

**Recommendations
On
Electronic Medical Records
Standards
In
India**

April 2013

Recommendations of **EMR Standards Committee**,
constituted by an order of Ministry of Health &
Family Welfare, Government of India and
coordinated by FICCI on its behalf

Acknowledgement

It gives us immense pleasure to present the, “Recommendations on Electronic Medical Records Standards in India” to the Ministry of Health and Family Welfare, Government of India.

We sincerely acknowledge the sincere efforts of the members of the sub-groups formed by the Ministry who have worked diligently to come up with this standards report. We place our heartfelt acknowledgment and thanks to Mr B S Bedi, Dr S B Bhattacharyya, Dr S V Mani, Prof Saroj K Mishra, Mr Gaur Sunder and Dr Indrajit Bhattacharya. A list of sub-group members is enclosed separately.

This report also bears the efforts of significant contributions through review and revision of the document. We acknowledge the contribution in this regard by Ms Sangita Reddy, ED, Apollo Hospitals Group and chairperson, FICCI Healthservices Committee, representatives from Dell Corporation; Mr Arvind Sivramakrishnan, Group CIO, Apollo Hospital; Mr Ashokkan, CIO, Columbia Asia Hospitals India; Mr. Sunil Kumar, Sr. Technical Director, NIC; Mr. Vishwajeet V Ringe, Sr. Technical Director, NIC; Mr. K.S. Jagadeesha Reddy, Deputy Director, IIB of India (IRDA); Dr. U.C. Biswal, Retd. HOD Surgery & IT Head, Dr. RML Hospital; Dr Somil Nagpal, Senior Health Specialist, World Bank; Dr. Praneet Kumar, CEO, BLK Super Speciality Hospital and Dr. P. Saxena, Director, CBHI, MOHFW.

FICCI Health Services

Sub-Group Task I (Standards)

Members:

1. Dr. S.V. Mani, TCS (Group Head)
2. Dr. R.R. Sudhir, Shankar Netralaya
3. Ms. Kala Rao, TCS
4. Dr. Ashok Kumar, CBHI
5. Ms. Shobha Mishra Ghosh, FICCI
6. Dr. Sameer A. Khan, Fortis Hospital

Sub-Group Task II (Data Connectivity)

Members:

1. Mr. B S Bedi, CDAC (Group Head)
2. Dr. Thanga Prabhu, GE Healthcare
3. Prof Supten Sarbadhikari, Centre for Health Informatics
4. Mr. Chayan Kanti Dhar, National Informatics Center
5. Mr. Gaur Sunder, CDAC
6. Dr. S. B. Bhattacharyya, TCS

Sub-Group Task III (Data Ownership)

Members:

1. Prof. Saroj K. Mishra, SGPGI (Group Head)
2. Prof. Indrajit Bhattacharya , IIHMR
3. Dr. Karanveer Singh, Sir Gangaram Hospital
4. Dr. Naveen Jain, CDAC
5. Mr. Madhu Aravind, Healthhiway

TABLE OF CONTENTS

1. BACKGROUND	7
2. MAJOR STAKEHOLDERS.....	9
3. ELECTRONIC HEALTH RECORDS/ELECTRONIC MEDICAL RECORDS.....	10
STUDY & ANALYSIS OF NATIONAL EHR/EMR PROGRAMS AROUND THE WORLD	10
4. INTEROPERABILITY AND STANDARDS	14
GOALS	15
CATEGORIES FOR ADOPTION OF STANDARDS	15
Vocabulary Standards.....	15
Content Exchange Standards	16
Clinical Standards	17
Recommended Healthcare IT Standards (for India)	17
Relevant Healthcare Informatics Standards (as adopted internationally).....	19
Issues 20	
Trends 20	
5. EHR MINIMUM DATA SET (MDS)	22
6. GUIDELINES	36
HARDWARE.....	36
NETWORKING AND CONNECTIVITY	36
SOFTWARE STANDARDS.....	36
PROPOSED MOBILE HEALTH RECORD	37
7. DATA OWNERSHIP OF EMR	38
8. DATA PRIVACY & SECURITY	43
9. REFERENCES.....	47
12. ACRONYMS, DEFINITIONS & GLOSSARY.....	48
13. FORMAT FOR MEDICAL RECORDS.....	64
14. ANNEXURES.....	66

LIST OF TABLES

TABLE 2: COUNTRY-WISE HCIT STANDARDS USAGE	11
TABLE 3: COUNTRY-WISE DATA EXCHANGE STANDARDS USAGE	12
TABLE 4: COUNTRY-WISE STANDARDS ADOPTION STATISTICS	13
TABLE 5: HCIT STANDARDS (RELEVANT TO INDIA- INITIAL SET)	19
TABLE 6: HEALTH INFORMATICS STANDARDS.....	20
TABLE 7: EMR MDS.....	35
TABLE 8: PATIENT IDENTIFYING INFORMATION.....	42

EXECUTIVE SUMMARY

Healthcare systems are highly complex, fragmented and use multiple information technology systems. With vendors incorporating different standards for similar or same systems, it is little wonder that all-round inefficiency, waste and errors in healthcare information and delivery management are all too commonplace an occurrence. Consequently, a patient's medical information often gets trapped in silos of legacy systems, unable to be shared with members of the healthcare community. These are some of the several motivations driving an effort to encourage standardization, integration and electronic information exchange amongst the various healthcare providers.

Developmental Origins of Health and Diseases (DOHAD) have successfully proven the importance of developmental records of individuals in predicting and/or explaining the diseases that a person is suffering from. In the current largely paper-based medical records world, invaluable data is more often than not unavailable at the right time in the hands of the clinical care providers to permit better care. This is largely due to the inefficiencies inherent in the paper-based system. In an electronic world, it is very much possible, provided certain important steps are taken beforehand, to ensure the availability of the right information at the right time.

In order to be meaningful, the health record of an individual needs to be from conception (better) or birth (at the very least). As one progresses through one's life, every record of every clinical encounter represents an event in one's life. Each of these records may be insignificant or significant depending on the current problems that the person suffers from. Thus, it becomes imperative that these records be arranged chronologically to provide a summary of the various clinical events in the lifetime of a person.

Electronic health records are a summary of the various electronic medical records that get generated during any clinical encounter. Without standards, a lifelong summary is not possible as different records from different sources spread across ~80+ years will potentially need to be brought into one summary. To achieve this, a set of pre-defined standards for information exchange that includes images, clinical codes and a minimum data set is imperative.

This report provides a structured overview of the key EMR standards with respect to Indian conditions. A detailed discussion on the interoperability and standards that include a discussion on the goals, categories of adoption of standards, clinical standards, EMR/EHR, ownership, privacy and security aspects, healthcare informatics standards, and the various coding systems are carried out followed by the detailing of the minimum data set that any Indian EMR must have. A background on EMR and EHR and its use is provided, followed by a list of the various stakeholders. A short study of the efforts world-wide including country-wise analysis of similar efforts and their current state is also outlined.

While any vendor may choose to have any additionally relevant information captured and presented, all must conform to the MDS. A short reference section and a detailed section of acronyms, definitions and glossary are added for everyone's benefit.

In conclusion, it must be added that these standards cannot be considered either in isolation or as "etched in stone for all eternity". These will need to undergo periodic (at a maximum of 24 month interval) review and update as necessary. This document must be a "living document".

1. BACKGROUND

Health Care sector in India has witnessed significant growth during the last few years, both in quality and capacity. The 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. The private sector has also 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 interoperable and sharable technology, standards utilization, connecting various institutions and service providers. The use of international experience, best practices and open technologies may be necessary in some scenarios.

Technology is a critical tool in achieving the benefits of health information exchange (HIE). However, technology alone is not sufficient. Healthcare industry stakeholders that base their HIE solutions solely on technology do so at the expense of underlying health information management principles. An abundance of disparate HIE principles, models, definitions, products, and standards camouflages some crucial policy and process decisions an HIE initiative must make in the early stages of its development. Transmitting patient data electronically without attending to the business processes surrounding data capture, translation, and transmission has the potential to increase patient risks and healthcare costs. Data accessibility, reliability, and accuracy are therefore critical success factors in obtaining the trust of stakeholders, including consumers, and in sustaining long-term data exchange on a large scale.

Electronic health records can improve care by enabling functions that paper medical records cannot deliver:

- EHRs can make a patient's health information available when and where it is needed – too often care has to wait because the chart is in one place and needed in another. EHRs enable clinicians secure access to information needed to support high quality and efficient care.
- EHRs can bring a patient's total health information together to support better health care decisions, and more coordinated care.
- EHRs can support better follow-up information for patients – for example, after a clinical visit or hospital stay, instructions and information for the patient can be effortlessly provided and reminders for other follow-up care can be sent easily or even automatically to the patient.
- EHRs can improve patient and provider convenience – patients can have their prescriptions ordered and ready even before they leave the provider's office, and insurance claims can be filed immediately from the provider's office.

It is important to note that a number of initiatives proposing standardization and health information exchange (HIE) including telemedicine had been undertaken by the Government of India from time to time. In 2003, MCIT had prepared and published a recommended framework for IT infrastructure for healthcare including recommendations on guidelines, standards and practices for telemedicine in India. The taskforce set up by MoHFW in 2005 for telemedicine also looked at the issues and standards related to EMR.

The current recommendations are a result of the deliberations of the EMR Standards Committee set up by MoHFW, GoI in September 2010. FICCI is the nodal agency for coordination of the exercise nominated by the Ministry.

2. MAJOR STAKEHOLDERS

This list includes the following:

- Citizens
- Health care providers
- Payers, i.e., insurance companies including TPA
- Education, research institutions and investigators
- Government departments and institutions including law enforcement and courts of law
- Public health agencies and NGOs
- Pharmaceutical industry and medical device makers
- Telemedicine institutions
- Software and hardware vendors

It must be noted that while there are a number of stakeholders who have a vested interest in the data collected in an electronic health record system, the only two of these stakeholders have an active interest are the citizens and healthcare providers.

Therefore, the standards, guidelines and regulations mentioned in this document will apply to the following¹:

- Healthcare providers
- Healthcare Institutions
- Patients
- Independent Software Vendors including EHR/EMR System Designers, Manufacturers, Suppliers, and Re-sellers

¹ The definitions for each of the above are provided in the Acronyms, Definitions & Glossary section below.

3. ELECTRONIC HEALTH RECORDS/ELECTRONIC MEDICAL RECORDS

According to the "Integrated Care EHR", as defined in ISO/DTR 20514, an "EMR is a repository of information regarding the health of a subject of care in computer-processable form that is able to be stored and transmitted securely, and is accessible by multiple authorized users".

It has a commonly agreed logical information model which is independent of EHR systems and its chief purpose is the support of continuing, efficient and quality integrated health care and it contains information which is retrospective, concurrent and prospective.

Broadly speaking, an EMR is a specific recording/episode of encounter and is case or purpose specific – Telemedicine/Care, while an EHR is an aggregation of EMRs and is usually life-long.

The benefits that an EMR is expected to bring in are:

- Paperless medical history
- Reduced healthcare costs
- Empowering the stakeholders to be able to deliver right treatment at the right time
- Promote the practice of evidence-based medicine
- Accelerate research and building effective medical practices
- Usher in ease in maintaining health information of patients
- With proper backup policies increase lifespan of health records of individuals that is from conception to cremation
- safety with access, audit and authorization control mechanisms
- Faster search and updates

Study & Analysis of National EHR/EMR Programs Around the World²

Review of Healthcare IT Programs World-wide

Country	National Healthcare IT Program
Australia	HealthConnect
Austria	ELGA
Canada	EHRs Blueprint
Denmark	MedCom
England	Spine
Hong Kong	eHR Infrastructure
Netherlands	AORTA
Singapore	EMRX
Sweden	National Patient Summary (NPO)

² Conducted by Medical Informatics Group, C-DAC, Pune as part of Project for Building Distributed National EHR funded by DIT, MCIT, Govt. of India

Taiwan	Health Information Network (HIN)
--------	----------------------------------

Table 1: Worldwide HCIT Programs

Country-wise Usage of Standards

	Australia	Austria	Canada	Denmark	England	Hong Kong	Netherlands	Sweden	Singapore	Taiwan
HL7 v2.5	N	N	N	N	N	Y	N	N	N	N
HL7 v3 Only	N	Y	Y	N	Y	Y	Y	Y	N	N
CDA	Y	Y	Y	N	Y	Y	N	N	N	Y
ASTM CCR	N	N	N	N	Y	N	N	N	N	N
CCD	N	N	N	N	Y	N	N	N	N	N
openEHR	Y	N	N	Y	N	N	N	Y	N	N
IHE	N	Y	Y	N	N	N	N	N	N	N
DICOM	N	Y	Y	N	N	N	N	N	N	N
EDIFACT	N	N	N	Y	N	N	N	N	N	N
EHRCom	N	N	N	N	N	N	N	Y	N	N

Table 2: Country-wise HCIT Standards Usage

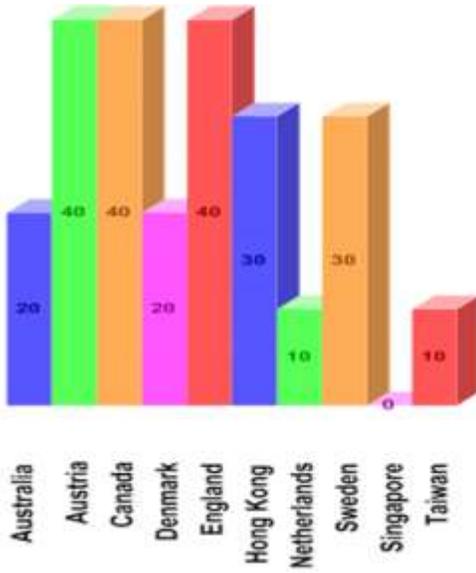


Table 3: Country-wise Data Exchange Standards Usage

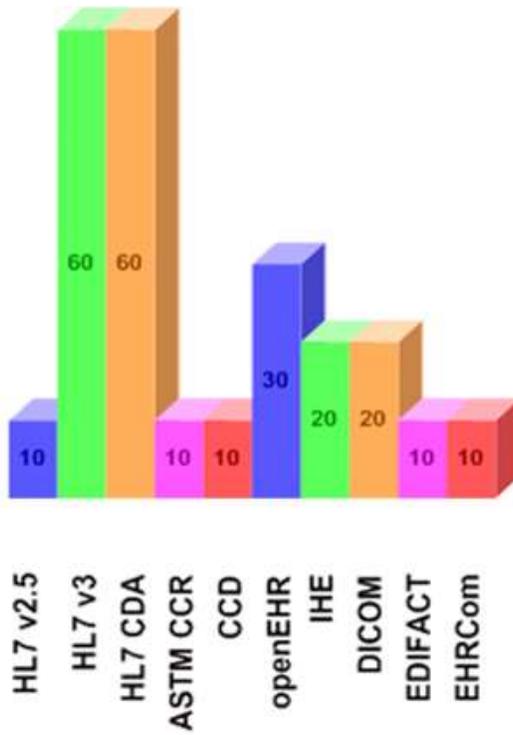


Table 4: Country-wise Standards Adoption Statistics

4. INTEROPERABILITY AND STANDARDS

The recommendations outlined in this section are an incremental approach to adopting standards, implementation specifications, and criteria to enhance the interoperability, functionality, utility, and security of health information technology and to support its widespread adoption. It is to be kept in mind that these standards should be flexible and modifiable to adapt to the demographic and resource variance observed in a large and developing country like India.

It is important to recognize that interoperability and standardization can occur at many different levels. To achieve interoperability, information models would need to be harmonized into a consistent representation.⁽⁸⁾

In other cases, organizations may use the same information model, but use different vocabularies or code sets (for example, Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®) or ICD10-CM within those information models. To achieve interoperability at this level, standardizing vocabularies, or mapping between different vocabularies (using tools like Unified Medical Language System (UMLS)) may be necessary. For some levels, (such as the network transport protocol), an industry standard that is widely used (e.g. Transmission Control Protocol (TCP) and the Internet Protocol (IP), (TCP/IP)) will likely be the most appropriate. Ultimately, to achieve semantic interoperability, it is anticipated that multiple layers – network transportation protocols, data and services descriptions, information models, and vocabularies and code sets – will need to be standardized and/or harmonized to produce an inclusive, consistent representation of the interoperability requirements.

It is further anticipated that using a harmonization process will integrate different representations of health care information into a consistent representation and maintain and update that consistent representation over time. For an information model, this process could include merging related concepts, adding new concepts, and mapping concepts from one representation of health care information to another. Similar processes to support standardization of data and services descriptions and vocabularies and codes sets may also be needed.

It is also recognized that a sustainable and incremental approach to the adoption of standards will require processes for harmonizing both current and future standards. This will allow the incremental updating of the initial set of standards, implementation specifications, and certification criteria and provide a framework to maintain them. The decision to adopt such updates will be informed and guided by recommendations from an appropriate authority akin to a National Health Information Authority.

Goals

- Promote interoperability and where necessary be specific about certain content exchange and vocabulary standards to establish a path forward toward semantic interoperability
- Support the evolution and timely maintenance of adopted standards
- Promote technical innovation using adopted standards
- Encourage participation and adoption by all vendors and stakeholders
- Keep implementation costs as low as reasonably possible
- Consider best practices, experiences, policies and frameworks
- To the extent possible, adopt standards that are modular and not interdependent.

Categories for adoption of standards

Vocabulary Standards

(i.e., standardized nomenclatures and code sets used to describe clinical problems and procedures, medications, and allergies);

This is to be achieved through the extensive use of Controlled Medical Vocabularies (CMV) that is detailed as follows:

- a) Logical Observation Identifiers Names and Codes (LOINC®): The purpose of LOINC® is to facilitate the exchange and pooling of clinical results for clinical care, outcomes management, and research by providing a set of universal codes and names to identify laboratory and other clinical observations. The Regenstrief Institute Inc., an internationally renowned healthcare and informatics research organization, maintains the LOINC database and supporting documentation, and the RELMA mapping program.
- b) International Classification of Diseases (ICD10): The ICD is the international standard diagnostic classification for all general epidemiological, many health management purposes and clinical use.
- c) Systematized Nomenclature of Medicine--Clinical Terms (SNOMED-CT): is a comprehensive clinical terminology, originally created by the College of American Pathologists (CAP) and owned, maintained, and distributed by the International Health Terminology Standards Development Organization (IHTSDO), a non-for-profit association in Denmark.
- d) Current Procedural Terminology, 4th Edition (CPT 4): The CPT-4 is a uniform coding system consisting of descriptive terms and identifying codes that are used primarily to identify medical services and procedures furnished by physicians and other health care professionals.
- e) RxNORM: RxNorm, produced by the National Library of Medicine (NLM) provides normalized names for clinical drugs and links its names to many of the drug vocabularies commonly used in pharmacy management and drug interaction software, including those of First Databank, Micromedex, MediSpan, Gold Standard Alchemy, and Multum. By providing

links between these vocabularies, RxNorm can mediate messages between systems not using the same software and vocabulary.

- f) ATC – Anatomic Therapeutic Chemical Classification of Drugs: is used for the classification of drugs. It is controlled by the WHO Collaborating Centre for Drug Statistics Methodology (WHOCC), and was first published in 1976. This pharmaceutical coding system divides drugs into different groups according to the organ or system on which they act and/or their therapeutic and chemical characteristics. Each bottom-level ATC code stands for a pharmaceutically used substance in a single indication (or use). This means that one drug can have more than one code: acetylsalicylic acid (aspirin), for example, has A01AD05 as a drug for local oral treatment, B01AC06 as a platelet inhibitor, and N02BA01 as an analgesic and antipyretic. On the other hand, several different brands share the same code if they have the same active substance and indications.

Content Exchange Standards

(i.e., standards used to share clinical information such as clinical summaries, prescriptions, and structured electronic documents)

- a) Health Level Seven (HL7) Clinical Document Architecture: is an XML-based mark-up standard intended to specify the encoding, structure and semantics of clinical documents for exchange. CDA is being used also in electronic health records projects to provide a standard format for entry, retrieval and storage of health information
- b) HL7 2.5.1: defines a series of electronic messages to support administrative, logistical, financial as well as clinical processes and mostly uses a textual, non-XML encoding syntax based on delimiters. HL7 v2.x has allowed for the interoperability between electronic Patient Administration Systems (PAS), Electronic Practice Management (EPM) systems, Laboratory Information Systems (LIS), Dietary, Pharmacy and Billing systems as well as Electronic Medical Record (EMR) or Electronic Health Record (EHR) systems
- c) Continuity of Care Record (CCR) is a health record standard specification developed jointly by ASTM International, the Massachusetts Medical Society (MMS), the Healthcare Information and Management Systems Society (HIMSS), the American Academy of Family Physicians (AAFP), the American Academy of Pediatrics (AAP), and other health informatics vendors. It is a core data set of the most relevant administrative, demographic, and clinical information facts about a patient's healthcare, covering one or more healthcare encounters. It provides a means for one healthcare practitioner, system, or setting to aggregate all of the pertinent data about a patient and forward it to another practitioner, system, or setting to support the continuity of care. The primary use case for the CCR is to provide a snapshot in time containing the pertinent clinical, demographic, and administrative data for a specific patient. To ensure interchange ability of electronic CCRs, this specification specifies XML coding that is required when the CCR is created in a structured electronic format. Conditions of security and privacy for a CCR instance must be established in a way that allows only properly authenticated and authorized access to the

CCR document instance or its elements. The CCR consists of three core components: the CCR Header, the CCR Body, and the CCR Footer.

- d) Digital Imaging and Communications in Medicine (DICOM): The DICOM Standards Committee exists to create and maintain international standards for communication of biomedical diagnostic and therapeutic information in disciplines that use digital images and associated data. The goals of DICOM are to achieve compatibility and to improve workflow efficiency between imaging systems and other information systems in healthcare environments worldwide. DICOM currently defines an upper layer protocol (ULP) that is used over TCP/IP (independent of the physical network), messages, services, information objects and an association negotiation mechanism. These definitions ensure that any two implementations of a compatible set of services and information objects can effectively communicate.

Clinical Standards

Clinical standards are health information standards to capture a patient's health information in a more coherent manner. This health information can include all or part thereof as relevant of the following:

- The illness a patient is suffering from
- The physician's observation of the patient's illness
- The diagnostic tests that need to be carried out to ascertain the patient's illness and to give the patient better treatment
- The results of the diagnostic tests
- The kind of treatment to be given to the patient
- The way the treatment should be given to the patient

Recommended Healthcare IT Standards (for India)

Name	Class	Comments
Phase 1		
UHID	Unique Health Identifier – to act as Patient Identifier	UID as a unique (primary or secondary) patient identifier. The UID should be used to identify a particular patient across all organizations (and their EMR systems); Aadhar number is recommended for use in EMR as either the primary or secondary, where the primary is an internal unique health identifier used by the healthcare provider organisation
XML (eXtensible Markup Language)	for data capture, integration and presentation layer	To access via SOAP-simple object access protocol

CCD (HL7/ASTM)	Clinical Data for Inter Department documents (the CDA CCD)	Likely to be used for exchanging the clinical documentation between two EHR solutions both within an organisation and outside
RXNORM/ATC Pharmacologic-Therapeutic Classification/NDC -national drug classification, FDB-first databank (USA) Indian Drugs – MIMS/CIMS from CMPmedica	Medicines	Needs to be researched as there is no universal drug reference database. The WHO Drug Dictionary ATC – anatomic therapeutic classification) may be a good choice to begin with
Dictionary of Medicine & Devices, UK	Medicines & Medical devices	UK standard used in NHS includes devices & drugs
LOINC	Clinical Laboratory Observations	Published and maintained by the Regenstrief Institute, USA, this is a universally accepted code for laboratory observations
HL7 V2.x	Messaging	Propose V2.3
HL7 V3.0 RIM	Reference Information Model	As this version is being superceded by FHIR from HL7, it would be preferable to adopt FHIR instead of V3.0 RIM
DICOM 3.0-2004	Medical Images	The latest version
CPT 4 or 5, US	Procedure & Therapy classification	As this will involve paying a licensing fee, this is optional
OPCS4, UK	Procedure & Therapy classification	
SNOMED-CT	Clinical Terminology	Provide comprehensive clinical granularity, used to capture problem list, allergies, diagnosis, procedures etc. – will immensely aid in clinical analytics, clinical decision support systems, automated clinical care pathway management systems, support evidence based practice, etc.
WHO ICD 10	Disease classification	WHO is actively working with IHTSDO to converge SNOMED-CT with ICD
WHO – PCS	Procedure coding system	
WHO – ICF	International classification of functioning, disability &	

	health	
Phase 2		
DSM	Psychiatric conditions	Diagnostic & statistical manual of mental disorders
NIC/NOC/NANDA	Nursing interventions classification	
CDT 2, US	Dental Procedures	
Unknown	AYUSH clinical terminology, treatment planning including medication details	Ayurveda, Yoga, Unani, Siddha, Homeopathy systems of medicine as distinct from the allopathic (Western) system of medicine

Table 5: HCIT Standards (relevant to India- Initial Set)

Relevant Healthcare Informatics Standards (as adopted internationally)

Organization	Standards
National Recommendations for Health Information Infrastructure in India	<ul style="list-style-type: none"> ➤ Information Technology Infrastructure for Health (ITI) framework ➤ Recommendations on Guidelines, Standards & Practices for Telemedicine in India ➤ Indian health information network development (iHIND) recommendations from the National Knowledge
International Organization for Standardization (ISO)	Requirements for Electronic Health Record Architecture (ISO / TS 18308)
European Committee for Standardization (CEN)	CEN / TC 251 EN 13606
Code of Federal Regulations (CFR)	Health Information Technology Standards, Implementation Specifications, and Certification Criteria and Certification Programs for Health Information Technology (Title 45, Part 170)
American Society for Testing & Materials (ASTM)	Continuity of Care Record (CCR)
Health Level 7 (HL7)	HL7 v2.x HL7 v3 CDA – 2 FHIR (Fast Health Interoperable Resources) – the newest version; easy upgrade from v2.x to FHIR EHR - System Functional Model
HL7 & ASTM Collaboration	Continuity of Care Document (CCD)

National Electrical Manufacturer's Association (NEMA)	Digital Imaging and Communications in Medicine (DICOM PS 3.0 2004 onwards)
Office of National Coordinator for Health Information Technology (ONCHIT) – USA	EHR Meaningful Use

Table 6: Health Informatics Standards

Issues

- Unique Identification
- Interoperability / Sharing
- Integrated systems require consistent use of standards in e.g. medical terminologies and high quality data to support information sharing across wide networks
- Ethical, legal and technical issues linked to the accuracy, security confidentiality and access rights.
- Common record architectures, structures
- Clinical information standards and communications protocols

Trends

- National UID and Healthcare
- Distributed EHR Concept

5. EHR MINIMUM DATA SET (MDS)

The following MDS is recommended for an EMR to be used in India. Vendors are free and indeed encouraged to opt for additional data to satisfy additional and the unmet needs of the various stakeholders, principally the patients and the clinical care providers.

Data Item	Data Type	Data Length	Format/Values	Status	Additional Observations
UHID	Numeric	12	As per Aadhar Specifications	Mandatory if no other concomitant ID is used in the system, else optional	Only the public key will be used and that too only for identification, aid in patient search, patient merge and demerge functionalities
Alternate UHID	Any	Any	As per institution/ vendor's specifications	Mandatory if no other concomitant ID is used in the system, else optional	Wherever Adhaar Number is unavailable and the healthcare provider wishes to use their own ID system, this field should be used; this ID may be used in addition to the UHID above
Patient Name	Alphanumeric	Sufficiently large	To be split into First Name, Middle Name and Last (Family) Name	Mandatory	MDDS (http://egovstandards.gov.in/standardsandFramework/metadata-and-data-standards/MDDS-Demographic%20Ver%201.1.pdf/at_download/file) may be referred to for patient demographics data; only the person identification part of the meta data and data standards are applicable
Patient Date of Birth	Date	Fixed	dd.mm.yyyy	Optional	

Patient Age	Numeric	Fixed	999,99,999 no preceding zero [years, months, days]	Mandatory	Age is to be automatically calculated if date of birth is entered/available; once the patient's age is available, all client systems must automatically "age" the patient. For this, unless the patient's date of birth is available, the age will be approximated with the assumption that the patient was born on the 1st day of January of the year that the entered age appears to point to. The record display will need to clearly show that this age is an approximated one and that the patient may actually be older by 1 additional year maximally
Patient Gender	Alphanumeric	1	To be shortened to one byte as M, F, U or T for Male, Female, Unknown and Transgender. Systems should translate and show the full form on user screens	Mandatory	
Patient Occupation	Alphanumeric	Sufficiently large		Mandatory	
Patient Address Type	Alphanumeric	9	Current/ Permanent/	Mandatory	

			Previous		
Patient Address Line 1	Alphanumeric	Sufficiently large		Mandatory	It is recommended that MDDS be followed; details are given above
Patient Address Line 2	Alphanumeric	Sufficiently large		Optional	It is recommended that MDDS be followed; details are given above
Patient City/Town/Village/Police Station	Alphanumeric	Sufficiently large		Mandatory	It is recommended that MDDS be followed; details are given above
Patient District	Alphanumeric	Sufficiently large		Optional	It is recommended that MDDS be followed; details are given above
Patient State	Alphanumeric	Sufficiently large		Optional	It is recommended that MDDS be followed; details are given above
Patient Pin Code	Alphanumeric	Sufficiently large		Optional	It is recommended that MDDS be followed; details are given above
Patient Country Code	Alphanumeric	Sufficiently large	As per ISO Country Codes	Optional	
Patient Phone Type	Alphanumeric	20	Landline/Mobile/ PP- Landline/Neighbour Landline/Relation Landline /Neighbour Mobile/Relation Mobile	Optional	
Patient Phone Number	Alphanumeric	16	(099)9999999999	Optional	

Patient Email ID	Alphanumeric	255	Must contain '@' and "." at appropriate positions	Optional	
Emergency Contact Person Name	Alphanumeric	Sufficiently large		Optional	It is recommended that MDDS be followed; details are given above
Emergency Contact Person Relationship	Alphanumeric	9	Spouse/Parent/Child/Partner/Cousin/Friend/Neighbour/Other	Mandatory, if used, else Optional	
Emergency Contact Person Address Type	Alphanumeric	9	Current/Permanent/Previous	Mandatory, if used, else Optional	
Emergency Contact Person Address Line 1	Alphanumeric	Sufficiently large		Mandatory, if used, else Optional	It is recommended that MDDS be followed; details are given above
Emergency Contact Person Address Line 1	Alphanumeric	Sufficiently large		Mandatory, if used, else Optional	It is recommended that MDDS be followed; details are given above
Emergency Contact Person Address Line 2	Alphanumeric	Sufficiently large		Optional	It is recommended that MDDS be followed; details are given above
Emergency Contact Person City/Town/Village/ Police Station	Alphanumeric	Sufficiently large		Mandatory, if used, else Optional	It is recommended that MDDS be followed; details are given above

Emergency Contact Person District	Alphanumeric	Sufficiently large		Optional, if used	It is recommended that MDDS be followed; details are given above
Emergency Contact Person State	Alphanumeric	Sufficiently large		Optional, if used	It is recommended that MDDS be followed; details are given above
Emergency Contact Person Pin Code	Alphanumeric	Sufficiently large		Optional, if used	It is recommended that MDDS be followed; details are given above
Emergency Contact Person Country Code	Alphanumeric	Sufficiently large	As per ISO Country Codes	Optional, if used	
Emergency Contact Person Phone Type	Alphanumeric	20	Landline/Mobile/ PP-Landline/ Neighbour Landline/Relation Landline /Neighbour Mobile/Relation Mobile	Optional	
Emergency Contact Person Phone Number	Alphanumeric	16	(099)9999999999	Optional	
Emergency Person Email ID	Alphanumeric	255	Must contain '@' and '.' at appropriate positions	Optional	
Care Provider Name	Alphanumeric	Sufficiently large		Optional	It is recommended that MDDS be followed; details are given above

Care Provider Address Type	Alphanumeric	9	Current/ Permanent/ Previous	Mandatory, if used, else Optional	
Care Provider Address Line 1	Alphanumeric	Sufficiently large		Mandatory, if used, else Optional	It is recommended that MDDS be followed; details are given above
Care Provider Address Line 2	Alphanumeric	Sufficiently large		Optional	It is recommended that MDDS be followed; details are given above
Care Provider City/Town/Village/ Police Station	Alphanumeric	Sufficiently large		Mandatory, if used, else Optional	It is recommended that MDDS be followed; details are given above
Care Provider District	Alphanumeric	Sufficiently large		Optional, if used	It is recommended that MDDS be followed; details are given above
Care Provider State	Alphanumeric	Sufficiently large		Optional, if used	It is recommended that MDDS be followed; details are given above
Care Provider Pin Code	Alphanumeric	Sufficiently large		Optional, if used	It is recommended that MDDS be followed; details are given above
Care Provider Country Code	Alphanumeric	Sufficiently large	As per ISO Country Codes	Optional, if used	
Care Provider Phone Type	Alphanumeric	20	Landline/Mobile/ PP-Landline/ Neighbour Landline/Relation Landline /Neighbour Mobile/Relation Mobile	Optional	
Care Provider Phone Number	Alphanumeric	16	(099)9999999999	Optional	

Care Provider Email ID	Alphanumeric	255	Must contain '@' and "." at appropriate positions	Optional	
Insurance Status	Alphanumeric	9	Insured/ Uninsured	Optional	
Insurance ID	Alphanumeric	25	As appropriate	Mandatory if Insurance Type is Entered, else Optional	
Organ Donor Status	Alphanumeric	1	Y - Yes or N - No	Optional	
Episode Type	Alphanumeric	8	New/Ongoing, alternatively New/ Active/Inactive	Optional	
Episode Number	Numeric	4	9999 format – no prefixed 0	Mandatory if Episode Type is Entered, else Optional	For definition of episode, please refer to the definitions chapter above
Encounter Type	Alphanumeric	14	Outpatient/ Inpatient/ Emergency/ Investigations	Mandatory	For definition of encounter, please refer to the definitions chapter above

Encounter Number	Numeric	4	9999 format – no prefixed 0	Mandatory	It must be ensured that the no encounter number is arbitrarily assigned. The system will need to ensure this. When linking records from diverse systems, episode and encounter reconciliation through appropriate merging and demerging will need to take place. However, this is a design and development issue, and out of scope for the work of MDS proposal
Encounter Date & Time	Datetime	Fixed	Complete date plus hours, minutes and seconds/Complete date plus hours, minutes, seconds and a decimal fraction of a second	Mandatory; should be auto-inserted by the system from system time that is synchronised with Indian Standard Time	
Reason for Visit	Alphanumeric	4096		Mandatory	More than one reason for visit may be entered

Present History	Alphanumeric	4096		Optional	Both structured and unstructured data can be used wherever the data type is alphanumeric and data length is 4096 and if necessary, it can be made longer- this is true for all fields in the MDS wherever they occur
Past History	Alphanumeric	4096		Optional	
Personal History	Alphanumeric	4096		Optional	
Family History	Alphanumeric	4096		Optional	
Menstrual & Obstetric History	Alphanumeric	4096	LMP, Cycle Duration, Gravida, Parity to be captured as structured data where LMP: date type; Cycle Duration, Gravida, Parity: numeric type;	Optional	Menstrual & Obstetric History to be available only if the chosen gender is female
Socio-economic Status	Alphanumeric	Sufficiently large		Optional	

Immunization History	Alphanumeric	4096		Optional	It is preferable that the details are captured in as granular a manner as is practical; multiple entries should be possible, with a list of values for each vaccine type and dates administered with current status (administered/not-administered)
Allergy Status	Alphanumeric	8	Active/Inactive	Optional	
Allergy History	Alphanumeric	4096		Optional	Allergies will be a list of values (drug generics, etc.) that would, in future, allow allergy alerts to be activated
Clinical Exam Vitals Systolic BP	Numeric	3	999 – no preceding 0	Optional	Unit of measurement is mmHg
Clinical Exam Vitals Diastolic BP	Numeric	3	999 – no preceding 0	Optional	Unit of measurement is mmHg
Clinical Exam Pulse Rate	Numeric	3	999 – no preceding 0	Optional	Unit of measurement is per minute
Clinical Exam Temperature (°C)	Floating	2 digits, 2 decimals	99.99	Optional	Unit of measurement is degrees Centigrade; if degrees Fahrenheit is to be used, then this may be converted at run time for display or data manipulation purposes by the system
Clinical Exam Temperature Source	Alphanumeric	6	Oral/Armpit/ Groin/Rectal	Mandatory, if Temperature is captured	

Clinical Exam Respiration Rate	Numeric	3	999 – no preceding 0	Optional	Unit of measurement is per minute
Clinical Exam Height (cms)	Floating	3 digits, 2 decimals	999.99	Optional	Unit of measurement is centimetres; if any other unit of measurement, like feet, is to be used, then this may be converted at run time for display or data manipulation purposes by the system
Clinical Exam Weight (kgs)	Floating	3 digits, 2 decimals	999.99	Optional	Unit of measurement is kilograms; if any other unit of measurement, like pounds, is to be used, then this may be converted at run time for display or data manipulation purposes by the system
Blood Group	Alphanumeric	3	A+/A-/B+/B- /AB+/AB-/O+/O-	Optional	
Clinical Exam Observation	Alphanumeric	4096		Optional	It is recommended that SNOMED-CT be used for all clinical terms/observations
Investigation Results	Alphanumeric	4096		Optional	It is recommended that LOINC be used for all laboratory observations

Clinical Summary	Alphanumeric	4096		Mandatory	It is recommended that SNOMED-CT be used for all clinical terms/observations
Diagnosis Type	Alphanumeric	11	Provisional/ Final/ Admission/ Interim/ Working/ Discharge	Mandatory	
Diagnosis Code Name	Alphanumeric	Sufficiently large	ICD/SNOMED CT/Free	Mandatory	
Diagnosis Code	Alphanumeric	Sufficiently large	Coding system dependent	Mandatory	Diagnosis Code should allow multiple entries per encounter record
Diagnosis (Description)	Alphanumeric	4096		Mandatory	
Treatment Plan Investigations	Alphanumeric	4096		Optional	The user may or may not enter any value
Treatment Plan Medication	Alphanumeric	4096		Optional	It is preferable that the details are captured in as granular a manner as is practical; for the allopathic system of medicine, it is suggested that something similar to the contents of the table below be followed - this requirement is not mandatory
Treatment Plan Procedure	Alphanumeric	4096		Optional	
Treatment Plan Referral	Alphanumeric	4096		Optional	For use in referral cases only

Other Treatment Plan Type	Alphanumeric	10	Diet/Life-style/ Others	Optional	
Other Treatment Plan Details	Alphanumeric	4096		Mandatory if Other Treatment Type is selected	
Current Clinical Status	Alphanumeric	255	[Free text]	Mandatory	Captures the current clinical status; synonymous with clinical outcome or condition at discharge; it is preferable that terms such as "Fair", "Relieved", "Better", "Same", "Worse", "Fatal", etc. be used instead of long narratives

MEDICATION DETAILS (for allopathic system of medicine only):

Data Item	Data Type	Data Length	Format/Values	Status	Additional Observations
Medication Name	Alphanumeric	Sufficiently large	As per the drug database	Mandatory	Should preferably be generic
Drug Code	Alphanumeric	Sufficiently large	As per the drug database	Mandatory	Auto populated by the system
Strength	Alphanumeric	Sufficiently large	As per the drug database	Mandatory	Should be presented as a LOV
Dose	Alphanumeric	Sufficiently large		Mandatory	To be entered by the care provider
Route	Alphanumeric	Sufficiently large		Mandatory	To be entered by the care provider

Frequency	Alphanumeric	Sufficiently large		Mandatory	To be entered by the care provider
-----------	--------------	--------------------	--	-----------	------------------------------------

Table 7: EMR MDS

6. GUIDELINES

Hardware

- The IT hardware used should meet (and preferably be better than) the optimal requirement given by the software (to be) used.
- The medical and IT hardware used must meet the relevant applicable specifications from BIS, NEMA, ISO, CE, RoHS, EnergyStar, apart from Medical and IT standards for the equipment.
- A backup or data preservation mechanism should be considered. Data capacity should be planned to meet the storage requirement as per the mandated rule/law.
- System redundancy at various levels (disk, power, network, etc.) should be planned to meet the organizational system availability requirement.
- Network and data security should be planned, implemented, and periodically audited. Please see section on Security and Privacy for requirements and functions to be supported and implemented.
- Hardware should be checked periodically for correctness and completeness of operation expected from them. An appropriate maintenance cycle should be planned and followed.
- Planned and expected Capacity and Quality requirement of the organization should be met by the hardware used. Periodic updates and upgrades should be carried out to meet the requirements.

Networking and Connectivity

- Should be able to harness any telecommunications-related connectivity like the Internet, LAN, WAN, WAP, CDMA, GSM or even Cloud Computing that will permit the various EMRs of an individual to be integrated into a single lifelong electronic health record
- As far as practical and affordable, the connectivity medium chosen should be reliable and fast enough to sustain a secure data exchange for the period expected for transaction of records and data. The speed of the connectivity medium should be chosen from among available options so as to provide an acceptable user experience and not cause software/system fault due to delays/noise/failure.
- Should be able to ensure that data exchange is performed in a secure manner to ensure data validity and non-repudiability
- The data exchange must further ensure that data integrity is maintained at all times

Software Standards

The software should

- Conform to the specified standards
- Satisfy specified requirements
- Be Interoperable
- Should be able to ensure role based access control at all times

- Should be able to support privacy, secrecy and audit trail
- Possess advanced search, merge, and demerge functionality to ensure that duplicates are robustly resolved
- Should be able to support conception-to-current medical records of a person
- Should be able to support digital archiving and retrieval of medical records after the death of a person for the total duration as specified by Government of India from time to time
- Should be able to construct a medical/clinical summary based on available records from the very first visit to current
- Should be able to support for rapid data capture-storage-retrieval-display of data
- Should be able to ensure user authentication and authorisation

Proposed Mobile Health Record

As patients move around the healthcare system there is a need to carry essential information to ensure quality healthcare which will give their treating clinician basic information viz., medical condition, drug/allergy information etc. CCR standard XML file format, with demographics, insurance info, problem list/diagnoses, medications, allergy and alerts, vital signs, and lab results, consultation reports, hospital discharge and operative reports and investigative and diagnostic results (e.g. ECG reports, tread mill test results, biochemistry results, histopathological findings, ultrasound findings, etc.) kept current and accurate by a person's healthcare team (nurses, doctors and pharmacists) which includes the patient. Conformance to m-governance guidelines of DEITY is imperative (<http://www.deity.gov.in/content/framework-mobile-governance>)

7. DATA OWNERSHIP OF EMR

The Ethical, Legal, Social Issues (ELSI) guidelines for Electronic Medical Record (EMR) are recommended as follows.

For the purposes of these recommendations, the term “**privacy**” shall mean that only those person or person(s) including organisations duly authorized by the patient may view the recorded data or part thereof. The term “**security**” shall mean that all recorded personally identifiable data will at all times be protected from any unauthorized access, particularly during transport (e.g. from healthcare provider to provider, healthcare provider to patient). The term “**trust**” shall mean that person, persons or organisations (doctors, hospitals, patients) are those who they claim they are.

The following approaches are to be adopted wherever applicable:

- Privacy would refer to authorization by the owner of the data (the patient)
- Security would have as components both public and private key encryption; the encryptions used in transit and at rest need to be through a different methodology.
- Trust would be accepted whenever a trusted third party confirms identify

Protected health information (PHI) would refer to any individually identifiable information whether oral or recorded in any form or medium that (1) is created, or received by a stakeholder; and (2) relates to past, present, or future physical or mental health conditions of an individual; the provision of health care to the individual; or past, present, or future payment for health care to an individual.

Electronic protected health information (ePHI) would refer to any protected health information (PHI) that is created, stored, transmitted, or received electronically. Electronic protected health information includes any medium used to store, transmit, or receive PHI electronically.

The following and any future technologies used for accessing, transmitting, or receiving PHI electronically are covered:

- Media containing data at rest (data storage)
 - Personal computers with internal hard drives used at work, home, or traveling
 - External portable hard drives, including iPods and similar devices
 - Magnetic tape
 - Removable storage devices, such as USB memory sticks, CDs, DVDs, and floppy disks
 - PDAs and smartphones
- Data in transit, via wireless, Ethernet, modem, DSL, or cable network connections
 - Email
 - File transfer

For data ownership, a distinction is to be made between

- a. The physical or electronic records, which are owned by the healthcare provider. These are held in trust on behalf of the patient, and
- b. The contained data which are the sensitive personal data of the patient is owned by the patient itself.
- c. The healthcare provider will have the privilege to change/append/modify any record in relation to the medical care of the patient as necessary with a complete documented trail of such change. No alteration of the previously saved data will be permitted. No update or update like command shall be utilised by the system to store a record or part thereof. A new record will be created with the unaltered parts of the existing record. The changed/appended/modified data will replace the relevant parts of that record. This record shall then be stored and marked as active while rendering the previous version or versions of the same record marked inactive. A strict audit trail shall be maintained of all activities at all times that may be suitably reviewed by an appropriate authority like auditor, legal representatives of the patient, the patient, healthcare provider, privacy officer, court appointed/authorised person, etc.
- d. The medium of storage or transmission of such electronic medical record will be owned by the healthcare provider.
- e. The “sensitive personal information (SPI) and personal information (PI)” of the patient is owned by the patient themselves. Refer to IT Act 2000 for the definition of SPI and PI.
- f. Sensitive Data: As per the Information Technology Act 2000, Data Privacy Rules, refer to ‘sensitive personal data or information’ (Sensitive Data) as the subject of protection, but also refer, with respect to certain obligations, to ‘personal information’. Sensitive Data is defined as a subset of ‘personal information’. Sensitive Data is defined as personal information that relates to:
 - i. Passwords;
 - ii. Financial information such as bank account or credit card or debit card or other payment instrument details;
 - iii. Physical, psychological and mental health condition;
 - iv. Sexual orientation;
 - v. Medical records and history;
 - vi. Biometric information;
 - vii. Any detail relating to (1) – (6) above received by the body corporate for provision of services; or
 - viii. Any information relating to (1) – (7) that is received, stored or processed by the body corporate under a lawful contract or otherwise

Data access and confidentiality would refer to:

- a. Regulations are to be enforced to ensure confidentiality of the recorded patient/medical data and the patient should have a control over this.
- b. Patients will have the sufficient privileges to inspect and view their medical records without any time limit. Patient's privileges to amend data shall be limited to correction of errors in the recorded patient/medical details. This shall need to be performed through a recorded request made to the healthcare provider within a period of 30 days from the date of discharge in all inpatient care settings or 30 days from the date of clinical encounter in outpatient care settings. An audit of all such changes shall be strictly maintained. Both the request and audit trail records shall be maintained within the system. Patients will have the privileges to restrict access to and disclosure of individually identifiable health information.
- c. All recorded data will be available to care providers on an 'as required on demand' basis
- d. Minimum data standards

Disclosure of information would be applicable as follows:

- a. For use for treatment, payments and other healthcare operations: In all such cases, a general consent must be taken from the patient or next of kin, etc. as defined by applicable laws by MCI.
- b. Fair use for non-routine and most non-health care purposes: a specific consent must be taken from the patient; format as defined by MCI.
- c. Certain national priority activities, including notifiable/communicable diseases, will be specified for which health information may be disclosed to appropriate authority as mandated by law without the patient's prior authorization

Responsibilities of any healthcare provider would include:

- a. Protect and secure the stored health information, as per the guidelines specified in this document (chapter 9 – Data privacy and security).
- b. While providing patient information, remove patient identifying information (as provided in Table 1), if it is not necessary to be provided
- c. Will ensure that there are appropriate means of informing the patient of policies relating to his/her rights to health record privacy
- d. Document all its privacy policies and ensure that they are implemented and followed. This will include:
 - i. Develop internal privacy policies
 - ii. Designate a privacy officer (preferably external, may be internal) who will be responsible for implementing privacy policies, audit and quality assurance

iii. Provide privacy training to all its staff

Patient will have the privilege to appoint a personal representative to carry out the activities detailed below.

- a. Patients will have the privilege to ask for a copy of its medical records held by a healthcare organization.
- b. Patients will have the privilege to request a healthcare organization which holds its medical records, to withhold specific information that he/she does not want disclosed to other organizations or individuals.
- c. Patient can demand information from a healthcare provider on the details of disclosures performed on the patients medical records.

Instances where denial of information will apply are as follows:

Healthcare provider will be able to deny information to a patient or representative or third party, in contravention of normal regulations, if in the opinion of a licensed healthcare professional the release of information would endanger the life or safety of the patients and others. This will include but not be limited to as follows:

- d. Information obtained from an anonymous source under a promise of confidentiality.
- e. Psychotherapy notes.
- f. Information compiled for civil, criminal or administrative action.

Instances where use and disclosure without individual authorization will be possible are as follows:

Disclosures can be performed without individual authorization in the following situations.

- **With Identifiers**, On production of court order
- However, as far as possible, and where appropriate, the data so provided should be anonymised to remove information that will allow identification of the patient. (Removing identifiers as indicated in Table 1 below)

Digital signatures are to be used to prevent non-repudiation (establishing authenticity of author of the document) and trust by the recipient.

Follow **e-Pramaan National e-Authentication service** offered by DeitY, Govt. Of India

<http://epramaan.gov.in/>

Reference Framework for e-authentication – ePramaan

<http://egovstandards.gov.in/policy/framework-document-for-e-authentication-epramaan>

Reference Guidelines for Digital Signatures, available at

<http://egovstandards.gov.in/guidelines/Guidelines%20for%20Digital-signature/view>

Additional Reference Guidelines for Information Security, available at <http://egovstandards.gov.in/guidelines/guidelines-for-information-security/view>

Patient Identifying Information

Data are "individually identifiable" if they include any of the under mentioned identifiers for an individual or for the individual's employer or family member, or if the provider or researcher is aware that the information could be used, either alone or in combination with other information, to identify an individual. These identifiers are as follows:

1. Name
2. Address (all geographic subdivisions smaller than street address, , and PIN code)
3. All elements (except years) of dates related to an individual (including birth date, date of death,
4. Telephone and/or Fax numbers
5. Email address
6. Medical record number
7. Health plan beneficiary number
8. Bank Account and/or Credit Card Number
9. Certificate/license number
10. Any vehicle or other any other device identifier or serial numbers
11. PAN number
12. Passport number
13. ADHAAR card
14. Voter ID card
15. Fingerprints/Biometrics
16. Voice recordings that are non-clinical in nature
17. Photographic images and that possibly can individually identify the person
18. Any other unique identifying number, characteristic, or code

Table 8: Patient Identifying Information

Applicable legislation details: The existing Indian laws including IT Act 2000 and as amended from time to time would prevail. (<http://deity.gov.in/content/information-technology-act-2000>).

8. DATA PRIVACY & SECURITY

Security of Electronic Health Information:

The Privacy Standards and the Security Standards are necessarily linked. Any health record system requires safeguards to ensure the data is available when needed and that information is not used, disclosed, accessed, altered, or deleted inappropriately while being stored or transmitted. The Security Standards work together with the Privacy Standards to establish appropriate controls and protections. Health sector entities that are required to comply with the Privacy Standards also must comply with the Security Standards.

Organizations must consider several factors when adopting security measures. How a healthcare provider satisfies the security requirements and which technology it decides to use are business decisions left to the individual organization. In deciding what security measures to adopt, an organization must consider its size, complexity, and capabilities; its technical infrastructure, hardware, and software security capabilities; the cost of particular security measures; and the probability and degree of the potential risks to the e-PHI it stores and transmits.

The Security Standards require healthcare providers to implement reasonable and appropriate administrative, physical, and technical safeguards. These safeguards seek to ensure the confidentiality, integrity, and availability of all the e-PHI they create, transmit, receive, or maintain; protect against reasonably anticipated threats or hazards to the security or integrity of their e-PHI; protect against uses or disclosures of the e-PHI that aren't required or permitted under the Privacy Standards; and ensure their workforce will comply with their security policies and procedures.

Standards

Purpose of the Security Standards

The Security Standards require healthcare providers to implement reasonable and appropriate **administrative, physical, and technical safeguards** to

- ensure the confidentiality, integrity, and availability of all the e-PHI they create, transmit, receive, or maintain
- protect against reasonably anticipated threats or hazards to the security or integrity of their e-PHI
- protect against uses or disclosures of the e-PHI that are not required or permitted under the Privacy Standards

ensure their workforce will comply with their security policies and procedures

Technical Standards

To protect the e-PHI handles by a healthcare provider, the provider must implement technical safeguards as part of its security plan. Technical safeguards refer to using technology to protect e-PHI by controlling access to it. Therefore, they must address the following standards focusing on the following. It is worth noting that they will need to use an EHR/EMR solution that is able to successfully and robustly demonstrate the possession and working of these functionalities.

Access control: The solution must assign a unique name and/or number for identifying and tracking user identity and establish controls that permit only authorized users to access electronic health information. In cases of emergency where access controls need to be suspended in order to save a life, authorized users (who are authorized for emergency situations) must be permitted to have unfettered access electronic health information during the duration of the emergency.

Automatic log-off: An electronic session after a predetermined time of inactivity must be forcibly terminated. To log in back, the user will have to initiate a new log in session. However, for the sake of ergonomics, it is recommended that the unsaved state of the system at the time of automatic log-off be saved and presented back to the user for further action. This should be a user-specific feature.

Audit log:

- All actions related to electronic health information in accordance with the standard specified in this document including viewing should be recorded.
- Based on user-defined events must be provided.
- All or a specified set of recorded information upon request or at a set period of time must be electronically displayed and printed.

Integrity:

- **During data transit** the fact that the electronic health information has not been altered in transit in accordance with the standard specified in this document must be verifiable.
- **Detection of events** – all alterations and deletions of electronic health information and audit logs, in accordance with the standard specified in this document must be detected.

Authentication:

- **Locally within the system** the fact that a person or entity seeking access to electronic health information is the one claimed and is authorized to access such information must be verifiable.
- **Across the network**, however extensive it might be –that a person or entity seeking access to electronic health information across a network is the one claimed and is authorized to access such information in accordance with the standard specified in this document must be verifiable.

Encryption:

- Generally, all electronic health information must be encrypted and decrypted as necessary according to user defined preferences in accordance with the best available encryption key strength.
- During data exchange all electronic health information must be suitably encrypted and decrypted when exchanged in accordance with an encrypted and integrity protected link.
- All actions related to electronic health information must be recorded with the date, time, patient identification, and user identification whenever any electronic health information is created, modified, deleted, or printed; and an indication of which action(s) took place must also be recorded.
- Appropriate verification that electronic health information has not been altered in transit shall be possible at any point in time. A secure hashing algorithm must be used to verify that electronic health information has not been altered in transit and it is recommended that the secure hash algorithm (SHA) used must be SHA-1 or higher.
- A cross-enterprise secure transaction that contains sufficient identity information such that the receiver can make access control decisions and produce detailed and accurate security audit trails must be used within the system.

Administrative Safeguards Standards

The Administrative Safeguards require healthcare providers to develop and implement a security management process that includes policies and procedures that address the full range of their security vulnerabilities. Being administrative in nature, these need to be internally designed and developed as SOP that must be published for all users to see and adhere to. Conformance to adherence may be delegated to the Privacy Officer detailed in the Data Ownership chapter above. To comply with the Administrative Safeguards, a healthcare provider must implement the following standards.

- The security management process standard, to prevent security violations;
- Assigned security responsibility, to identify a security officer;
- Workforce security, to determine e-PHI user access privileges;
- Information access management, to authorize access to e-PHI;
- Security awareness training, to train staff members in security awareness;
- Security incident procedures, to handle security incidents;
- Contingency plan, to protect e-PHI during an unexpected event; and
- Evaluation, to evaluate an organization's security safeguards.

Physical Safeguards Standards

Physical safeguards are security measures to protect a healthcare provider's electronic information systems, related equipment, and the buildings housing the systems from natural and environmental hazards, and unauthorized intrusion. Covered entities must fulfill four standards. However, because most of the implementation specifications in this category are addressable, healthcare providers will have considerable flexibility in how to comply with the requirements as long as these are internally designed and developed as SOP and published for all users to see and adhere to. Conformance to adherence may be delegated to the Privacy Officer detailed in the Data Ownership chapter above.

The required physical standards are:

- The facility access control standard, to limit actual physical access to electronic information systems and the facilities where they're located;
- The workstation use standard, to control the physical attributes of a specific workstation or group of workstations, to maximize security;
- The workstation security standard, to implement physical safeguards to deter the unauthorized access of a workstation; and
- The device and media controls standard, to control the movement of any electronic media containing e-PHI from or within the facility.

9. REFERENCES

- (1) Final Recommendation, Framework for Information Technology Infrastructure for Health in India (ITIHI), Volumes I & II, DIT, MCIT, Govt. of India
- (2) Recommendations on Guidelines, Standards & Practices for Telemedicine in India, DIT, MCIT, Govt. of India
- (3) HIM Principles in Health Information Exchange (Practice Brief)
- (4) 2006 HIMSS RHIO Definition Workgroup
- (5) <http://healthit.hhs.gov/portal/server.pt?open=512&objID=2996&mode=2> (see below)
- (6) Institute of Medicine (2000). "To Err Is Human: Building a Safer Health System (2000)". The National Academies Press.
<http://fermat.nap.edu/catalog/9728.html#toc>. Retrieved 2006-06-20.
- (7) Charatan, Fred (2000). "Clinton acts to reduce medical mistakes". BMJ Publishing Group.
http://bmj.bmjournals.com/cgi/content/full/320/7235/597?ijkey=190e9b6dd6e8fec4ca3c2e353f290efb8237b334&keytype=tf_ipsecsha. Retrieved 2006-03-17
- (8) Department of Health and Human Services, USA, USA Billing Code: 4150-45
- (9) HIPAA Laws: Privacy and Security 45 CFR 142
- (10) EHR Meaningful Use
- (11) CCR – <http://www.astm.org/Standards/E2369.htm>
- (12) ATC – http://www.whocc.no/atc_ddd_index/

12. ACRONYMS, DEFINITIONS & GLOSSARY

[A]

ADSL (Asymmetric Digital Subscriber Line): A type of DSL that uses copper telephone lines to transmit data faster than a traditional modem. ADSL only works within short distances because it uses high frequencies with short signals.

Allergy List: This is a list of all the patient's allergies.

Allopathic, Allopathy: Defined as relating to or being a system of medicine that aims to combat disease by using remedies (as drugs or surgery) which produce effects that are different from or incompatible with those of the disease being treated

Ambulatory care: Any medical care delivered on an outpatient basis.

ANM: Auxillary Nurse Midwife

ASHA: Accredited Social Health Activist is usually a literate 25 - 45 yr old married/ widowed/ divorced lady selected from the village itself and accountable to it and trained to work as an interface between the community and the public health system. This is position is one of the key components of the National Rural Health Mission aimed at providing every village in the country with a trained female community health activist

ATC: Anatomical Therapeutic Chemical Classification System, controlled by the WHO Collaborating Centre for Drug Statistics Methodology (WHOC), is used for drug classification.

Authentication: The verification of the identity of a person or process.

Authorization: Any document designating any permission. Authorization or waiver of authorization for the use or disclosure of identifiable health information for research (among other activities) is required. The authorization must indicate if the health information used or disclosed is existing information and/or new information that will be created. The authorization form may be combined with the informed consent form, so that a patient need sign only one form. An authorization must include the following specific elements: a description of what information will be used and disclosed and for what purposes; a description of any information that will not be disclosed, if applicable; a list of who will disclose the information and to whom it will be disclosed; an expiration date for the disclosure; a statement that the authorization can be revoked; a statement that disclosed information may be re-disclosed and no longer protected; a statement that if the individual does not provide an authorization, she/he may not be able to receive the intended treatment; the subject's signature and date.

AYUSH: Ayurveda, Yoga, Unani, Siddha and Homeopathy. Falls under the broad category of Indian Systems of Medicines and Homoeopathy (ISM&H) governed by Ministry of Health and Family Welfare, Government of India

[C]

CCD (Continuity of Care Document): A joint effort of HL7 International and ASTM. CCD fosters interoperability of clinical data by allowing physicians to send electronic medical information to other providers without loss of meaning and enabling improvement of patient care. CCD is an implementation guide for sharing Continuity of Care Record (CCR) patient summary data using the HL7 Version 3 Clinical Document Architecture (CDA), Release 2. It establishes a rich set of templates representing the typical sections of a summary record, and these same templates for vital signs, family history, plan of care, and so on can then be used for establishing interoperability across a wide range of clinical use cases.

CDT: Common Dental Terminology

Chain of Trust Agreement: A contract needed to extend the responsibility to protect health care data across a series of sub-contractual relationships.

Chief Complaint (CC), Reason for Consultation (RFC), Reason for Visit (ROV): for recording a patient's disease symptoms.

Client/Server architecture: An information-transmission arrangement, in which a client program sends a request to a server. When the server receives the request, it disconnects from the client and processes the request. When the request is processed, the server reconnects to the client program and the information is transferred to the client. This usually implies that the server is located on site as opposed to the ASP (Application Server Provider) architecture.

Clinical Care: Synonymous to Healthcare.

Clinical Care Provider: Synonymous to Healthcare Provider.

Clinical Data Repository (CDR): A real-time database that consolidates data from a variety of clinical sources to present a unified view of a single patient. It is optimized to allow clinicians to retrieve data for a single patient rather than to identify a population of patients with common characteristics or to facilitate the management of a specific clinical department.

Clinical Decision support system (CDSS): A clinical decision support system (CDSS) is software designed to aid clinicians in decision making by matching individual patient characteristics to computerized knowledge bases for the purpose of generating patient-specific assessments or recommendations.

Clinical Establishment: Clinical establishment means (1) a hospital, maternity home, nursing home, dispensary, clinic, sanatorium or an institution by whatever name called that offers services, facilities requiring diagnosis, treatment or care for illness, injury, deformity,

abnormality or pregnancy in any recognised system of medicine established and administered or maintained by any person or body of persons, whether incorporated or not; or (2) a place established as an independent entity or part of an establishment referred to above, in connection with the diagnosis or treatment of diseases where pathological, bacteriological, genetic, radiological, chemical, biological investigations or other diagnostic or investigative services with the aid of laboratory or other medical equipment, are usually carried on, established and administered or maintained by any person or body of persons, whether incorporated or not. (Clinical Establishment Act – CEA 2010)

Clinical Guidelines (Protocols): Clinical guidelines are recommendations based on the latest available evidence for the appropriate treatment and care of a patient’s condition.

Clinical messaging: Communication of clinical information within the electronic medical record to other healthcare personnel.

Code Set: Any set of codes used to encode data elements, such as tables of terms, medical concepts, medical diagnostic codes, or medical procedure codes. This includes both the codes and their descriptions.

Coded Data: Data are separated from personal identifiers through use of a code. As long as a link exists, data are considered indirectly identifiable and not anonymous or anonymized.

Coding: A mechanism for identifying and defining physicians’ and hospitals’ services. Coding provides universal definition and recognition of diagnoses, procedures and level of care. Coders usually work in medical records departments and coding is a function of billing. Medicare fraud investigators look closely at the medical record documentation, which supports codes and looks for consistency. Lack of consistency of documentation can earmark a record as “up-coded” which is considered fraud. A national certification exists for coding professionals and many compliance programs are raising standards of quality for their coding procedures.

Computer-Based Patient Record (CPR): A term for the process of replacing the traditional paper-based chart through automated electronic means; generally includes the collection of patient-specific information from various supplemental treatment systems, i.e., a day program and a personal care provider; its display in graphical format; and its storage for individual and aggregate purposes. CPR is also called “digital medical record” or “electronic medical record”.

Computerized Patient Record (CPR): Also known as an EMR or EHR. A patient's past, present, and future clinical data stored in a server.

Computerized Physician Order Entry (CPOE): A system for physicians to electronically order labs, imaging and prescriptions

CPT (Current Procedural Terminology) Code: A recognizable five-digit number used to represent a service provided by a healthcare provider. It is a manual that assigns five digit codes to medical services and procedures to standardize claims processing and data analysis. The

coding system for physicians' services developed by the CPT Editorial Panel of the American Medical Association.

[D]

Data Content: All the data elements and code sets inherent to a transaction, and not related to the format of the transaction.

Data: This is factual information (as measurements or statistics) used as a basis for reasoning, discussion, or calculation. It additionally points to the information output by a sensing device or organ that includes both useful and irrelevant or redundant information and must be processed to be meaningful.

Database Management System (DBMS): The separation of data from the computer application that allows entry or editing of data.

DICOM (Digital Imaging and Communications in Medicine): Digital Imaging and Communications in Medicine (DICOM) is a standard to define the connectivity and communication between medical imaging devices.

Disease Management: A type of product or service now being offered by many large pharmaceutical companies to get them into broader healthcare services. Bundles use of prescription drugs with physician and allied professionals, linked to large databases created by the pharmaceutical companies, to treat people with specific diseases. The claim is that this type of service provides higher quality of care at more reasonable price than alternative, presumably more fragmented, care. The development of such products by hugely capitalized companies should be the entire indicator necessary to convince a provider of how the healthcare market is changing. Competition is coming from every direction—other providers of all types, payers, employers who are developing their own in-house service systems, the drug companies.

Document Imaging: Is a process of converting paper documents into an electronic format usually through a scanning process.

Document Management: The Document Manager allows the medical institution to store vital patient documents such as X-Ray's, Paper Reports, and Lab Reports etc.

Documentation: The process of recording information.

DOHAD: Developmental Origins of Health and Diseases

Drug Formulary: Varying lists of prescription drugs approved by a given health plan for distribution to a covered person through specific pharmacies. Health plans often restrict or limit the type and number of medicines allowed for reimbursement by limiting the drug formulary list. The list of prescription drugs for which a particular employer or State Medicaid program will pay. Formularies are either "closed," including only certain drugs or "open," including all

drugs. Both types of formularies typically impose a cost scale requiring consumers to pay more for certain brands or types of drugs. See also Formulary.

Drug Formulary Database: This EMR feature is used for electronic prescribing, electronic medical record (EMR), and computerized physician order entry (CPOE) systems to present formulary status to the provider while during the prescribing decision.

DSM: Diagnostic and Statistical Manual for Mental Diseases

[E]

EDI: Acronym for Electronic Data Interchange. Electronic communication between two parties, generally for the filing of electronic claims to payers.

EDI Translator: Used in electronic claims and medical record transmissions, this is a software tool for accepting an EDI transmission and converting the data into another format, or for converting a non-EDI data file into an EDI format for transmission. See also Electronic Data Interchange.

EHR/EMR System Designer, Developer, Manufacturer, Vendor, Supplier, Retailer, Re-seller: Any entity that is involved in the design, development, testing, manufacturing, supplying, selling including re-selling of Electronic Health Records or Electronic Medical Records Systems as a whole or part thereof.

Electronic Data Interchange (EDI): The automated exchange of data and documents in a standardized format. In health care, some common uses of this technology include claims submission and payment, eligibility, and referral authorization. This refers to the exchange of routine business transactions from one computer to another in a standard format, using standard communications protocols.

Electronic Health Records (EHR): is a distributed personal health record in digital format. The EHR provides secure, real-time, patient-centric information to aid clinical decision-making by providing access to a patient's health information at the point of care. Patient health records including treatment history, medical test reports, and images stored in an electronic format that can be accessed by healthcare providers on a computer network

Electronic Medical Records (EMR): A computer-based record containing health care information. This technology, when EMR fully developed, meets provider needs for real-time data access and evaluation in medical care. Together with clinical workstations and clinical data repository technologies, it provides the mechanism for longitudinal data storage and access. A motivation for healthcare entities to implement this technology derives from the need for medical outcome studies, more efficient care, speedier communication among providers and management of health plans. This record may contain some, but not necessarily all, of the information that is in an individual's paper-based medical record.

Electronic protected health information (ePHI): Electronic protected health information (ePHI) is any protected health information (PHI) that is created, stored, transmitted, or received electronically. Electronic protected health information includes any medium used to store, transmit, or receive PHI electronically. The following and any future technologies used for accessing, transmitting, or receiving PHI electronically are covered. Media containing data at rest (data storage) like personal computers with internal hard drives used at work, home, or traveling, external portable hard drives, including iPods and similar devices, magnetic tape, removable storage devices, such as USB memory sticks, CDs, DVDs, and floppy disks, PDAs and smartphones and data in transit, via wireless, Ethernet, modem, DSL, or cable network connections, Email, File transfer. (For Protected Health Information – PHI, please see below)

Encounter: A clinical encounter is defined by ASTM as "(1) an instance of direct provider/practitioner to patient interaction, regardless of the setting, between a patient and a practitioner vested with primary responsibility for diagnosing, evaluating or treating the patient's condition, or both, or providing social worker services. (2) A contact between a patient and a practitioner who has primary responsibility for assessing and treating the patient at a given contact, exercising independent judgment." Encounter serves as a focal point linking clinical, administrative and financial information. Encounters occur in many different settings -- ambulatory care, inpatient care, emergency care, home health care, field and virtual (telemedicine). [<http://www.ncvhs.hhs.gov/040127p1.htm>]

Episode: An episode of care consists of all clinically related services for one patient for a discrete diagnostic condition from the onset of symptoms until the treatment is complete [http://www.ncmedsoc.org/non_members/pai/PAI-FinalWorkbookforVideo.pdf] Thus, for every new problem or set of problems that a person visits his clinical care provider, it is considered a new episode. Within that episode the patient will have one to many encounters with his clinical care providers till the treatment for that episode is complete. Even before the resolution of an episode, the person may have a new episode that is considered as a distinctly separate event altogether. Thus, there may be none, one or several ongoing active episodes. All resolved episodes are considered inactive. Hence they become part of the patient's past history. A notable point here is that all chronic diseases are considered active and may never get resolved during the life-time of the person, e.g., diabetes mellitus, hypertension, etc.

EPR: Broadly defined, a personal health record is the documentation of any form of patient information—including medical history, medicines, allergies, visit history, or vaccinations—that patients themselves may view, carry, amend, annotate, or maintain. Today, when we refer to PHRs, we typically mean an online personal health record—which may variously be referred to as an ePHR, an Internet PHR, an Internet medical record, or a consumer Internet Medical Record (CIMR). Generally, such records are maintained in a secure and confidential environment, allowing only the individual, or people authorized by the individual, to access the medical information. Not all electronic PHRs are Internet PHRs. PC-based PHRs may be set up to capture medical information offline.

Evidence based medicine: Evidence-based medicine (EBM) is the integration of best research evidence with clinical expertise to aid in the diagnosis and management of patients.

[F]

Family History: A list of the patient's family medical history including the chronic medical problems of parents, siblings, grandparents, etc.

FHIR: Fast Health Interoperable Resources, the newest version from HL7 org for messaging.

Formatting and Protocol Standards: Data exchange standards which are needed between CPR systems, as well as CPT and other provider systems, to ensure uniformity in methods for data collection, data storage and data presentation. Proactive providers are current in their knowledge of these standards and work to ensure their information systems conform to the standards.

Formulary: An approved list of prescription drugs; a list of selected pharmaceuticals and their appropriate dosages felt to be the most useful and cost effective for patient care. Organizations often develop a formulary under the aegis of a pharmacy and therapeutics committee. In HMOs, physicians are often required to prescribe from the formulary. See also Drug Formulary.

[G]

Growth Chart: A feature for a Primary Care or EMR that can be used for paediatric patients. Age, height, weight, and head measurements can be entered over the patient's lifetime, and the feature creates a line graph.

[H]

Health Care Operations: Institutional activities that is necessary to maintain and monitor the operations of the institution. Examples include but are not limited to: conducting quality assessment and improvement activities; developing clinical guidelines; case management; reviewing the competence or qualifications of health care professionals; education and training of students, trainees and practitioners; fraud and abuse programs; business planning and management; and customer service. Under the HIPAA Privacy Rule, these are allowable uses and disclosures of identifiable information "without specific authorization." Research is not considered part of health care operations.

Health Care, Healthcare: Care, services, and supplies related to the health of an individual. Health care includes preventive, diagnostic, therapeutic, rehabilitative, maintenance, or palliative care, and counseling, among other services. Healthcare also includes the sale and dispensing of prescription drugs or devices.

Health Information: Information in any form (oral, written or otherwise) that relates to the past, present or future physical or mental health of an individual. That information could be created or received by a health care provider, a health plan, a public health authority, an

employer, a life insurer, a school, a university or a health care clearinghouse. All health information is protected by state and federal confidentiality laws and by HIPAA privacy rules.

Health Level Seven (HL7): A data interchange protocol for health care computer applications that simplifies the ability of different vendor-supplied IS systems to interconnect. Although not a software program in itself, HL7 requires that each healthcare software vendor program HL7 interfaces for its products. The organisation is one of the American National Standards Institute accredited Standard Developing Organization (SDO) - Health Level 7 domain is the standards for electronic interchange of clinical, financial and administrative info among healthcare oriented computer systems. Is a not-for-profit volunteer organization. It develops specifications, most widely used is the messaging standard that enables disparate health care applications to exchange key sets of clinical and administrative data. It promotes the use of standards within and among healthcare organizations to increase the effectiveness and efficiency of healthcare delivery. It is an international community of healthcare subject matter experts and information scientists collaborating to create standards for the exchange, management and integration of electronic healthcare information.

Health: The state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity. It is recognized, however, that health has many dimensions (anatomical, physiological, and mental) and is largely culturally defined. The relative importance of various disabilities will differ depending upon the cultural milieu and the role of the affected individual in that culture. Most attempts at measurement have been assessed in terms of morbidity and mortality.

Healthcare provider: A health care provider is an individual or an institution that provides preventive, curative, promotional or rehabilitative health care services in a systematic way to individuals, families or communities. An individual health care provider may be a health care professional, an allied health professional, a community health worker, any or other person trained and knowledgeable in medicine, nursing or other allied health professions, or public/community health workers like , ASHA, ANM, midwives, paramedical staff, OT/lab/radio-diagnostic technicians, etc. An institution will include hospitals, clinics, primary care centres and other service delivery points of health care individual clinics, polyclinics, diagnostic centres, etc., i.e., any place where a medical record is generated during a patient-care provider encounter (in conformance to CEA 2010 – please refer to Clinical Establishment item above)

History of Present Illness (HPI): The HPI is the history of the patient's chief complaint.

Human Subject: Refers to a living subject participating in research about whom directly or indirectly identifiable health information or data are obtained or created.

Hybrid Record: Term used for when a provider uses a combination of paper and electronic medical records during the transition phase to EMR.

[1]

Independent Software Vendor (ISV): A company specializing in making or selling software products that runs on one or more computer hardware or operating system platforms.

Immunisation: A complete list of all immunizations that the patient has had.

Informatics: The application of computer technology to the management of information.

Integration: Integration allows for secure communication between enterprise applications.

Interface: A means of communication between two computer systems, two software applications or two modules. Real time interface is a key element in healthcare information systems due to the need to access patient care information and financial information instantaneously and comprehensively. Such real time communication is the key to managing health care in a cost effective manner because it provides the necessary decision-making information for clinicians, providers, other stakeholders, etc.

International Classification of Diseases: This is the universal coding method used to document the incidence of disease, injury, mortality and illness. A diagnosis and procedure classification system designed to facilitate collection of uniform and comparable health information. The ICD-9-CM was issued in 1979. This system is used to group patients into DRGs, prepare hospital and physician billings and prepare cost reports. Classification of disease by diagnosis codified into six-digit numbers. See also coding.

International Health Terminology Standards Development Organization (IHTSDO): Denmark-based organization that maintains and licenses SNOMED codes worldwide.

Interoperability: The capability to provide successful communication between end-users across a mixed environment of different domains, networks, facilities and equipment.

ISP: Internet Service Provider

[J]

J-Codes: A subset of the HCPCS Level II code set with a high-order value of "J" that has been used to identify certain drugs and other items.

[L]

LAN (Local Area Network): A LAN supplies networking capability to a group of computers in close proximity to each other such as in an office building, a school, or a home.

Legacy System Integration: The integration of data between a legacy system and some other software program most commonly using HL-7 standards.

Legacy Systems: Computer applications, both hardware and software, which have been inherited through previous acquisition and installation. Most often, these systems run business

applications that are not integrated with each other. Newer systems which stress open design and distributed processing capacity are gradually replacing such systems.

Length of Stay (LOS): The duration of an episode of care for a covered person. The number of days an individual stays in a hospital or inpatient facility. May also be reviewed as Average Length of Stay (ALOS).

LEPR (Longitudinal Patient Record): Longitudinal Patient Record is an EHR that includes all healthcare information from all sources.

[M]

Management Information System (MIS): The common term for the computer hardware and software that provides the support of managing the plan.

Master Patient / Member Index: An index or file with a unique identifier for each patient or member that serves as a key to a patient's or member's health record.

Maximum Defined Data Set: All of the required data elements for a particular standard based on a specific implementation specification. An entity creating a transaction is free to include whatever data any receiver might want or need. The recipient is free to ignore any portion of the data that is not needed to conduct their part of the associated business transaction, unless the inessential data is needed for coordination of benefits.

MCI: Medical Council of India

Medical Code Sets: Codes that characterize a medical condition or treatment. These code sets are usually maintained by professional societies and public health organizations. Compare to administrative code sets.

Medical Informatics: Medical informatics is the systematic study, or science, of the identification, collection, storage, communication, retrieval, and analysis of data about medical care services to improve decisions made by physicians and managers of health care organizations. Medical informatics will be as important to physicians and medical managers as the rules of financial accounting are to auditors.

Medical Management Information System (MMIS): A data system that allows payers and purchasers to track health care expenditure and utilization patterns. It may also be referred to as Health Information System (HIS), Health Information Management (HIM) or Information System (IS). See also Electronic Medical Record (EMR).

MIMS: Monthly Index of Medical Specialities

Minimum Data Set: The minimum set of data elements that must be captured, stored, made available for retrieval, presentation, relay and sharing by an EHR system. It comprises of all of the essential data elements required for implementation. An entity creating a transaction must

include the mandatory data elements at all times and is free to exclude optional data elements. The entity is free to additionally include whatever other data elements that any receiver might want or need. The recipient is free to ignore any portion of the data that is not mandatory and is further free to ignore any other portion of the data that is not needed to conduct their part of the associated transaction, unless required by sender, intermediaries or receiver. This minimum data set represents the most common data, and system designers are at liberty to add to it as they deem necessary to enrich or enhance their EHR systems.

Modifier: Additional character of a code added to an existing code that is used to help in extending or localization of the existing code.

[N]

NANDA: North American Nursing Diagnosis Association

National Council for Prescription Drug Programs: An ANSI-accredited group that maintains a number of standard formats for use by the retail pharmacy industry.

Non-Participating Physician (or Provider): A provider, doctor or hospital that does not sign a contract to participate in a health plan, usually which requires reduced rates from the provider. In the Medicare Program, this refers to providers who are therefore not obligated to accept assignment on all Medicare claims. In commercial plans, non-participating providers are also called out of network providers or out of plan providers. If a beneficiary receives service from an out of network provider, the health plan (other than Medicare) will pay for the service at a reduced rate or will not pay at all.

[O]

Open Access: A term describing a member's ability to self-refer for specialty care. Open access arrangements allow a member to see a participating provider without a referral from another doctor. Health plan members' abilities, rights or invitation to self refer for specialty care. Also called Open Panel.

OR: Operating Room – synonymous to OT as below

OT: Operation Theatre

OTC: Over the counter (drugs). Refers to those drugs that are available off the shelf without any prescription or advise from a registered medical practitioner

Outcome: A clinical outcome is the "change in the health of an individual, group of people or population which is attributable to an intervention or series of interventions". (Taken from: Frommer, Michael; Rubin, George; Lyle, David (1992). "The NSW Health Outcomes program". New South Wales Public Health Bulletin 3: 135. doi:10.1071/NB92067)

Outpatient Care: Care given a person who is not bedridden. It is also called ambulatory care. Many surgeries and treatments are now provided on an outpatient basis, while previously they had been considered reason for inpatient hospitalization. Some say this is the fastest growing segment of healthcare

[P]

Participating Physician: A primary care physician in practice in the payer's managed care service area who has entered into a contract.

Past History: A list of a patient's past health problems, surgeries and specialists.

Patient Demographics: All patient's pertinent information such as first and last name, SSN, DOB, insurance, etc.

Patient Portal: A secure web-based system that allows a patient to register for an appointment, schedule an appointment, request prescription refills, send and receive secure patient-physician messages, view lab results, pay their bills electronically, access physician directories.

Patient: A person who is under medical care or treatment

PC Based: A program designed to run on an individual PC. This typically means data is not shared in real time among other PCs (users).

PCP: Primary care physician who often acts as the primary gatekeeper in health plans. That is, often the PCP must approval referrals to specialists. Particularly in HMOs and some PPOs, all members must choose or are assigned a PCP.

PHR: A personal health record or PHR is typically a health record that is initiated and maintained by an individual. An ideal PHR would provide a complete and accurate summary of the health and medical history of an individual by gathering data from many sources and making this information accessible online.

Picture Archive Communication System (PACS): Used by radiology and diagnostic imaging organizations to electronically manage information and images

Practice Parameters, Practice Guidelines: Systematically developed statements to standardize care and to assist in practitioner and patient decisions about the appropriate health care for specific circumstances. Practice guidelines are usually developed through a process that combines scientific evidence of effectiveness with expert opinion. Practice guidelines are also referred to as clinical criteria, protocols, algorithms, review criteria, and guidelines. The American Medical Association defines practice parameters as strategies for patient management, developed to assist physicians in clinical decision-making. Practice parameters may also be referred to as practice options, practice guidelines, practice policies, or practice standards.

Prescription Drug: Drug that the law says can only be obtained by prescription.

Primary Care Physician: A “generalist” such as a family practitioner, pediatrician, internist, or obstetrician. In a managed care organization, a primary care physician is accountable for the total health services of enrollees including referrals, procedures and hospitalization. Also see Primary Care Provider.

Primary Care Provider: The provider that serves as the initial interface between the member and the medical care system. The PCP is usually a physician, selected by the member upon enrollment, who is trained in one of the primary care specialties who treats and is responsible for coordinating the treatment of members assigned to his/her plan.

Primary Care: Basic or general health care usually rendered by general practitioners, family practitioners, internists, obstetricians and pediatricians who are often referred to as primary care practitioners or PCPs. Professional and related services administered by an internist, family practitioner, obstetrician-gynecologist or pediatrician in an ambulatory setting, with referral to secondary care specialists, as necessary.

Principal Diagnosis: The medical condition that is ultimately determined to have caused a patient’s admission to the hospital. The principal diagnosis is used to assign every patient to a diagnosis related group. This diagnosis may differ from the admitting and major diagnoses.

Privacy Standards: The Privacy standards restrict the use & disclosure of individually identifiable health information. Privacy standard applies to all protected health information may it is in physical or electronic form.

Privacy: Privacy means an individual’s interest in limiting who has access to personal health care information. Specific patient authorization is required for use and disclosure of clinical notes. As per Fernando & Dawson, 2009, privacy is control of access to private information avoiding certain kinds of embarrassment and can be shared or not shared with others; Only authorized (by the patient) people can view the recorded data or part thereof

Progress Note: The documentation of a patient visit or encounter including all or part of the SOAP format.

Protected health information (PHI): Any individually identifiable information whether oral or recorded in any form or medium that is created, or received by a health care provider, health plan or health care Healthcare provider and relates to past, present, or future physical or mental health conditions of an individual; the provision of health care to the individual; or past, present, or future payment for health care to an individual.

[R]

Real Time: The instantaneous sharing of data among a user group. It is common to a client/server database configuration.

Referral: Some insurance companies require that on specific plans a referral must be obtained for certain procedures or visits to specialists. The referral is acquired by the primary care physician (PCP) by contacting the insurance company by phone or mail. This is a request for the service. The referral consists of an authorization code, a number of visits allowed (if applicable) and an expiration date.

Referring Provider: is the provider that referred the patient to a specialist or for a specific procedure.

Relational Database: A database program that stores data in a manner similar to Excel, with the difference being the data elements are related (linked) to each other.

Remote Access: Data travels through a private, protected passage via the Internet, allowing healthcare providers to access from home or another practice location and allows EMR vendor to perform system maintenance off-site

Rendering/Performing Provider: The provider actually treating the patient.

ROS (Review of Systems): A series of questions related to the system(s) that the patient is having complaints about (i.e. respiratory for cold symptoms).

RXNORM: RxNorm is the name of a US-specific terminology in medicine that contains all medications available on US market; it provides normalized names for clinical drugs and links its names to many of the drug vocabularies commonly used in pharmacy management and drug interaction software.

[S]

Secondary Care: Services provided by medical specialists who generally do not have first contact with patients (e.g., cardiologist, urologists, dermatologists). In the U.S., however, there has been a trend toward self-referral by patients for these services, rather than referral by primary care providers. This is quite different from the practice in England, for example, where all patients must first seek care from primary care providers and are then referred to secondary and/or tertiary providers, as needed.

Security Standards: The Security Standards require measures to protect the confidentiality, integrity and availability of e-PHI while it's being stored & exchanged. The security standard applies to all electronic PHI.

Security: This refers to the methods and techniques adopted to protect privacy and are a defense mechanism from any attack (Hong et al., 2004)

SNOMED CT is the universal health care terminology. It is comprehensive and covers procedures, diseases, and clinical data. SNOMED CT helps to structure and computerize the medical record. It allows for a consistent way of indexing, storing, retrieving and aggregating clinical data across sites of care (i.e. hospitals, doctors offices) and specialties. By standardizing

the terminology, the variability in the way data is captured, encoded and used for clinical care of patients and research is reduced. Allows for more accurate reporting of data. It is currently available in English, Spanish and German.

SNOMED: (SNOMED CT) Systemized Nomenclature of Medicine Clinical Terms –

Social History: A description of a patient's social habits and history including marital status, alcohol and drug use and exercise habits.

Solo Practice, Solo Practitioner: A physician who practices alone or with others but does not pool income or expenses. This form of practice is becoming increasingly less common as physicians band together for contracting, overhead costs and risk sharing.

SOP: Standard operating procedures or protocols

SQL: Structured Query Language – is a computer language aimed to store, manipulate and retrieve data stored in relational databases.

Subjective: Section in a progress note where a patient's account of their current problem is documented. Consists of chief complaint, HPI and ROS.

Sx: Abbreviation for symptoms

[T]

T1, T3 line: A high-speed internet connection provided via telephone lines often used by businesses needing internet connection speeds greater than DSL/Cable.

Therapeutic Alternatives: Strong Drug products that provide the same pharmacological or chemical effect in equivalent doses. Also see Drug Formulary.

TPA: Third Party Administrator

Treatment Episode: The period of treatment between admission and discharge from a modality, e.g., inpatient, residential, partial hospitalization, and outpatient, or the period of time between the first procedure and last procedure on an outpatient basis for a given diagnosis. Many healthcare statistics and profiles use this unit as a base for comparisons.

Treatment: The provision of health care by one or more health care providers. Treatment includes any consultation, referral or other exchanges of information to manage a patient's care.

[V]

Vital Statistics: Statistics relating to births (natality), deaths (mortality), marriages, health, and disease (morbidity). Vital statistics for the United States are published by the National Center

for Health Statistics. Vital statistics can be obtained from CDC, state health departments, county health departments and other agencies. An individual patient's vital statistics in a health care setting may also refer simply to blood pressure, temperature, height and weight, etc.

VPN: Virtual Private Network – A VPN “tunnel” is a secure connection, typically firewall to firewall that provides for remote access to your data server.

[X]

XML (Extensible Markup Language): Used for defining data elements on a Web page and communication between two business systems. Example: Standard messaging system for and EMR to integrate with another software such as a practice management or drug formulary database.

13. FORMAT FOR MEDICAL RECORDS

(As specified by Medical Council of India)

Name of the patient:

Age:

Sex:

Address:

Occupation:

Date of ^{1st} visit:

Clinical note (summary) of the case:

Provisional Diagnosis:

Investigations advised with reports:

Diagnosis after investigation:

Advice:

Follow up

Observations:

Date:

Signature in full

.....

Name of Treating Physician

1.3 Maintenance of medical records

1.3.1

Every physician shall maintain the medical records pertaining to his / her indoor patients for a period of 3 years from the date of commencement of the treatment in a standard proforma laid down by the Medical Council of India and available above.

1.3.2

If any request is made for medical records either by the patients / authorised attendant or legal authorities involved, the same may be duly acknowledged and documents shall be issued within the period of 72 hours.

1.3.3

A Registered medical practitioner shall maintain a Register of Medical Certificates giving full details of certificates issued. When issuing a medical certificate he / she shall always enter the identification marks of the patient and keep a copy of the certificate. He / She shall not omit to record the signature and/or thumbmark, address and at least one identification mark of the patient on the medical certificates or report. The medical certificate shall be prepared as in Appendix 2.

1.3.4

Efforts shall be made to computerize medical records for quick retrieval.

14. Annexures



Government of India

**Ministry of Health and Family Welfare
Department of Health and Family Welfare
Nirman Bhawan, New Delhi-110108**

No. Z.28015/79/2010-Hosp.

Dated: 13 /09/2010

OFFICE MEMORANDUM

Subject: - Standardization of Electronic Medical Records.

The undersigned is directed to refer to the meeting of Experts held on 10th August, 2010 under the chairpersonship of Secretary (Health & Family Welfare) wherein it has been decided to constitute a Committee of Experts for development of an Information Technology (IT) based electronic medical records maintenance system for hospitals.

There is a need to initiate a project for developing an IT enabled uniform system of electronic medical records maintenance for hospitals that will maintain the records of treatment, identification, healthcare providers, cost of treatment, standard of healthcare availability and quality of treatment etc. Availability of electronic medical records will help data monitoring of available information to enforce the Standard Treatment Protocols which are separately being developed under the guidance of a Core Committee of Experts constituted under the chairpersonship of Secretary (Health & Family Welfare).

Accordingly, the Govt. have decided to constitute a Committee of Experts for development of standards on electronic medical records (EMR) maintenance system for hospitals. The composition of the Committee and its Terms of Reference are as under:

Sl. No.	Name	
1.	Mr. L.C. Goyal,	Chairman

	Additional secretary & DG, CGHS Ministry of Health & Family Welfare, Nirman Bhawan, New Delhi.	
2.	Dr. D.C. Jain, Spl. DG Directorate General of Health Services, Nirman Bhawan, New Delhi	Co-Chairman
3.	Dr. B. S. Bedi, Vice President, Telemedicine Society of India and Advisor- Health Informatics CDAC, Govt. of India. bedi11@yahoo.com	Member
4.	Dr. R. R. Sudhir, Sr. Consultant-Cornea Deptt. Sankara Nethralaya drrrs@snmail.org	Member
5.	Dr. S.B. Bhattacharya, President, Indian Association of Medical Health	Member
6.	Ms. Sangeeta Reddy, Executive Director, Apollo Hospitals sangita_reddy@apollohealthstreet.com	Member
7.	Dr. Supten Sarbadhikari Director, CAL2CAL Group supten@cal2cal.com	Member
8.	Dr. Thanga Prabhu Clinical Director - Healthcare IT GE Healthcare arokiaswamy.thangaprabhu@ge.com	Member
9.	Prof. Saroj K. Mishra Head, School of Telemedicine and Biomedical Informatics, Sanjay Gandhi PG Inst. of Medical Sciences skmishra@sgpgi.ac.in	Member
10.	Prof. Indrajit Bhattacharya Professor, IIHMR indrajit@iihmr.org	Member
11.	Dr. Sameer A. Khan, Director Medical Technology & Planning Fortis Healthcare Limited sameer.khan@fortishealthcare.com	Member
12.	Mr. Madhu Aravind, CEO HealthHiway madhu@healthhiway.com	Member
13.	Ms Kala Rao, Sr Consultant, TCS sumanth.raman@tcs.com	Member
14.	Mr. Jay Kumar	Member

	Dy. Director, Insurance Information Bureau, IRDA, Hyderabad	
15.	Ms. Jyoti Vij, Asst Secretary General, FICCI, New Delhi jyoti@ficci.com	Member
16.	Mr. Y.K. Sharma, DDG, NIC, New Delhi	Member
17.	Mr. Sunder Gaur, Head, Medical Informatics, CDAC, Pune	Member
18.	Dr. Ashok Kumar Director, CBHI, New Delhi	Convenor

The Terms of Reference of the Committee:

1. The Objective

The objective of the said Committee will be to recommend a set of EMR Standards for India to be followed by both public and private healthcare providers, implementation of the standards, procedure for dissemination and the procedure for continuous updation of the standards.

2. Scope

The standards to be developed will include the following:

- Diagnosis coding
- Procedure coding
- Laboratory coding
- Clinical Standards
- EDI (Electronic Data Interchange) including
 - Data flow across hospitals
 - Integration with Telemedicine program
 - Integration with National Administrative Labs for data analysis
 - Middleware for interpreting with proprietary system
- Standards for Continuity of Care Records which include administrative, demographic and clinical information
- Common drug codes
- Guidelines to meet standards set by organizations such as CCHIT, NABH, JCAHO, Meaningful Use etc.
- Standards for interoperability both in terms of hardware and software
- Security protocols for information security
- Data privacy
- Legal compliance
- Standard formats/templates for clinical information capture including preparation of a data dictionary

As a part of its activities towards the above, the committee will, among other things;

- Study the existing standards prevalent in the developed countries
- Adopt, as far as possible, standards such as ICD 10, HL7, DICOM, LOINC and CPT, wholly or partly as applicable in the Indian environment.
- Study the work done by the Task Force on Tele Medicine commissioned by the Ministry of Health and Family welfare in the year 2007.
- Study and recommend coding procedures for coding of hospitals, healthcare providers, healthcare professionals, drug manufacturers, healthcare providers and insurance companies.
- Develop Standards for reporting

- Study guiding standards such as WHO standards for interoperability <http://sdmx-hd.org> , Ministry of Communications and Information Technology standards: <http://egovstandards.gov.in/>, Ministry of Communications and IT security standards http://egovstandards.gov.in/INFO_SEC_STD_APP, and recommend appropriately.

3. Deliverables

- Draft set of Indian EMR Standards and guidelines.
- Organize the workshop with a broad set of stakeholders to deliberate on draft EMR standards and guidelines
- Create subcommittees for adaption/implementation of standards

4. Schedule

All activities are to be completed in a timeframe of six months from the date of issue of the OM. The Committee may submit an interim report within 2-3 months.

5. Resources and Budget allocation

MoHFW will provide the requisite resources and budget to the Committee for completing the activities.

Payment:

All non official members of the Committee, who are outstation, will be eligible for reimbursement of air travel by the economy class / shortest direct route and per diem and other non-official members per diem, as per rules for the Committee's meetings.

This issues with the approval of Secretary (Health and Family Welfare).

-Sd-

(V. P. Singh)

Deputy Secretary to the Govt. of India

Tel. 011-23062791

To

All the members of the Expert Committee (As per list)

Copy to: -

PPS to Secretary (H&FW)/ PPS to DGHS/ PPS to AS & DG, CGHS /PS to JS (H)

GO related to Sub-Groups Formation



Government of India

**Ministry of Health and Family Welfare
Department of Health and Family Welfare
Nirman Bhawan, New Delhi-110108**

No. Z.28015/79/2010-Hosp.

Dated: 19 /10/2010

OFFICE MEMORANDUM

Subject: - Standardization of Electronic Medical Records.

The undersigned is directed to refer to the decisions taken in the 1st meeting of EMR Standards Committee dated 30th Sept., 2010 regarding constitution of Sub-Groups for taking up various tasks for development of EMR standards. It has been decided to constitute the following Sub-Groups with the composition given herein as under:

Sub-Groups for Development of EMR Standards

Tasks	Members of Sub Group	Group Head
Task 1: Standards Terminology, Coding standards et al.	1. Prof. Dr. S.V. Mani 2. Dr. R.R. Sudhir 3. Ms. Kala Rao 4. Dr. Ashok Kumar 5. Ms. Shobha Mishra Ghosh, FICCI 6. Dr. Sameer A. Khan	Prof. Dr. S.V. Mani, TCS
Task 2 : Data connectivity Including hardware, software and interoperability.	1) Dr. B.S. Bedi 2) Dr.Supten Sarbadhikari 3) Dr. S.B. Bhattacharya 4) Dr. Thanga Prabhu 5) Mr. Sunder Gaur 6) Mr. S.K.Dhar, NIC	Dr. B.S. Bedi, CDAC
Task 3: Data ownership Data protection and security including legal aspects/complaints, guidelines and reports already available.	1. Prof. Saroj K. Mishra 2. Prof. Indrajit Bhattacharya 3. Prof. Sita Naik, MCI 4. Dr. Karanveer Singh 5. Dr. Naveen Jain, CDAC 6. Dr. Arun Bal 7. Mr. Madhu Aravind	Prof. S.K. Mishra, SGPGI

--	--	--

Contd...2/-

-2-

The Group Heads and the members of the sub groups are requested to complete the tasks assigned to them within the stipulated time frame as per the TOR.

Payment : All non-official members of the Sub-Groups, who are outstation, will be eligible for reimbursement of air travel by the economy class / shortest direct route and per diem @ Rs. 1000/- and other non-official members per diem @ Rs. 1000/- for the Sub-Group's meetings. Out station non-official members will also be entitled for reimbursement of hotel accommodation expenses as per actual subject to a ceiling of Rs. 5000/-. TA /DA of official members of the Sub-Groups for attending the meetings shall be met from the same source from which their salary is drawn.

This issues with the approval of Secretary (Health & Family Welfare).

(V. P. Singh)

Deputy Secretary to the Govt. of India

Ph. No.2306 2791

To

All the members of the EMR Standard Committee / Sub-Groups (As per list)

Copy to: -

PPS to HFM/ PPS to MOS(DT)/ PPS to Secretary (H&FW)/
PPS to DGHS/ PPS to AS & DG, CGHS /PS to JS (H)

ANNEXURE II

Preparatory Process for Draft Recommendations

Committee Discussions

- Post formation initiation
- Communication via email, teleconferences
- Physical meetings where ever possible
 - TSI Congress at Bhubaneshwar, Odisha
 - Indo-Swedish Workshop at Pune, Maharashtra
 - Informal discussion amongst sub-group members
 - Informal meetings between important/nominated members and Chairman, sub-groups