REPORT OF THE WORKING GROUP ON
HEALTH INFORMATION NETWORK

INDIAN HEALTH INFORMATION NETWORK DEVELOPMENT

USE OF ICT IN HEALTH CARE AND KNOWLEDGE MANAGEMENT

RECOMMENDATIONS FOR THE NATIONAL KNOWLEDGE COMMISSION

1.0 BACKGROUND:

Health Care sector in India has witnessed significant growth during the last few years, both in quality and capacity. Relatively lower cost of health care, as compared to developed countries, coupled with international quality, has positioned India as a major destination for health care services. In spite of such developments, heath care facilities in the country remain inadequate to meet the needs of the citizens, particularly in rural areas, where approximately 70% of the people live.

To address these problems, the government has launched major national initiatives such as National Rural Health Mission, establishment of six new AIIMS like institutions, up gradation of existing public hospitals and labs, etc. Management of communicable as well as non-communicable diseases has also been a major area of concern to the government. An Integrated Disease Surveillance Program (IDSP) is already under implementation. The Non-communicable Disease Risk Factor Surveillance under IDSP will track trends of selected major risk factors in the urban and rural population, aged between 15 and 64 years. Innovative systems are, however, required for quick reporting of such incidents when they occur and to implement an effective system of intervention to provide the best diagnostic and medical care to the affected patients and prevent further spread of the disease.

India also has a strong base for medical research. Extensive work is being done as a part of postgraduate work in medial institutions, ICMR labs and other institutions. There is, however, a strong need of sharing of knowledge and resources amongst the researchers and healthcare providers.

In addition, private sector has initiated massive investments in various facets of healthcare. This is expected to position health care as one of the largest service sectors and a significant contributor to the GDP. As the health sector is poised for major growth in next decade, the sheer size of healthcare sector in the country will necessitate extensive use of information and communication technology (ICT) infrastructure, services and databases for policy planning and implementation. Such a framework would require services based on inter-operable and sharable technology,

connecting various institutions and service providers. The use of international experience, best practices and open technologies may be necessary in some scenarios.

2.0 VISION:

The vision is to establish ICT as a major facilitator of heath care and knowledge management in the country, which will enable various stakeholders to have easy and affordable access to information, whenever and wherever they need it.

The medical knowledge and health care information generated as an outcome of this endeavor will significantly improve the health status of the people of India.

3.0 OBJECTIVES:

3.1 The recommendations made in this proposal are aimed to establish ICT infrastructure and services in India, covering all aspects of health care.

3.2 To facilitate creation and management of a comprehensive knowledge database.

3.3 To use such knowledge database to improve the quality of day-to-day health care services and help in enhancing the quality of research work.

3.4 To set up ICT based systems at various levels, in a phased manner, in all public and private institutions engaged in health care services.

3.5 **To** develop inter-operable health management systems through the use of appropriate technologies, which may also necessitate the use of open technologies and standards in some cases.

3.6 To collaborate with international institutions to integrate Indian initiatives with global developments.

3.7 Most of these objectives should be achieved during XIth Plan period

4.0 MACRO BENEFITS OF ICT TO HEALTH CARE

While benefits of ICT in enhancing efficiency at individual and institutional level are well known, a unified health management system will deliver the following distinct benefits to the nation:

4.1 Knowledge Dissemination and Public Health

Sharing of information between scientists and end users has obvious benefits. Even now, enormous data exists in national institutions like ICMR, CDRI and other educational establishments. This information and new knowledge should be readily available for the health care providers and end users in remote locations. International linkages of these premier Indian institutions will also enable Indian researchers and scientists take advantage of global developments in real time, instead of relying on secondary sources of information.

4.2 Health Care Planning

Accurate and validated regional and national data is the foundation for planning, which only an ICT based system can provide.

4.3 Natural Disasters

The speed of delivery of emergency health care services in the first 24 to 72 hours is critical in saving lives after any natural disaster. Real time information about the nature and extent of injuries, resource requirement and mobilization can augment the success of disaster management.

4.5 Bio-Terrorism

This is a real threat waiting to happen. ICT can help in advance planning and surveillance while immediate response can limit the damage.

4.6 Health Care Finance and Future Technology

The explosion of knowledge in the following technologies will revolutionize health care in next 50 years:

- Genetic engineering and biotechnology
- Nanotechnology
- Medical informatics

This knowledge will cure many diseases, alleviate suffering and prolong life but only if the laboratory-to-patient dissemination is fast. Simultaneously, the new knowledge (e.g. Gene therapy) will also escalate health care costs beyond the reach of most people. It is important to take steps now to lay the infrastructure to benefit maximum number of people while optimizing the costs to bridge the gap between what is technologically possible and what is affordable.

In India today, there is a reasonably good understanding of the broad contours of how health care is financed. However, there is not as good an understanding of the effects of the current health care financing systems on health system performance, nor of the advantages and disadvantages of different strategies for improving the current situation. Building a balance between the economic platform and public health programs is a key to success. The multi-disciplinary approach of convergence of health care sector and economic sector with effective deployment of IT can help not only for building the economic sector but also for advancement of public health.

4.7 Drug Surveillance

India is fast becoming a center for new drug development and clinical trials. It is important for the authorities and pharmaceutical industry to have tools to monitor the safety data after marketing of new drugs and also prevent abuse of spurious drugs.

4.8 Fraud and Abuse Prevention

With increasing penetration of private health insurance and enhanced public spending on public health, fraud and abuse of the system will increase. Health care administrators need applications and methods to curtail the abuse.

4.9 Medical Errors

It is estimated that about 90,000 people die every year in the USA because of avoidable medical errors. One can only guess the magnitude of this problem in India with three times the population and minimal IT infrastructure. Medical institutions need innovative ICT applications to reduce these errors.

5.0 MAJOR STAKEHOLDER OF THE SYSTEM

- Citizens
- Health care providers and payers
- Education, research institutions and investigators
- Government departments and institutions
- Public health agencies and NGOs
- Pharmaceutical industry and medical device makers
- Telemedicine institutions
- Software and hardware developers

6.0 CHALLENGES:

6.1 Leadership

Health care is a public good. A dedicated leadership and their concerted effort will be needed to overcome many barriers to widespread implementation of health IT systems. It will also require a sincere public-private partnership in achieving the objectives, as private practitioners and private sector health care services serve large segment of people.

6.2 Standards

Contemporary health care information systems are made up of multiple-component systems manufactured by multiple vendors, owned by multiple entities. Without standards, the different systems used in various organizations will not be compatible and each organization will be its own pioneer. The lack of data standards is a major obstacle to the adoption of both electronic health records and data exchange systems.

Considerable work has already been done internationally to define standards for various aspects of medical informatics. This work will provide useful input while formulating standards for India. Ministry of Health in collaboration with Department of IT has already initiated an exercise in this regard.

6.3 Connectivity

Comprehensive information system products, which seamlessly integrate data and coordinate processes across the entire continuum of health care services, do not exist. Connectivity will enable medical care providers to share data throughout their geographically dispersed clinical delivery sites, and to a lesser degree, reach the patient at home or at least at a central place in the village. To the extent that health care becomes dependent on access to computer networks, policymakers need to pay special attention to the needs of the medically underserved population to ensure that lack of network access does not further impede their access to care.

6.4 Privacy and Security

Health care data of individuals is personal and private. At the same time, it is also valuable to various other stakeholders such as researchers. Adequate privacy and protection mechanisms will have to be built in line with current regulations with mechanisms for amendments, which may be required from time to time.

6.5 User Needs

Although user acceptance was a major barrier in the past, more users are demanding electronic means for accessing and managing patient data. This is not to say that the cultural and organizational barriers associated with major change are not substantial, but the users' awareness of the potential benefits will become a catalyst for change.

One of the challenging issues confronting health IT system developers is creating effective and user friendly interfaces for health data entry and retrieval. Current tools in health care institutions can typically help retrieve some information but they are not designed to answer many of the common questions clinicians and other users ask about patient data. The lack of multi-lingual systems also acts as an impediment for collecting information by the field workers. System developers will need to address these needs to satisfy the all users.

6.6 ICT and Domain Knowledge

Extensive technology and domain knowledge is already available within the country from institutions like CDAC, NIC, ISRO, Ministry of Health, Ministry of Communications and IT, ICMR, medical colleges, private companies and many others. These institutions have done considerable work in this field. World experience is also readily available. All this knowledge, which currently exists in separate silos, needs to be harmonized and harnessed.

6.7 Funding

The capital to develop and operate a system on a unified national grid will be substantial. The early phase of a development should be government initiated and funded. Federal investments should support the development of critical building blocks of this infrastructure, especially those that are unlikely to receive adequate support from the private sector, such as, a secure platform for data exchange. The government should also provide financial incentives to encourage public-private participation in development of electronic health record systems.

The private sector can be expected to invest a significant portion of the capital to build a national system, if they are allowed to share data relevant to them. This will involve building controls to protect privacy of the data.

A major coordinated national effort with federal funding and strong support from the private sector is needed to accelerate the pace of change in India.

7.0 RECOMMENDATIONS:

7.1 Facilitate ICT penetration in medical and health care services

Massive efforts are required to promote extensive use of ICT in health sector. Following steps need to be taken in this respect:

- All public institutions engaged in delivery of health care services in urban and rural areas need to be e-enabled urgently to help them to improve the management of their services. Appropriate ICT solutions need to be evolved at all levels of the public health infrastructure, right up to the level of health workers in rural areas.

- Formulate common national standards for creation and exchange of minimal data sets related to health care services. These standards will have to be prescribed at the policy level, and a robust regulatory framework also needs to be evolved.

- Launch a massive promotional program to encourage the use of ICT based systems in development of health management.

- Build technological and legal mechanisms to ensure privacy and security of health data. While health care data of individuals is private, yet it is valuable to various other stakeholders such as researchers, policy makers etc. Adequate privacy protection mechanisms will have to be built. Ownership of data, access and flow of private information also needs regulation.

7.2 Networking of Institutions

All medical colleges, research institutions and premier health service providers in the country must be networked using the infrastructure being set up as a part of knowledge network.

7.3 Creation of comprehensive Knowledge base of Medical Research

Urgent steps need to be taken to create a knowledge repository not only to share knowledge among participating institutions but also to make research in medical field more focused. Extensive domain knowledge is already available within the country from institutions like ICMR, medical colleges, Ministry of Health, private companies and many others. All this knowledge, which currently exists in separate silos, needs to be harmonized and harnessed and made available in interoperable formats.

7.4 Linkages with International organizations

The premier research institutions in medical field need to collaborate with their international counterparts so as to be part of global developments in their fields. Such linkages would be facilitated through the knowledge network and need to be encouraged.

7.5 Medical Informatics to be part of medical and paramedical curriculum

Medical education needs to take full advantage of the power of ICT. A well-structured health informaticscurriculum needs to be made an integral part of medical education at all levels. Basic ICT facilities, such as good quality access to Internet and e-Journals, need to be made compulsory at all medical colleges in the country.

For capacity building, ICT tools should be effectively deployed to train the large number of health workers. Short and medium term courses need to be developed to address training needs of workers in the field. It should be made

affordable and easily available for small players. There is need to evolve common formats for data reporting to facilitate IT empowerment of medical manpower at all levels.

7.6 Development of Electronic Health Record (EHR)

Develop a common national EHR with minimal data set and make it available in open domain to encourage wide spread use in the country. This would facilitate standards based development of knowledge base.

As large number of citizens rely on practitioners of traditional medicine, there is need to develop an Ayurvedic EHR, which is interoperable with the other EHR.

The new applications especially those used for recording information at the primary healthcare worker level should have multi-lingual capabilities.

7.7 Develop econometric models

Develop tools and deploy them over the health information grid for analyzing health care financing, its technical/allocative efficiency, cost benefit analysis, and trends predicting. This will help in optimal utilization of professional, institutional facilities and resources.

7.8 Institutional Framework

A mission mode structure needs to be created, in the form of a special purpose vehicle (SPV), to achieve the objective of establishing an ICT system for management of health sector, in a time bound manner. Such a structure should have participation of various stakeholders in government as well as private sector.

7.9 Financial Support

The government should provide the investments to the proposed SPV to establish the ICT infrastructure in public health institutions at various levels, including in rural health system. Initial funding for supporting the functioning of the SPV should come from the government but the SPV should be able to become financially self-sustaining in about five years.

7.10 Legal Promotional Framework

7.10.1 Guiding Principles

The central government should establish a promotional framework for the use of information and communication technology (ICT) in the health sector based on the following guiding principles:

- The framework should enable and not stifle the growth of health ICT sector.
- To enable growth this framework should encourage:
    - Common national health IT standards
    - Common clinical nomenclature
    - Interoperability of health IT systems
    - Time schedule for ensuring electronic transaction of all health care encounters by all health care establishments.
- In order not to stifle growth, the framework should be adopted in phases and enough time should be given for each phase to evolve and perform to its full potential
    - Development Phase: encourage technology, connectivity and health ICT innovation
    - Growth Phase: encourage extensive use of ICT applications and ICT penetration
    - Stabilization phase: ensure sustainability
    - Corrective phase: ensure privacy and confidentiality
- The framework should not be punitive.
- The framework needs to be substantially similar and aligned to state health acts, in order to avoid conflicts between central and state legislations creating jurisdictional dilemmas.
- Once the growth of the health ICT sector is on a good foundation of common national standards and interoperability, a national health information authority (NHIA) or a similar body may be established to maintain the flow of information between various health care establishments and provide guidelines in the context of commercial activities.
- The NHAI or similar body should be a public-private partnership with representatives from all stakeholders.
- The NHIA or a similar body may undertake appropriate technical and organizational measures for ensuring proper collection, access, use and security of health data and for the protection of the privacy of the patients, through laws and regulations, at both state and central levels aiming at preventing the following:
    - Denial of the services of the system,
    - Accidental or deliberate destruction of data,
    - Unauthorized access to, or disclosure of, data,

o Accidental or deliberate alteration of data,
o Unauthorized creation of data.

7.**10.2 Collection of Information**

- All the public healthcare units as well as of registered private healthcare establishments need to be integrated into the electronic archiving system in a phased manner.
- Informed consent of individuals needs to be sought while collecting health information for registration purpose. Implied consent is also acceptable for sharing patient information within the "circle of care," (includes the individuals and activities related to the care and treatment of a patient i.e. within the health care establishments). However, due to the diverse nature in language, culture and ethnicity and wide prevalence of illiteracy, the collection of health information can be made on the basis of verbal consent (in the presence of a related witness or an individual in whom the patient has trust) during the initial years.
- Individuals should have freedom to opt out from registering their personal information the system and preventing its primary and secondary use.
- The National Ethical Guidelines on Biomedical research to be followed to address ethical concerns.

7.10.3 Exceptions to providing informed consent

- Individuals with notifiable diseases.
- Information on deceased patients for the purpose of assessing cause of death.
- When information is needed by courts for the trial of individuals for criminal offences.
- For tabulating data related to disease prevalence/ incidence/ burden/ risk factors, keeping the identity of the individual is anonymous, particularly for surveys.
- During epidemic outbreaks, disaster and emergencies

7.10.4 Ownership of health information

While the patient owns his or her health information, the custodial ownership of the health information will reside with the central government and for all practical purpose the custodial ownership is deemed to be with NHIA. This custodial ownership will regulate the access and flow of information without compromising the privacy and confidentiality of the data.

7.10.5 Primary use of health information

- Primary use of health information covers the health care providers who deliver care and services for the primary therapeutic benefit of the patient and it covers related activities such as laboratory work and professional or case consultation with other health care providers. Transmission of personal health data between the "circles of care" should be utilized only for the purposes of medical care.
- Health Information should not be used to discriminate the patient while seeking medical benefits.

7.10.6 Secondary use of health information

The most challenging issue that may arise in complying with statutory requirements is secondary uses of information for purposes such as research and commercial use of the database. The NHIA will regulate the secondary use of health information based on the following fundamental principles:

- Individuals have a right for their personal health information to be kept confidential and the release of health data for research purposes should be non-identifiable with a patient.
- The revenue generated from the commercial use of EHR database should be used for strengthening the health care establishments.
- The NHIA should also hold a share on patent rights of innovations in pharmaceutical and genomic research carried out with EHR database
- If a third party organization wishes to use EHR database for a new purpose that is not otherwise permitted by law, that organization must approach NHIA to seek permission for that new use.

7.10.7 Security and safety of information

The issue of privacy, confidentiality and security of personal health information and EHRs needs to be assured. In addition to consent rules, NHIA will frame requirements, in consultation of other existing rules and regulation, for organizations to safeguard the security of personal information through technological security measures such as firewalls and encryption mechanisms, other organizational practices and procedures including physical restrictions that impede unauthorized access.

7.10.8 Complaints and grievance mechanisms

NHIA will have sufficient authority to investigate complaints and carryout regular audits of the EHR management practices of organizations and initiate regulatory/legal proceedings, if necessary.

7.10.9 Accreditation

NHIA will encourage the enrolment of healthcare establishments through accreditation to maintain a certain level of quality for the health ICT system.

APPENDIX A

EXECUTION OUTLINE: FIRST STEPS
The objective of the execution plan will be to achieve three goals:
- Establish national standards for health IT
- Establish legal and regulatory framework.
- Create a financially viable time bound implementation plan.

This section outlines the **major first steps** for implementation of the recommendations given in the paper.

Institutional Framework: This body will be responsible of planning and implementing the time bound project
- Create an execution team under the Ministry of Health with representation from the following areas:
  - Domain knowledge experts from medical field
  - Health IT experts
  - Legal experts
  - Parliamentary standing committee on health
  - Public health experts from the states/ districts
  - Health officials from states/ districts

Financial Support:
- The execution team will write the financial plan for the project and advise about various sources of funding the project.
- They will also create a revenue model to make the project self-sustaining.

Legal framework:
- Frame laws and regulations and get them approved by the proper authorities. This may include formation of a regulatory body as mentioned in the recommendations.

Standards:
- Establish interoperable health IT standards and clinical terminology standards.
- Create a national EHR

Implementation Plan:

- Create a time bound implementation plan to be executed in phases with defined end points**.**

APPENDIX B: ACKNOWLEDGEMENT

The following people served as the members of the working group for Indian Health Information Network Development. (I-HIND)

Prof. N.K Ganguly, Chairman, Working Group, I-HIND
Director General
Indian Council of Medical Research

Dr B.S Bedi
Adviser, CDAC & Media Lab Asia,
Former Senior Director & Head Med. Electronics and Telemedicine
Dept. of IT, Govt. of India

Mr. Partha Chattopadhya
CD (DRS), Ministry of Health and Family Welfare

Dr Shiban Ganju
Convener, I- HIND

Dr A K Shiva Kumar
Member, National Advisory Council

Dr Ramakrishnan
Director General, CDAC

Prof. K Srinath Reddy
President, Public Health Foundation of India

Mr. Rajdeep Sahrawat
Vice President, NASSCOM

Mr. Raj Shah
Chairman &CEO, Capital Technology Information Services
Washington, DC

Dr YK Sharma
Deputy Director General, NIC

Mr. Anil Srivastava, Special Invitee I-HIND
Executive VP, Capital Technology Information Services
Washington DC

The following experts provided valuable contribution in preparing this document.

Dr Khalid Moidu
Professor, Health Informatics
Purdue University, USA

Dr Arvind Pandey
Director National Institute of Medical Statistics
ICMR, Delhi

Dr D Prabhakaran
Professor Cardiology, AIIMS, Delhi

Dr. Bela Shah
Senior Deputy Director General
ICMR, Delhi

Dr. Prashant Mathur
Assistant Director General
ICMR, Delhi

Mr. Mehul Shah
Chief Operating Officer
C-SAM, USA

Execution Team

Dr Ajay V.S
Centre for Chronic Disease Control. Delhi

Mr. Jibanananda Khuntia
University of Maryland, USA

Ms Mitakshara Kumari,
Research Associate, National Knowledge Commission

Dr. Y Prasannaya
Atrimed, Bangalore

Mr. V G Srinivas
CTIS, Washington DC

The following published references were used in preparing this document.

1. Health Information and Telemedicine legal framework: prepared by the Department of Information Technology, Government of India

2. Ilioudis C, Pangalos G. A Framework for an Institutional High Level Security Policy for the Processing of Medical Data and their
Transmission through the Internet. J Med Internet Res 2001; 3(2): e14
www.pubmedcentral.nih.gov/articlerender.fcgi?artid=1761901)

3. Personal Information Protection and Electronic Documents Act 2000, c.5, Government of Canada
http://laws.justice.gc.ca/en/ShowTdm/cs/P-8.6///en)