Providing sterilization services requires well-trained medical personnel and well-equipped facilities. A permanent method may not be preferred when levels of infant and child mortality are high, or because of religious beliefs. Therefore, sterilization should be the last resort than the first one in the contraceptive choices given to the public. So there is a need to expand the range of choices of contraceptives as well as to improve the quality of services provided to couples, both in rural and urban areas.

3. There is an urgent need to restructure the existing PHCs and SCs. Does it make sense to have the same number of ANMs per population in every state, given that birth-rates differ considerably from state to state? Whether the Government has the capacity and funds to adequately maintain and to operate the current level of infrastructure? How best we can attract qualified doctors to government health care institutions in rural areas. Answers to such persisting questions should be immediately found within the framework of NHRM. Some successful experiments made to address these concerns should be carefully looked into for implementation at a wider scale.

4. There is a need for specially focusing on poorly performing districts based on the available data from the DLHS and Facility Surveys. To bridge the gap in essential health infrastructure and manpower, state should have a more flexible approach. Care should be taken to ensure the uninterrupted supply of essential

drugs, vaccines and contraceptives of required quality and quantity to all the CHCs, PHCs and SCs.

5. The Panchayati Raj Institutions should play a bigger role in the supervision and monitoring of PHCs. In most states the PRI involvement is not very effective mainly because the health management committees are not functioning or not representing the poor. Even when the health committees are active they have no authority over medical and paramedical personnel. In many cases, there is the need to develop better co-ordination mechanism between local self-governments and health care institutions. It is necessary to orient the PRI members about their roles and responsibilities in providing better public health services as well as the need for assigning top priority to health issues among the activities of the PRIs. Although the NRHM Framework for implementation approved by the Union Cabinet specifically addresses this issue, the challenge lies in its implementation.

6. Concerted efforts are necessary to improve the coverage and quality of registration of births, deaths, marriages and pregnancies. A motivated ANM, Anganwadi Worker or ASHA can play an important role in this regard. The responsibility of ensuring the complete registration can be entrusted to the local bodies with clear-cut guidelines.

7. Strict enforcement of the Child Marriage Restraint Act, 1976, implying prevention of marriages of girls and boys below the legally permissible ages of 18 and 21, respectively, would facilitate not only reduction of high risk teenage pregnancies but also help in human resource development amongst these younger girls and boys during their formative years towards improvement in the quality of life in the long run. The Group recommends a national campaign against Child Marriages, sex selection against the girl child & for promoting institutional delivery by the Central & State Governments.

8. Focused attention on antenatal and institutional delivery care would help towards reduction in neo-natal component of infant mortality as well as maternal mortality, which in turn has externalities towards better acceptance of the family welfare program interventions and thus accelerate the process of fertility transition and population stabilization.

9. To improve the operational efficiency of the programmes, the Health Management Information System (HMIS) needs to be strengthened. The timely and accurate information gives the health managers the ability to monitor inputs and outputs of the system and help them to assess the costs and returns from various procedures. In many cases, measuring performance and distributing that information will automatically provide certain incentives for the service providers to perform.

10. The success of the Family Welfare Programme depends to a great extent on the personnel working in various institutions. Regular in-service training to enhance their knowledge and skills and to familiarize them with the new programmes should become a part of regular activity of the health department.

They should also be in a position to develop local level health plans taking into account the health conditions of the people and their requirements.

11. It is important to periodically assess the utilization of health services and customer satisfaction. Regular surveys, both for clients as well as for health care providers, to be undertaken. The findings from these periodic surveys should provide feedback to the health department as well as to the local bodies.

Annexure: A

India in comparison with other countries

Indicator	India	China	USA	Sri Lanka	Thailand
IMR/1000 live-births	68	<30	2	8	15
Under-5 mortality/1000 live-births	87	37	8	15	26
Fully Immunized (%)	67	84	93	99	94
Births by skilled attendants	43	97	99	97	99
Health expenditure as % of GDP	4.8	5.8	14.6	3.7	4.4
Government share of Total Expenditure (%)	21.3	33.7	44.9	48.7	69.7
Government health spending to total government spending (%)	4.4	10	23.1	6	17.1
Per capita spending in international dollars	96	261	5274	131	321

Source: **World Health Report, 2005,** World Health Organization, Geneva

Annex 1A

No. 2(12)/ 06-H & F.W
Government of India
Planning Commission
(Health, Family Welfare & Nutrition)

Yojana Bhawan
Sansad Marg
New Delhi
25th May, 2006

ORDER

Subject: Constitution of Working Group on Population Stabilization for the Eleventh Five-Year Plan (2007-2012).

In the context of formulation of the Eleventh Five Year Plan (2007-12), it has been decided to set up a Working Group on Population Stabilization under the Chairmanship of Secretary, Department of Health & Family Welfare, Government of India. The composition of the Working Group will be as follows:

1.	Secretary, Department of Health & Family Welfare, New Delhi.	Chairman
2.	Representative, National Commission on Population, New Delhi	Member
3.	Representative, Deptt. of AYUSH, Ministry of Health & Family Welfare, New Delhi.	Member
4.	Representative, Department of Elementary Education & Literacy, Ministry of Human Resource Development, New Delhi.	Member
5.	Representative, Ministry of Panchayati Raj, New Delhi	Member
6.	Representative, Ministry of Information & Broadcasting, New Delhi	Member
7.	Representative, Ministry of Youth Affairs & Sports, New Delhi	Member
8.	Representative, Ministry of Rural Development, New Delhi.	Member
9.	DG/ Representative, Central Statistical Organization, New Delhi	Member
10.	Representative, M/o Women & Child Development , New Delhi	Member
11.	Registrar General of India/ Representative, New Delhi	Member
12.	Secretary (H&FW), Govt. of Punjab, Chandigarh	Member
13.	Secretary (H&FW)/Representative, Govt. of Chhattisgarh, Raipur	Member
14.	Shri. A. Kumar, H&FW Division, Planning Commission, New Delhi	Member
15.	Shri. K.M. Gupta, Director, Ministry of Finance, New Delhi	Member
16.	Representative, PP Division, Planning Commission	Member
17.	Representative, LEM Division, Planning Commission	Member
18.	Director, International Institute for Population Sciences, Mumbai	Member
19.	Director, National Institute of Health & Family Welfare, New Delhi	Member
20.	Dr. S.C. Gulati, Professor, Institute of Economic Growth, Delhi.	Member
21.	Prof. Ashish Bose, New Delhi	Member
22.	Representative, FICCI, New Delhi	Member
23.	Executive Director/Representative, Population Foundation of India, New Delhi	Member

24.	Dr. G Rama Rao, Former Director, IIPS, Mumbai	Member
25.	Joint Secretary, NCP, Ministry of Health & Family Welfare, N.Delhi	Member-Secretary

2. The terms of reference of the Working Group will be as follows:

1) To review:

   a. The current demographic projections for the Eleventh Plan and beyond and the time by which the country's population is likely to stabilize;
   b. The goals indicated in the National Population Policy (NPP) 2000.

2) Keeping in view the current mortality, fertility and couple protection rate in different states, to suggest:

   a. A strategy for achieving population stabilization as early as possible;
   b. Fixation of goals for the Eleventh plan i.e. by the terminal year 2012 and individual years for birth rate and IMR, etc state wise;
   c. Fixation of state wise goals for couple protection rates, immunization/ ante natal, intrapartum, neonatal and child health care, etc;

3) To assess the current status and future requirement (short, medium and long-term) of demographic, bio-medical, social and behavioral research aimed at meeting the felt needs for health care of women and children, adolescents and aged during the Eleventh Plan.

4) To project financial implications for implementation of the Family Welfare Programme during the XI Plan including the plan and non-plan requirements and the Centre-State participation in the funding.

5) To deliberate and give recommendations on any other matter relevant to the topic.

3. The Chairman may form sub-groups and co-opt official or non–official members as needed. The Working Group will submit its report by 31st August, 2006.

4. Ms. Radha R. Ashrit, SRO (H & FW), Room No. 343, Planning Commission, New Delhi-110001 will be the nodal officer for all further communications. (Tel.No. 23096666-2383 Email radha-pc@nic.in).

5. The expenditure on TA/DA in connection with the meetings of the Working Group in respect of the official members will be borne by the parent Department /Ministry to which the official belongs as per the rules of entitlement applicable to them. The non- official members of the Working Group will be entitled to TA/DA as permissible to Grade I officers of the Government of India under SR 190 (a) and this expenditure will be borne by the Planning Commission.

(Ambrish Kumar)

Director (H & FW)
23096530
(ambrish.kumar@nic.in)

To Chairman and Members of the Working Group.

Copy to:

1. PS to Deputy Chairman/MOS(Planning)/ Members(KP)/(AS)/(VLC)/(BLM)/SH/(BNY)/(AH)/ Member-Secretary, Planning Commission, New Delhi
2. All Pr. Advisers/Advisers/ HODs in Planning Commission,
3. Prime Minister's Office, South Block, New Delhi
4. Cabinet Secretariat, Rashtrapati Bhawan, New Delhi
5. US(Admin.I) / Pay & Accounts Officer/ Accounts-I-Section, Planning Commission / DDO, Planning Commission
6. Information Officer, Planning Commission

(Ambrish Kumar)
Director (H & FW)

Annexure : C

Time lag between Kerala and other States in Selected Demographic Parameters in 2002

State/India	CBR 2002	CDR 2002	IMR 2002	Time lag for CBR	Time lag for CDR	Time lag for IMR
Andhra Pradesh	20.7	8.1	62	14	25	32
Assam	26.6	9.2	70	27	31	35
Bihar	30.9	7.9	61	23	25	31
Gujarat	24.7	7.7	60	19	24	31
Haryana	26.6	7.1	62	27	23	30
Karnataka	22.1	7.2	55	17	23	26
Madhya Pradesh	30.4	9.8	85	30	32	38
Maharashtra	20.3	7.3	45	14	23	22
Orissa	23.2	9.8	87	18	32	39
Punjab	20.8	7.1	51	15	23	25
Rajasthan	30.6	7.7	78	24	24	37
Tamil Nadu	18.5	7.7	44	12	24	23
Uttar Pradesh	31.6	9.7	80	30	32	37
West Bengal	20.5	6.7	49	14	20	24
India	25.0	8.1	63	20	25	30

Source: K. Srinivasan, **Proceedings of the Dr. C. Chandrasekaran Memorial Lecture**, **IIPS Newsletter,** 2006, IIPS, Mumbai.

Annexure: D

Healthcare Workforce and Health Facilities in Public and Private Sectors in India.

Indicator and measure	*Value*
Doctors	
Total number (1998) (includes all systems) (CBHI)	1,109,853
Population per Doctor	880
Percentage of doctors in rural areas (1981) (census)	41
Percentage of all doctors in private sector (estimated)	80-85
Nurses	
Total number (1996)	867,184
Population per nurse	976
Doctor per nurse (1996)	1.4
Hospitals	
Total Number (1996)	15,097
Population per hospital	56,058
Percentage of hospital in private sector	68
Estimated total number of hospitals	71,860
Estimated population per hospital	11,744
Estimated percentage of hospitals in private sector	93
Hospital beds	
Total number (1996) (CBHI)	623,819
Population per hospital bed	1,357
Percentage of beds in rural areas	21
Percentage of beds in Private sector	37
Estimated total number of beds	1,217,427
Estimated population per bed	693
Percentage of beds in private sector	64
PHCs	
Total number	22,975
Rural population per PHC	27,364

Note: The estimate for manpower is based on Medical Council lists. The estimate for the number of hospitals and beds are based on the extent of underestimation in government. Data found in Andhra Pradesh in a 1993 census of all hospitals by the Director of Health Services and the Vaidya Vidhan Parishad; they found 2,802 hospitals and 42,192 hospital beds in the private sector in Andhra Pradesh as against only 266 hospitals and 11,103 beds officially reported by CBHI in that year. Thus, compared with the official (CBHI) data, the number of private hospital was larger by a factor of 10.5, and the number of beds by a factor of 3.8.
Source: as cited by Peters *et al*, **Better Health Systems for India's Poor: Findings, Analysis and Options,** The World Bank, Washington DC, 2002.

Annexure: E

The Coverage under NRHM

The Mission has the following coverage:

Population coverage	-	740 million
Households	-	148 million (approx.)
Birth Rate in Rural Areas	-	26.6, nearly 20 million births
Sub Health Centres	-	1,75,000 (on population, distance and work load norm)
P H Cs	-	27,000 (single MO, 2 MO, 1 AYUSH)
C H Cs	-	7,000 (every Block)
Sub Divisional/Taluk Hospitals	-	1,800
District Hospital	-	600
ANMs at SHC	-	3.50 lakhs
Staff Nurses at PHC	-	81,000
Staff Nurses at CHC	-	63,000
MOs in PHCs	-	40,500
Specialists in CHCs	-	49,000
ASHAs	-	4 - 5 lakhs, in all distant habitations/villages
Village Health & Sanitation Committees	-	7 lakhs – in all villages/big hamlets

Source: **National Rural Health Mission, Framework for Implementation 2005-2012**, Government of India.

Annexure: F

Human Development Goals for India as Outlined in Tenth Five Year Plan, 2002-2007

Goal	Situation Circa 1990	Situation Circa 2000	Goal for 2007	Goal for 2012
Reduction in poverty ratio	36	27	22	15
Schooling for children: % 6-11 year old attending school				
Boys	76	85	100	
Girls	59	78	100	
All	66	82	100	-
Reduction in gender gap in literacy	0.71	0.77	1.0	1.0
Reduction in IMR	76	70	45	28
Reduction in MMR	780	407	200	100
% with provision of drinking water				
Rural	61	79	100	
Urban	88	95	100	-

Source: Government of India, **Population and Development: Ten Years after ICPD, India Country Report,** 2004.

KEY INDICATORS, INDIA

DISTRICT LEVEL HOUSEHOLD SURVEY- REPRODUCTIVE AND CHILD HEALTH, (DLHS-RCH), 2002-04

Sample size	
Households surveyed	6,20,107
Currently married women age 15-44	5,07,622
Husband's of eligible women	3,30,820
Characteristics of households	
Percent rural	66.9
Percent Hindu	86.4
Percent Muslim	8.6
Percent other religion (Christian)	3.5
Percent scheduled caste	22.7
Percent scheduled tribe	5.8
Percent with electricity	73.1
Percent with flush toilet	26.2
Percent with no toilet facility	60.8
Percent living in *Kachcha* houses	30.4
Percent living in *Pucca* houses	31.1
Percent with low standard of living	42.3
Percent with high standard of living	23.9
Percent with idolzed salt (15+ppm)	29.7
Characteristics of currently married women age 15-44 years	
Percent below age 30	51.2
Percent with age at first cohabitation below age 18.	55.2
Percent illiterate	48.5
Percent having 10 or more years of schooling	19.3
Percent with illiterate husband	26.7
Percent with husband 10+ years of schooling	34.6
Marriage	
Mean age at marriage for boys	24.5
Mean age marriage for girls	19.5
Percent of boys married below age 21	20.5
Percent of girls married below age 18	28.0
Fertility	
Mean children ever born women age 40-44 years	4.0
Percent of births of order 3 and above[1]	42.0
Current use of family planning method	
Any method	53.0
Any modern method	45.7
Pill	3.5
IUD	1.9
Condom	4.8
Female sterilization	34.3
Male sterilization	0.9
Any traditional method	7.3
Rhythm/safe period	4.1
Withdrawal	2.7
Unmet need for family planning	
Percent with unmet need for spacing	8.5
Percent with unmet need for limiting	12.7
Percent with total unmet need	21.5
Maternal care[2]	
Percent of women received antenatal check-ups	73.4
Antenatal check-up at home	06.1
Antenatal check-up in first trimester	40.2
Three or more visit for ANC	50.1
Two or more tetanus toxoid injections	71.8
Adequate iron folic acid tablets/syrup[3]	20.4
Full antenatal check-up[4]	16.4
Delivery characteristics[2]	
Delivery at home	59.0
Delivery at government health institutions	18.7
Delivery at private health institutions	21.8
Delivery attendant by skilled persons[5]	47.6
Child health	
Percent of children whose mother squeezed out milk from her breast[6]	56.6
Percent of children[7] with diarrhoea[8] who received ORS	29.7
Percent of children[7] with pneumonia[8] who were taken to a health facility or provider	73.7
Percent of children who received vaccinations[9]	
BCG	74.7
DPT (3 injections)	59.0
Polio (3 drops)	58.2
Measles	58.0
All vaccinations[10]	47.6
No vaccination at all.	19.8
Percentage of women who had	
Pregnancy complication[2]	34.2
Delivery complication[2]	40.8
Post delivery complication[2]	31.4
Symptoms of RTI/STI	32.3
Problems of vaginal discharge	15.8
Menstruation related problem	17.2
Awareness of RTI/STI and HIV/AIDS	
Percent of women who have heard of RTI/STI	44.2
Percent of women who have heard of HIV/AIDS	53.6
Utilization of government health services	
Antenatal care	32.9
Treatment for pregnancy complication	32.1
Treatment for post-delivery complication	24.4
Treatment for vaginal discharge	27.2
Treatment for children with diarrhoea	19.8
Treatment for children with pneumonia	18.2
Quality of family planning services	
Percent non-users ever advised to adopt the family planning method	11.7
Percent users told about side effects of method	28.0
Percent users who received follow-up services	26.2
Characteristics of husband of eligible women	
Percent of husband knowing NSV	34.4
Percent of men who have heard of RTI/STI	52.9
Percent of men who have heard of HIV/AIDS	75.8
Percentage who had any symptoms of RTI/STI	7.6
Sought treatment for RTI/STI	40.2

[1] For births in past three years, [2] For live/still births during three years preceding the survey, [3] 100 or more IFA tablets/Syrup, [4] A minimum of three visits for ANC, atleast one TT injections and 100 or more IFA tablets/syrup, [5] Either institutional delivery or home dolivory assisted by Doctor/ANM/nurse, [6] Children age below 3 years, [7] Last but one living children below age 3 years, [8] Last two weeks preceding the survey, [9] Last but one living children (age 12-35 months) born during three years preceding the survey. [10] BCG, three injections of DPT, three drops of polio and measles.

KEY INDICATORS, (RURAL) INDIA

DISTRICT LEVEL HOUSEHOLD SURVEY, 2002-04
REPRODUCTIVE AND CHILD HEALTH

Characteristics of currently married women age 15-44 years	
Percent below age 30	53.9
Percent with age at first cohabitation below age 18	63.3
Percent illiterate	59.0
Percent having 10 or more years of schooling	10.4
Percent with illiterate husband	33.0
Percent with husband 10+ years of schooling	26.3
Current use of family planning method	
Any method	48.8
Any modern method	42.0
Pill	3.0
IUD	1.1
Condom	2.8
Female sterilization	34.1
Male sterilization	0.9
Any traditional method	6.8
Rhythm/safe period	4.0
Withdrawal	2.2
Unmet need for family planning	
Percent with unmet need for spacing	9.7
Percent with unmet need for limiting	13.5
Percent with total unmet need	23.2
Maternal care[2]	
Percent of women received antenatal check-ups	67.5
Antenatal check-up at home	7.9
Antenatal check-up in first trimester	33.3
Three or more visit for ANC	41.9
Two or more tetanus toxoid injections	67.6
Adequate iron folic acid tablets/syrup[3]	16.9
Full antenatal check-up[4]	12.8
Delivery characteristics[2]	
Delivery at home	69.8
Delivery at government health institutions	15.0
Delivery at private health institutions	14.8
Delivery attendant by skilled persons[5]	37.2
Percent of children who received vaccinations[9]	
BCG	70.1
DPT (3 injections)	53.2
Polio (3 drops)	52.5
Measles	52.3
All vaccinations[10]	41.7
No vaccination at all.	23.5
Quality of family planning services	
Percent non-users ever advised to adopt the family planning method	11.4
Percent users told about side effects of method	27.9
Percent users who received follow-up services	31.9

[2] For live/still births during three years preceding the survey, [3] 100 or more IFA tablets/Syrup, [4] A minimum of three visits for ANC, at least one TT injections and 100 or more IFA tablets/syrup, [5] Either institutional delivery or home delivery assisted by Doctor/ANM/nurse, [9] Last but one living children (age 12-35 months) born during three years preceding the survey. [10] BCG, three injections of DPT, three drops of polio and measles.

KEY INDICATORS, INDIA

FACILITY SURVEY, 2003
REPRODUCTIVE AND CHILD HEALTH

Sample size	
District Hospitals surveyed	370
First Referral Units surveyed	1,882
Community Health Centres surveyed	1,625
Primary Health Centers surveyed	9,688
Sub Centers surveyed	18,385
ISM&H Hospitals surveyed	2,151
ISM&H Dispensaries surveyed	7,064
District hospital adequately equipped	
Infrastructure	92.7
Staff	79.5
Supply	44.9
Equipment	84.1
Percentage of DH utilized as referral[10]	37.2
First referral units adequately equipped	
Infrastructure	75.8
Staff	37.0
Supply	31.6
Equipment	61.3
Percentage of FRU utilized as referral[11]	39.4
CHCs adequately equipped	
Infrastructure	62.8
Staff	14.2
Supply	24.1
Equipment	46.0
Percentage of CHCs utilized as referral[12]	46.4
PHCs adequately equipped	
Infrastructure	31.8
Staff	48.2
Supply	39.9
Equipment	41.3
Training	19.9
Medical officer (at least one)	78.2
Female medical officer	15.5
Sub Centres	
Female health worker[13]	95.1
Male health worker[13]	67.7
Functioning in govt. building	45.2
Tap water supply[14]	21.1
ANM staying in allotted quarter	22.5
ISM&H hospital	
Own building	16.7
Medical officer (at least one)	76.8
Staff nurse (at least one)	76.0
Pharmacist (at least one)	84.4

[10] Referred cases are taken from those DHs which have conducted delivery, [11] Referred cases are taken from those FRUs which have conducted delivery, [12] Referred cases are taken from those CHCs which have conducted delivery. [13] Staff in position is for number of health facilities having sanctioned post. [14] For those functioning in government building

ANNEXURE : B KEY INDICATORS FOR STATES AND UNION TERRITORIES

District Level Household Survey (2002-04) & Facility Survey (2003) - Reproductive & Child Health

State/ Union territory	Census, 2001		Percent of households					Girls marriage below 18 years	Mean age at marriage		Percent of rural women[4]	Birth order 3+
	Population in millions	Percent female[1] literacy	With electricity	With drinking water[2]	With toilet facility	With low SLI	Using iodized salt[3]		Boy	Girl		
India	**1028.6**	**53.7**	**73.1**	**88.5**	**39.2**	**42.3**	**29.7**	**28.0**	**24.5**	**19.5**	**68.2**	**42.0**
North												
Delhi	13.9	74.5	98.7	90.6	96.2	2.2	81.8	10.8	23.8	20.6	6.3	42.2
Haryana	21.1	55.7	91.2	48.7	91.7	19.3	55.3	27.8	22.7	19.0	70.8	38.4
Himachal Pradesh	6.1	67.4	97.9	43.7	86.5	25.2	78.0	2.9	26.0	21.7	78.3	24.4
Jammu & Kashmir	10.1	43.0	80.4	78.7	82.3	20.6	45.0	5.1	25.9	22.8	76.2	32.1
Punjab	24.4	63.4	96.2	60.3	98.8	11.8	64.8	10.2	23.8	20.9	68.9	32.4
Rajasthan	56.5	43.9	64.9	34.1	79.0	45.3	33.0	49.4	20.6	17.3	70.8	47.4
Uttaranchal	8.5	59.6	67.1	50.8	77.3	37.5	8.6	9.8	24.6	20.5	72.6	45.9
Central												
Chhatishgarh	20.8	51.9	67.6	21.0	82.2	63.5	33.1	31.1	22.7	19.0	69.8	44.9
Madhya Pradesh	60.3	50.3	76.2	30.2	76.1	55.6	40.8	43.5	21.8	18.2	68.9	49.4
Uttar Pradesh	166.2	42.2	41.5	33.3	90.8	54.2	13.7	41.4	21.5	18.1	70.4	56.9
East												
Bihar	83.0	33.1	24.7	30.1	93.2	66.3	29.6	51.5	21.9	17.4	72.6	54.4
Jharkhand	26.9	38.9	38.7	26.2	54.4	65.8	37.2	43.8	22.8	18.3	68.8	48.9
Orissa	36.8	50.5	47.3	25.6	73.0	62.4	36.6	23.1	25.4	20.5	71.1	42.1
West Bengal	80.2	59.6	51.6	55.5	93.1	51.8	54.8	45.9	24.7	18.5	67.6	31.0
Northeast												
Arunachal Pradesh	1.1	43.5	69.5	75.4	81.7	50.0	67.1	26.6	23.4	19.5	72.8	48.8
Assam	26.7	54.6	43.6	75.4	72.9	56.3	53.4	23.8	27.2	20.7	73.0	40.6
Manipur	2.2	60.5	80.8	92.7	44.2	46.9	79.6	9.6	27.5	24.1	81.0	43.1
Megahalaya	2.3	59.6	57.1	63.5	50.2	64.8	41.2	16.7	22.8	20.8	75.9	59.5
Mizoram	0.9	86.7	83.8	97.9	73.1	39.7	56.8	14.0	25.1	21.6	64.3	41.5
Nagaland	2.0	61.5	78.6	91.8	65.2	48.2	39.9	7.4	27.1	22.5	71.8	57.7
Sikkim	0.5	60.4	88.2	85.3	80.6	34.2	60.9	12.0	24.5	21.9	87.5	30.5
Tripura	3.2	64.9	76.8	98.1	83.8	38.2	44.5	21.6	27.3	20.9	70.6	17.9
West												
Goa	1.3	75.4	96.3	72.8	85.4	12.1	60.5	3.6	29.0	24.4	49.3	20.0
Gujarat	50.7	57.8	86.2	47.5	87.4	34.6	35.1	24.6	22.3	19.4	65.4	38.1
Maharashtra	96.9	67.0	83.6	41.7	82.0	41.1	46.9	21.1	24.6	19.1	63.6	32.4
South												
Andhra Pradesh	76.2	50.4	84.1	42.1	87.3	38.5	24.8	38.6	23.2	18.4	66.3	22.5
Karnataka	52.9	56.9	87.0	39.5	90.9	44.6	22.9	31.4	25.1	19.1	67.7	29.6
Kerala	31.8	87.7	79.0	91.0	65.3	16.1	56.3	6.6	28.0	21.9	67.3	15.5
Tamil Nadu	62.4	64.4	87.0	41.0	92.6	33.0	24.9	15.5	26.4	20.7	56.6	21.6
Union Territory												
A & Nicobar Islands	0.4	75.2	84.8	64.4	86.6	22.8	94.9	4.3	25.8	21.2	82.8	17.1
Chandigarh	0.9	76.5	97.8	87.1	99.9	7.3	73.8	4.4	24.6	22.8	12.6	38.5
Dadra & Nagar Haveli	0.2	40.2	97.7	56.3	94.9	40.4	50.5	25.6	22.9	19.7	70.5	37.6
Daman & Diu	0.2	65.6	96.2	48.4	83.0	13.4	53.3	12.3	26.7	23.0	60.7	32.5
Lakshadweep	0.1	80.5	99.7	98.4	26.3	1.3	54.3	13.7	26.7	20.7	50.1	46.6
Pondichhery	1.0	73.9	94.9	71.1	97.6	15.0	49.1	4.9	27.6	22.4	20.2	13.6

[1] age 7+ years [2]Piped or from hand pump. [3] Cooking salt that has an iodine content of at least 15 parts per million (ppm). [4] Currently married women age 15-44 years.

Annexure B KEY INDICATORS contd.

District Level Household Survey (2002-04) & Facility Survey (2003) - Reproductive & Child Health

State/ Union territory	Contraceptive prevalence rate			Unmet need for family planning		Antenatal care[6]			Delivery characteristics[6]		
	Any method	Any modern method[5]	Condom	Limiting	Spacing	3+ ANC visit	At least one TT injection	Received IFA tablets	Govt. Institute	Home	Assisted by skilled person[7]
India	**53.0**	**45.7**	**4.8**	**12.7**	**8.5**	**50.1**	**80.1**	**20.4**	**18.7**	**59.0**	**47.6**
North											
Delhi	64.1	55.8	19.3	11.4	5.0	67.3	82.5	45.7	29.5	49.3	59.9
Haryana	60.3	54.4	10.0	9.2	5.5	48.6	85.8	17.1	10.6	64.8	43.2
Himachal Pradesh	70.1	65.4	12.9	8.4	3.4	68.0	89.6	42.8	36.9	54.3	51.4
Jammu & Kashmir	54.8	51.9	18.1	10.7	14.1	80.5	80.8	53.7	55.9	28.4	73.1
Punjab	68.2	57.2	15.8	7.6	2.7	64.5	87.2	20.3	9.5	51.1	64.3
Rajasthan	46.9	42.3	6.2	13.7	8.1	33.3	69.0	8.0	19.4	68.0	44.4
Uttaranchal	48.7	44.2	11.1	17.1	9.8	28.0	71.2	20.0	10.7	76.2	32.5
Central											
Chhatishgarh	46.6	41.7	2.6	12.4	9.3	48.7	79.3	16.5	9.6	79.6	29.1
Madhya Pradesh	50.5	47.3	5.2	13.6	7.4	34.6	77.5	8.5	17.6	71.5	35.5
Uttar Pradesh	35.6	26.2	7.3	20.3	13.3	24.7	69.5	8.7	8.5	77.2	28.7
East											
Bihar	31.0	27.3	2.0	21.8	14.9	19.6	75.4	8.1	5.4	76.8	29.5
Jharkhand	37.9	33.3	2.9	19.3	13.6	32.8	71.2	12.6	5.3	77.3	27.8
Orissa	54.7	41.9	2.7	13.1	6.0	47.3	84.8	24.3	25.6	64.4	43.5
West Bengal	74.1	51.0	4.6	6.6	4.4	64.6	92.0	18.1	34.3	51.6	54.1
Northeast											
Arunachal Pradesh	38.8	35.6	1.8	21.9	13.3	40.9	54.2	12.9	27.1	64.9	37.7
Assam	57.5	28.7	2.3	14.3	8.2	42.6	65.9	13.4	13.9	71.9	33.2
Manipur	33.5	21.1	3.5	25.6	15.3	58.2	78.4	12.2	37.2	54.9	57.8
Megahalaya	17.1	14.7	2.4	19.5	36.2	43.8	48.1	14.1	23.7	68.9	34.5
Mizoram	53.8	52.6	2.3	8.9	16.1	56.3	72.1	28.5	47.1	46.8	60.6
Nagaland	39.6	33.0	6.1	14.7	19.2	33.1	61.5	11.8	8.2	81.8	29.6
Sikkim	65.3	55.3	5.9	12.9	5.2	67.9	85.9	30.3	53.4	40.9	61.9
Tripura	54.4	42.7	10.9	18.5	6.6	66.4	71.4	15.9	57.4	37.5	65.1
West											
Goa	33.5	29.8	5.2	28.5	14.6	84.2	88.3	57.7	40.0	8.6	93.3
Gujarat	59.2	52.4	4.8	9.5	6.8	61.4	85.8	30.2	12.7	47.5	62.1
Maharashtra	63.3	60.8	4.9	7.1	5.5	72.0	90.9	28.1	24.1	41.7	62.6
South											
Andhra Pradesh	62.8	62.4	0.4	6.1	5.6	88.1	87.9	48.3	22.1	38.6	69.0
Karnataka	59.3	57.7	1.4	8.5	6.6	80.1	85.6	33.3	29.0	41.9	66.6
Kerala	68.5	54.7	4.3	5.4	9.8	96.9	95.4	73.6	40.5	2.0	98.3
Tamil Nadu	57.7	55.0	2.1	12.7	5.4	96.1	97.4	24.7	44.5	13.4	89.2
Union Territory											
A & Nicobar Islands	59.2	58.5	5.1	15.0	11.3	96.5	94.2	85.6	71.6	25.2	76.9
Chandigarh	60.9	58.0	22.4	13.8	4.0	75.6	86.2	43.6	36.8	52.6	59.1
Dadra & Nagar Haveli	50.4	45.1	6.3	14.2	5.9	79.1	91.7	34.3	15.6	53.3	54.7
Daman & Diu	55.6	52.8	4.8	12.8	10.8	83.7	89.7	36.7	23.6	31.9	71.5
Lakshadweep	30.4	10.6	3.1	6.8	37.9	96.6	96.9	73.6	73.0	19.8	83.8
Pondichhery	63.3	57.6	5.2	12.1	4.5	97.9	97.5	30.2	70.2	2.3	98.5

[5] Include Female sterilization, Male sterilization, IUD, Pills or Condom. [6] Women who were given their last live/still births during three years preceding the survey. [7]Either institutional delivery or home delivery assisted by Doctor/ANM/Nurse.

Annexure B KEY INDICATORS contd.

District Level Household Survey (2002-04) & Facility Survey (2003) - Reproductive & Child Health

State/ Union territory	Immunization[8]			Percent received ORS	Ranking of the state[10]	Percent of PHC adequately equipped					EO care Kit[13]
	DPT 3 injections	Measles	Full[9]			Infrastru-cture[11]	Staff[12]	Supply[11]	Equipment[11]	Training[11]	
India	**59.0**	**58.0**	**47.6**	**29.7**		**31.8**	**43:6**	**39.9**	**41.4**	**19.9**	**32.2**
North											
Delhi	71.1	76.4	61.0	37.6	10	60.0	60.0	80.0	80.0	0.0	20.0
Haryana	75.7	69.2	62.9	32.1	21	54.6	59.3	46.2	41.2	50.4	28.2
Himachal Pradesh	91.2	89.7	79.4	50.9	5	39.7	29.9	44.2	42.7	20.1	25.1
Jammu & Kashmir	48.1	83.0	38.6	69.5	8	31.4	27.8	28.6	40.3	30.3	12.4
Punjab	82.8	79.1	75.3	26.2	7	40.8	57.4	43.7	43.7	19.7	36.6
Rajasthan	36.4	36.8	25.4	29.4	31	33.2	28.0	69.2	53.9	14.8	36.1
Uttaranchal	57.7	56.9	47.2	21.4	24	27.8	40.5	23.6	27.1	7.6	13.2
Central											
Chhatishgarh	70.5	70.2	60.9	42.2	25	2.8	26.7	14.1	8.8	3.8	50.6
Madhya Pradesh	43.9	50.1	32.5	25.7	28	9.9	34.7	32.0	26.2	11.4	32.6
Uttar Pradesh	37.9	37.7	28.1	15.5	33	17.2	47.2	19.5	28.6	12.4	22.1
East											
Bihar	35.0	28.2	24.4	14.2	35	8.9	17.4	11.4	6.2	15.5	28.4
Jharkhand	39.3	34.5	29.3	25.1	32	9.8	26.9	50.5	21.4	42.5	24.9
Orissa	70.0	69.9	55.1	48.4	23	3.2	5.2	3.5	15.1	13.4	10.3
West Bengal	69.8	67.6	54.4	44.0	20	12.0	23.2	23.0	8.6	9.1	10.0
Northeast											
Arunachal Pradesh	36.0	39.3	22.5	51.8	29	70.7	43.8	31.7	26.8	19.5	36.6
Assam	39.5	39.1	19.3	45.1	27	21.0	27.5	50.0	32.4	29.7	38.6
Manipur	48.8	55.6	37.0	63.4	26	12.5	64.0	56.3	28.1	37.5	46.9
Megahalaya	31.2	30.3	14.1	45.5	34	56.0	58.3	60.0	68.0	56.0	44.0
Mizoram	48.7	61.6	35.3	61.6	22	70.4	55.7	44.4	96.3	59.3	59.3
Nagaland	32.5	40.2	14.4	32.8	30	59.5	50.0	59.5	40.5	18.9	48.6
Sikkim	74.0	82.6	50.2	48.0	11	100.0	62.5	45.8	100.0	67.7	12.5
Tripura	47.9	44.7	26.7	53.7	19	100.0	56.6	100.0	81.8	100.0	81.8
West											
Goa	87.7	93.1	81.5	74.6	9	100.0	88.2	58.8	88.2	64.7	58.8
Gujarat	68.9	69.4	57.7	24.4	18	89.0	76.3	83.4	80.6	17.1	71.3
Maharashtra	88.5	88.0	74.3	42.0	12	76.5	78.4	67.4	91.4	31.9	48.7
South											
Andhra Pradesh	78.7	74.4	62.9	58.6	13	59.2	64.8	40.3	84.5	34.5	34.5
Karnataka	84.5	80.4	74.1	32.7	15	58.1	37.3	88.9	61.1	23.1	76.5
Kerala	90.7	90.0	81.2	54.2	1	42.9	49.8	55.7	34.3	18.6	32.9
Tamil Nadu	96.8	95.7	92.1	35.8	4	64.7	72.9	77.8	92.2	27.7	14.4
Union Territory											
A & Nicobar Islands	86.3	90.4	47.7	81.9	3	100.0	52.9	52.9	76.5	47.1	64.7
Chandigarh	78.6	79.0	53.3	46.6	6	50.0	0.0	50.0	0.0	0.0	0.0
Dadra & Nagar Haveli	92.1	87.0	85.2	54.3	16	83.3	100.0	100.0	83.3	16.6	100.0
Daman & Diu	77.7	78.6	57.3	28.4	14	100.0	100.0	66.7	66.7	0.0	100.0
Lakshadweep	86.9	91.8	67.6	72.6	17	100.0	75.0	75.0	100.0	50.0	100.0
Pondichhery	93.8	95.8	89.4	47.7	2	57.9	21.1	63.2	68.4	21.1	73.7

[8] Last but one living children (age 12-35 months) born during three years prior to the survey. [9] BCG+3 DPT injection+ 3 Polio drops+ Measles. [10] Based on 10 RCH indicators.
[11] Having at least 60 percent of critical input (based on Phase-2 only) . [12]Having at least 60 percent of staff (base on Phase1 and Phase2). [13]Essential obstetric care kit