ELECTRONIC HEALTH RECORD (EHR) STANDARDS FOR INDIA (2016)

Standards Set Recommendations v2.0

National Resource Centre for EHR Standards (NRCeS)

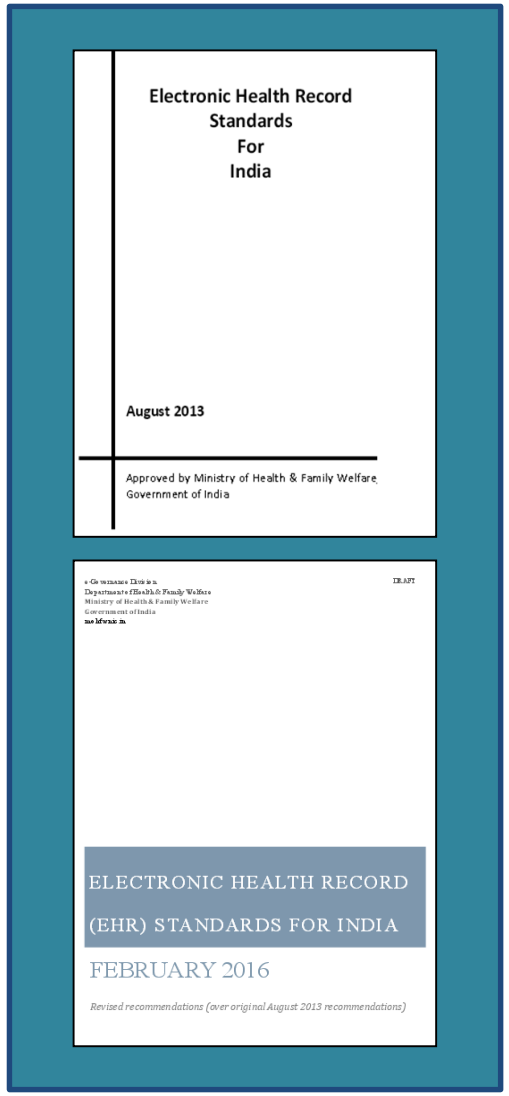
C-DAC Pune

Contents

EXECUTIVE SUMMARY

Introduction

- Ministry of Health & Family Welfare (MoH&FW) notified the Electronic Health Record (EHR) Standards for India in Sept 2013
- The notified standards were not only supported by professional bodies, regulatory bodies, stakeholders, but various technical and social commentators also
- Revised EHR Standards for India were notified in Dec 2016



Need for Electronic Health Record Standards

- For a health record of an individual to be clinically meaningful it needs to be from conception or birth, at the very least
- Record of every clinical encounter (health-related event) can collectively provide a summary of the various healthcare events in the life of a person
- An Electronic Health Record (EHR) is a collection of various medical records that get generated during any clinical encounter or events
- Purpose of collecting medical records, as much as possible, are manifold:
  - Better and evidence based care
  - Increasingly accurate and faster diagnosis
  - Avoid repeating unnecessary tests
  - Predictive analytics to support personalized care
  - Improved health policy decisions
  - Better understanding of the underlying issues
  - *All translating into improved personal and public health*
- Without standards, a *lifelong interoperable* medical record is hardly *interoperable*

Strategic Highlights

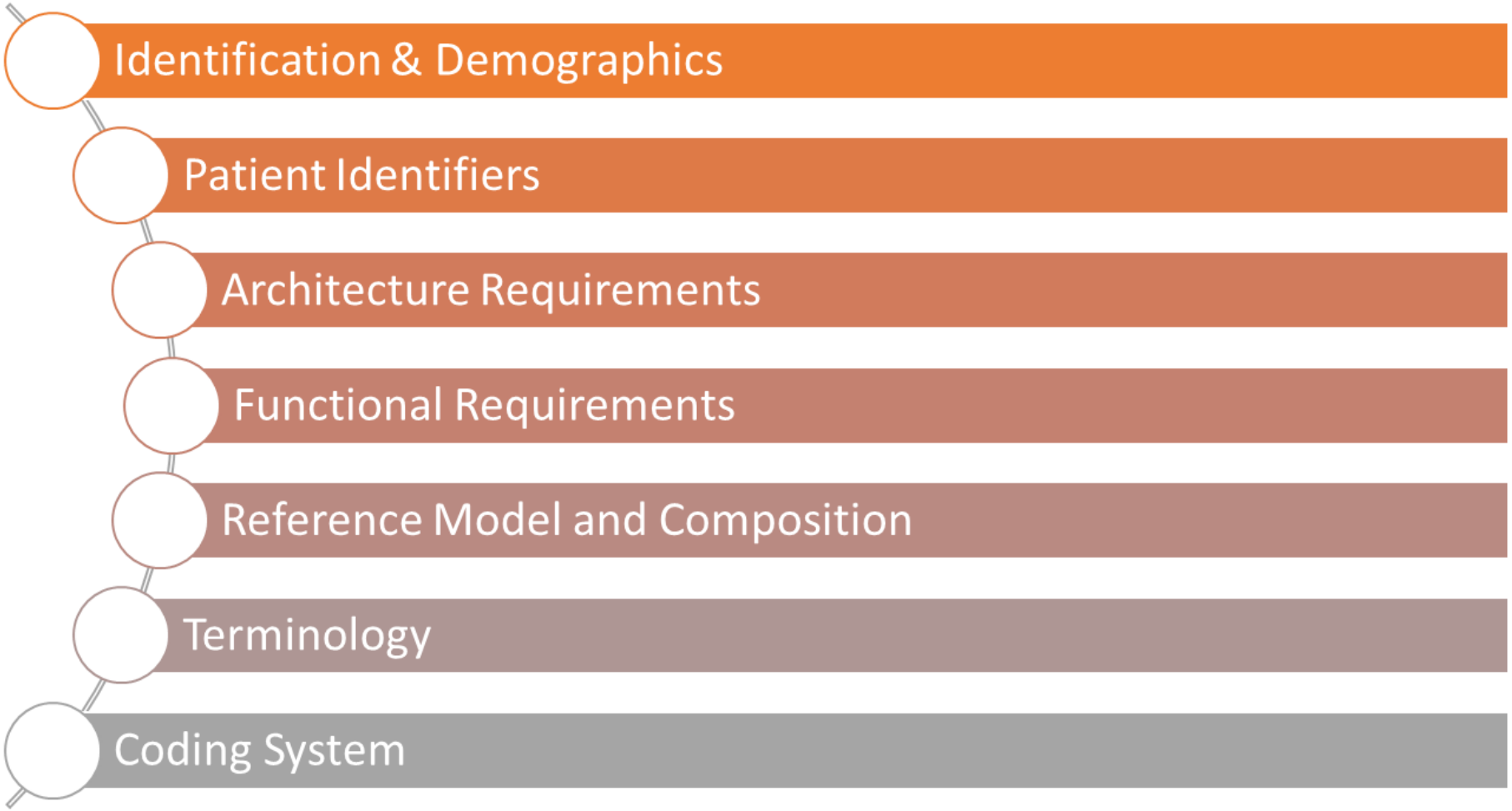
- EHR Standards for India (2016) provides a structured overview of the key EHR standards with respect to Indian healthcare system
- Detailed recommendation on the various aspects of EHR systems standardization perspective
- Short guideline regarding implementation specific to the item-in-context included
- It is understood that with proper adoption interoperability of both meaning and data can be achieved.
- **Aim**: *Any person in India can go to any health service provider/practitioner, any diagnostic center or any pharmacy and yet be able to access and have fully integrated and always available health records in an electronic format*

Goals

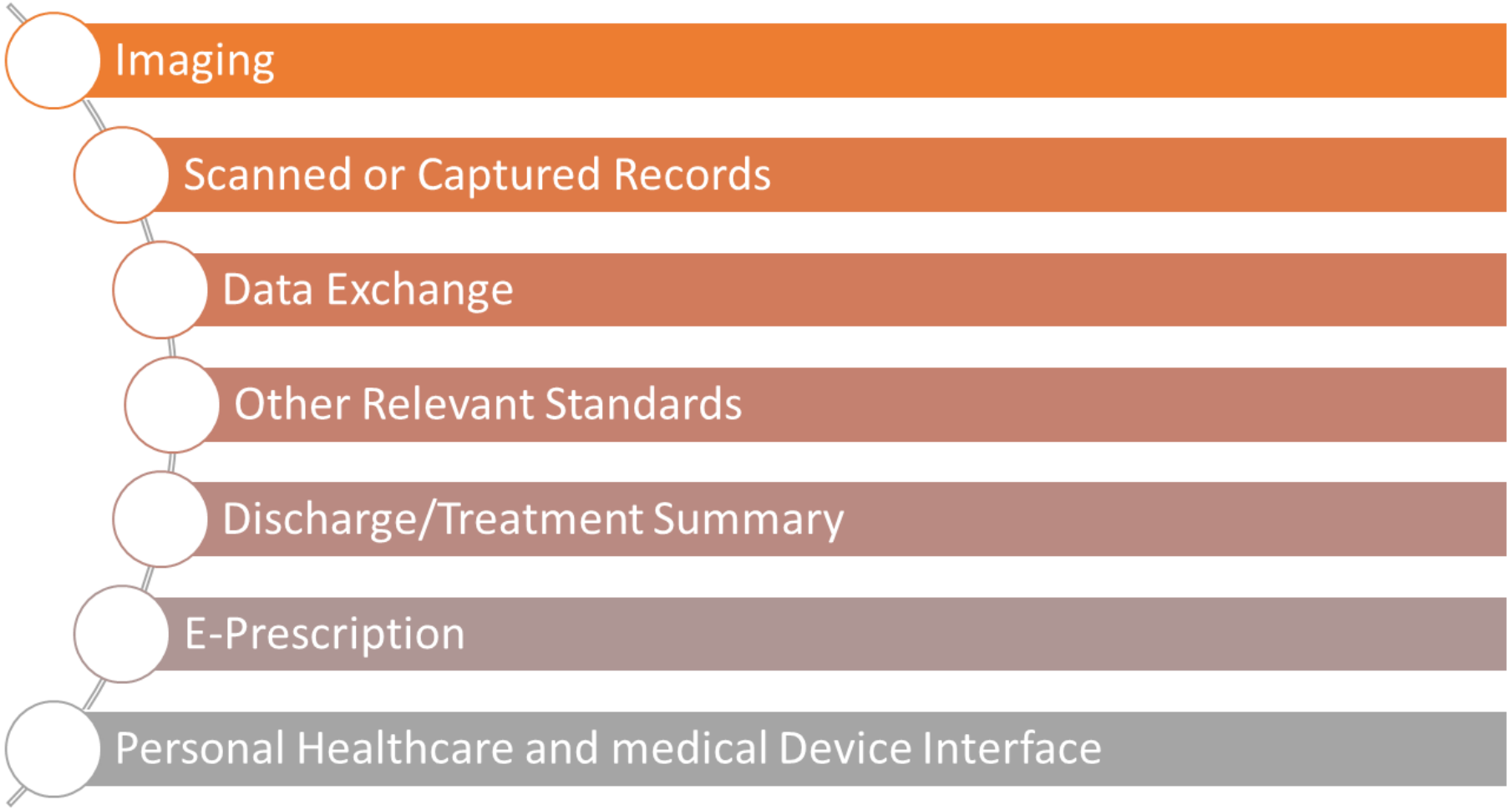
- Promote interoperability
- Support the evolution and timely maintenance of adopted standards
- Promote technical innovation using adopted standards
- Encourage participation and adoption by all vendors and stakeholders
- Keep implementation costs as low as reasonably possible
- Consider best practices, experiences, policies and frameworks

STANDARDS AT A GLANCE

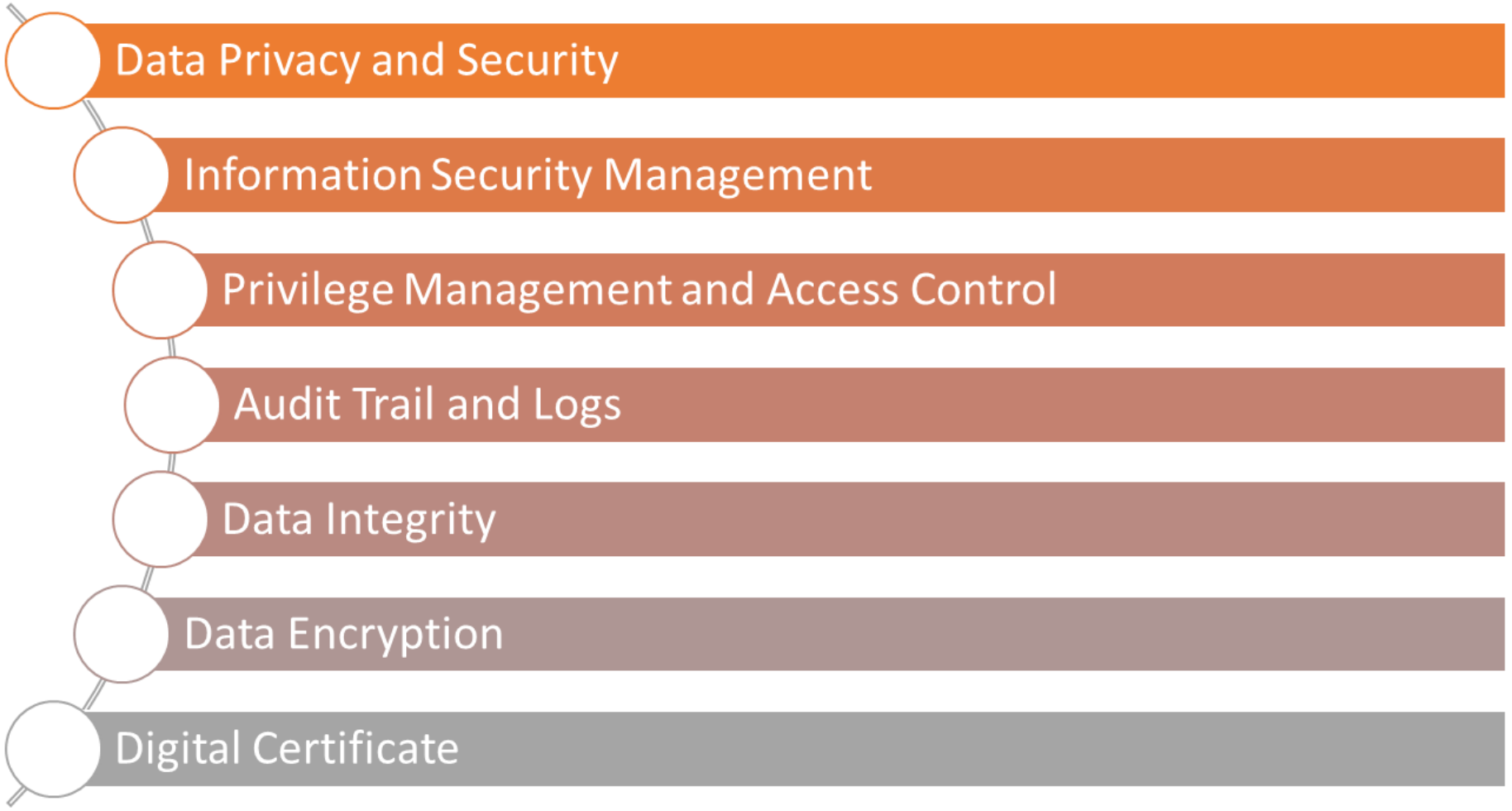
Architecture and Data Content



Information Exchange



Access and Security



Health Record IT Standards

- Identification & Demographics
- Architecture & Functional Requirements
- Information Model
- Terminology & Coding
- Image, Multimedia, Waveform & Document
- Data Exchange
- Discharge Summary
- e-prescription
- Personal healthcare & Medical Devices Interfacing
- Principles of Data change
- Other Relevant Standards

Identification & Demographic Information of Patient

- Patient Unique Identifier is necessary in a health record system that identifies a patient
  - UIDAI Aadhar Number (Preferred where available)
  - Both of the following, if Aadhar is not available
    - Local Identifier (As per scheme used by HSP)
    - Any Central or state Government Issued Photo Identity Card Number
- Links all artifacts and records of the patient
- Recommended standards:
  - ISO/TS 22220:2011 Health Informatics – Identification of Subjects of HealthCare
  - MDDS- Demographic (Person Identification an Land Region Codification) Version 1.1 from E-Governance Standards, Govt. of India

Architecture Requirements & Functional Specifications

- A health record system must meet architectural requirements and functional specifications
  - To meet the needs of service delivery
  - Be clinically valid and reliable
  - Meet legal and ethical requirements &
  - Support good medical practices
- Recommended standards:
  - ISO 18308:2011 Health Informatics- Requirements for an Electronic Health Record Architecture
  - ISO/HL7 10781:2015 health Informatics – HL7 Electronic Health Records System Functional Model release 2 (EHR FM)
- To be implemented as per scope/type of application

Logical Information Reference Model & Structural Composition

- A health record system must accumulate observable data and information for all clinically relevant events and encounters
- Captured artefacts should have common semantic and syntactic logical information model and structural composition
- Standardized data capture makes it possible to communicate and exchange data across systems
- Recommended standards:
  - ISO 13940 Health Informatics -System of Concepts to Support Continuity of Care
  - ISO 13606 Health Informatics -Electronic Health Record Communication (Part 1 through 3)
  - OpenEHR Foundation Models Release 1.0.2
    - Required Model Specifications: Base Model, Reference Model, Archetype Model
    - Optional Model Specifications: Service Model, Querying, Clinical Decision Support

Medical Terminology & Coding

- Common terminology standard is necessary to:
  - Have semantic interoperability between different health record systems
  - Express unambiguous meaning of data captured, stored, transmitted, and analyzed
- Coding Terminology standards are used for:
  - Storing clinically relevant terms, observations, etc.
- Classification and aggregation of infoRecommended standards:
  - **Primary Terminology**: SNOMED CT
  - **Test, Measurement and Observation Codes**: Logical Observation Identifiers Names and Codes (LOINC)
  - **Classification Codes**: WHO Family of International Classifications (WHO-FIC)
    - WHO ICD-10: International Classification of Diseases (ICD)
    - WHO ICF: International Classification of Functioning, Disability and Health (ICF)
    - International Classification of Health Interventions (ICHI)
    - International Classification of Diseases for Oncology (ICD-O)

Image, Multimedia, Waveform & Document

- Cater to the need of data records and files of various types:
  - Documentary records of various diagnostic
  - Prescriptive data or information generated
  - Image (series or single)
  - Waveforms (ECG/EEG)
  - Audio (such as Digital Stethoscope)
  - Video (such as endoscope/USG etc.)
- Recommended standards:
  - NEMA Digital Imaging & Communication in medicine (DICOM) PS3.0 2015
  - Image: JPEG lossy (or lossless) with size and resolution not less than 1024px x 768px at 300dpi
  - Audio/Video: ISO/IEC 14496 – Coding of Audio Visual Objects
  - Scanned Documents: ISO 19005 -2 Document Management –Electronic Document file format for long term preservation Part-2: Use of ISO 32000-1 (PDF/A-2)
- To be implemented as per scope/type/need of application

Data Exchange Standards

- In-order to enable Data Exchange across healthcare systems, it is advisable to:
  - Capture and provide as comprehensible medical information as possible
  - Capture and retain information in standardized format
- Recommended Standards (as applicable):
  - Event/Message Exchange: ANSI/HL7 V2.8.2-2015 HL7 Standard Version 2.8.2 -An Application Protocol for Electronic Data Exchange in Healthcare Environments
  - Summary Records Exchange: ASTM/HL7 CCD Release 1 (basis standard ISO/HL7 27932:2009)
  - EHR Archetypes: ISO 13606-5:2010 Health informatics -Electronic Health Record Communication -Part 5: Interface Specification [Also, refer to openEHR Service Model specification]
  - Imaging/Waveform Exchange: NEMA DICOM PS3.0-2015 using DIMSE services& Part-10 media/files)

Other Relevant Standards

- Where not specifically provided, as a general rule, standards created or ratified by following Standard Development Organizations (SDOs) should be used:
  - Bureau of Indian Standards and its MHD-17 Committee
  - ISO TC 215 set of standards
  - IEEE/NEMA/CE standards for physical systems and interfaces

Discharge/ Treatment Summary

- Medical Council of India (MCI): Appendix - 3 of Code of Ethics Regulation 2002 (amended up to Feb-2016)
  - Logical information model which includes data elements for discharge/treatment summary has to with the format as specified by MCI notification
  - The printed reports should meet MCI prescribed formats whenever any discharge or treatment summary is prepared

E-Prescription

- Pharmacy Practice Regulations, 2015 Notification No. 14-148/ 2012-PCI by Pharmacy Council of India (PCI)
  - Logical information model that includes data elements for e-Prescription has to satisfy requirements of the format for Medical Prescription as specified by the Pharmacy Council of India
  - Electronic version should be digitally signed by a registered medical practitioner
  - The pharmacists shall be able to print a copy of e-Prescription in the required format along with other relevant digital authentication details

Personal healthcare & Medical Devices Interfacing

- Required for clinical data exchange, retrieval, storage, etc. for medical devices
- Recommended standard:
  - IEEE 11073 health informatics standards and related ISO standards

Principles of Data Change

- The data once entered into a health record system must become immutable
- <u>Possible to update/append, provided</u>:
  - A complete audit trail of such change is maintained by the system
  - A new copy of data is created and original is retained through versioning

As-Is Principal

- The "As-Is Principal" requires that the data captured in the first instance should be retrievable at any given point of time later in **same** as it was provided during the time of record creation:
  - Format
  - Clarity
  - Size and
  - Detail
- No changes to original data after creation
- Changes in data can be in a copy, with versioning and due information to user or through SOP

Informed Format Change

- Change in data, format, or its nature in the system should be done with the explicit consent through:
  - Doctor / technician / person that is entering or managing the data
  - Set of preferences set by users
- The rule of conversion should be declared in the SOP of site/application

Guidelines

- Hardware
- Network & Connectivity
- Software Standards
- Health Record in Mobile Device

Hardware

- The IT hardware used should meet:
  - Optimal requirements specified by the software used
  - Relevant specifications from Medical and IT standards for the equipment

- The following details should be planned and audited periodically:
  - Backup or data preservation
  - Data capacity
  - System redundancy at various levels (disk, power, network, etc.)
  - Network and Data security
  - Capacity planning and quality requirements

Networking & Connectivity

- Should be able to harness any telecommunications-related connectivity such as LAN, WAN, Cloud etc.
- Ensure reliable and fast connectivity
- Ensure secure data exchange
- Ensure data exchange with data integrity

Software Standards

- EHR system should ensure:
  - Conformance to the specified standards & requirements
  - Capturing, storing, retrieving, viewing, and analyzing healthcare records
  - Interoperability
  - Privacy, security and audit trail
  - Search, merge, and demerge features
  - Digital archiving of records of a person

Health Record in Mobile Devices

- There is an increasing demand for information delivery over mobile devices.
- EHR data delivery applications on the mobile shall be governed by "Framework for Mobile Governance 2012" of MeitY, Government of India
- Essential health information over mobile device can be used for collecting:
  - Demographics, medical condition, drug/allergy information, insurance info, medications, allergy and alerts, and vital signs
  - Certain clinical and lifestyle related information from the patient
- The information should be shared to extent relevant for emergency care and quick reference

Data Ownership of Health Records

- Ethical, Legal, Social Issues
- Protected Health Information
- Data Ownership
- Data Access and Confidentiality
- Disclosure of Protected / Sensitive Information
- HSP Responsibilities
- Patient Privileges
- Denial of Information
- Data Preservation
- Patient Identity
- Legislation

Ethical, Legal, Social Issues (ELSI) Guidelines

- 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 encryption techniques used in transit and at rest need to be through different methodologies
- Trust would be accepted whenever a trusted third party confirms identity

Protected Health Information

- Protected Health Information (PHI) would refer to any individually identifiable information whether oral or recorded in any form or medium that:

  Is created, or received by a stakeholder.

  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.

- e-PHI refers to any PHI that is created, stored, transmitted or received electronically
- Sensitive Information Includes:
  - Passwords
  - Financial information such as bank account or credit card or debit card or other payment instrument details
  - Physical, psychological and mental health condition
  - Sexual orientation
  - Medical records and history
  - Biometric information
  - Any detail relating to above received by the body corporate for provision of services
  - Any information relating to that is received, stored or processed by the body corporate under a lawful contract or otherwise

Data Ownership

- All health records generated by the healthcare provider, are held in trust by them on behalf of the patient
- All Protected health information contained in the EHR is owned by the patient himself / herself
- The medium of storage or transmission of such electronic medical record will be owned by the healthcare provider
- The “sensitive personal information (SPI) and personal information (PI)” of the patient is owned by the patient themselves

Data Access & Confidentiality

- HSP to ensure confidentiality of the patient records
- Patients will have the sufficient privileges to:
  - Inspect and view their medical records without any time limit.
  - Restrict access to and disclosure of individually identifiable health information.
  - Need to provide explicit consent, which will be audited, to allow access and/or disclosures.
- All recorded data will be available to care providers on an ‘as required on demand’ basis.
- Patient’s privileges to amend data shall be limited to correction of errors in the recorded patient/medical details.
- Audit trail to be strictly maintained for all changes.

Disclosure of Protected/Sensitive Information

- Consent from patient or next of kin is necessary:
  - General: For use in treatment, payments and other healthcare operations as defined by applicable laws by MCI
  - Specific: Fair use for non-routine and non-health care purposes
- Information disclosure without patient's consent in the case of:
  - Reporting notifiable/communicable diseases as mandated by law
  - Complete record with all identifiers in an "as-is" state, on production of court order
  - Totally anonymized data

Responsibility of a Healthcare Provider

- Protect and secure the stored health information, as per the guidelines
- Remove patient identifying information if it is not necessary to be provided
- Ensure informing the patient of policies related to their rights to health record privacy
- Document all its privacy policies and ensure that they are implemented and followed:
  - Develop internal privacy policies
  - Ensure implementation of privacy policies, audit and quality assurance
  - Provide privacy training to all its staff

Privileges of Patient or Personal representative

- Patients can demand from a healthcare provider for:
  - A copy of the medical records held by that HSP (within 30 days of request)
  - To withhold, temporarily or permanently, specific information that he/she does not want disclosed to other organizations or individuals

  - Details of disclosures performed on the patient's medical records for any reason whatsoever including:
    - Date of the disclosure
    - Name and address of the entity or person who received the information
    - Brief description of the medical information disclosed
    - Brief summary of the purpose of the disclosure

Denial of Information

- Denial of the information to patient is possible on following grounds:
  - Information obtained from an anonymous source under a promise of confidentiality
  - Psychotherapy notes
  - Information compiled for civil, criminal or administrative action

Electronic Medical Records Preservation

- All health records must compulsorily be preserved and not destroyed during the life-time of the person, ever
- <u>Records may be turned to inactive status:</u>
  - Upon the demise of the patient (when there are no pending procedures, court cases)
  - Preferable to follow the “three (3) year rule” where all records of a deceased are made inactive three (3) years after death
- It is however preferred, and the HSPs are strongly encouraged to ensure, that the records are never be destroyed or removed permanently
- Analysis of health data of all persons is expected to greatly benefit in the understanding of health, disease processes and the amelioration thereof

Patient Identifying Information

- Name
- Address (all geographic subdivisions smaller than street address, and PIN code)
- All elements of dates related to an individual (date of birth, date of death, etc.)
- Telephone, mobile, Fax numbers
- Email address
- Bank Account, Credit Card Number
- Medical record number
- Health plan beneficiary number
- Certificate/license number
- Any vehicle or other any other device identifier or serial numbers
- PAN number
- Passport number
- AADHAAR card
- Voter ID card
- Fingerprints/Biometrics
- Voice recordings that are non-clinical in nature
- Photographic images and that possibly can individually identify the person
- Any other unique identifying number, characteristic, or code

Applicable Legislation

- Existing Indian laws including IT Act 2000 and their amendments from time to time would prevail

Data Privacy and Security

- Security Technical Standards
- Administrative Safeguards
- Physical Safeguards

Purpose

- To implement reasonable and appropriate technical, administrative and physical 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

Security Technical Standards

- **Requirements Standard**
  - ISO/TS 14441:2013 Health Informatics – Security & Privacy Requirements of EHR Systems for Use in Conformity Assessment
- **Authentication**
  - Locally within the system/ Across the network
- **Automatic log-off**
  - An electronic session after a predetermined time of inactivity must be forcibly terminated
- **Overall information security management**
  - ISO 27799 Health informatics -Information Security Management in Health using ISO/IEC 27002
  - Other security management and standard / practices / guidelines given by Law (such as IT Act 2000and amendments) or regulatory / statutory / certification bodies (such as National Accreditation Board for Hospitals & Health care Providers (NABH))

Security Technical Standards (contd…)

➢ Privilege management and access control

- ISO 22600:2014 Health informatics -Privilege Management and Access Control (Part 1 through 3)
- Rule / policy based access is expected to give better control and flexibility in defining and enforcing access control
- Role Based, Policy Based, or Singular user are acceptable as long as conformant to applicable data security law(s) and rules

➢ Audit log

- ISO 27789:2013 Health informatics -Audit Trails for Electronic Health Records
- All actions related to electronic health information must be recorded with the date, time, record identification, and user identification whenever created, modified (non-clinical data only), deleted (stale and non-clinical data only), or printed;
- An indication of which action(s) took place must also be recorded

Security Technical Standards (contd…)

Integrity

- It should be verifiable that Data is not altered during transmission
- Through *Detection of events and Appropriate verification mechanisms*
- *It is recommended that the Secure Hash Algorithm (SHA), SHA -256 or higher must be used*

Encryption

- Information must be encrypted and decrypted as necessary according to organization preferences and best available encryption key strength
- Data exchange must be through encrypted and integrity protected link
- *HTTPS, SSL v3.0, and TLS v1.2 standards should be used*

Digital Certificates

- *Use of Digital Certificate is for identification and digital signing is recommended in health record system*
- ISO 17090 Health informatics -Public Key Infrastructure (Part 1 through 5)

Administrative Safeguards Standards

- Healthcare providers should design, develop and implement standard operating procedure (SOP)
- A healthcare provider must implement the following standards:
  - 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
  - Evaluation, to evaluate an organization's security safeguards

Physical Safeguards Standards

- Required to protect electronic information systems
- Required physical standards are:
  - *Facility access control standard*: Limit actual physical access to electronic information systems and the facilities where they're located.
  - *Workstation use standard*: Control the physical attributes of a specific workstation or group of workstations, to maximize security.
  - *Workstation security standard*: Implement physical safeguards to deter the unauthorized access of a workstation.
  - *Device and media controls standard*: Control the movement of any electronic media containing ePHI from, to or within the facility.

GLOSSARY

Electronic Health Record (EHR)

- Electronic Health record is a
  - Computer processable information relevant to wellness, health and health care of an individual
  - Stored in one or more repositories
  - Integrated physically or virtually
  - Communicated securely
  - Accessible to multiple authorized users,
  - Represented using a Common logical information Model
- Primary purpose is the support of life-long, effective, high quality and safe integrated healthcare

Electronic Medical Records (EMR)

- EMR is a special case of EHR that holds records specific to the scope to the medical domain
  - Departmental EMR: Contains a patient's medical information entered by a single hospital department (e.g. pathology, radiology, pharmacy)
  - Inter-departmental EMR: Contains a patient's medical information from two or more hospital departments
  - Hospital EMR: Contains a patient's clinical information from a particular hospital
  - Inter-hospital EMR: Contains a patient's medical information from two or more hospitals
- EHR: longitudinal collection of health information from all sources

Electronic Protected Health Information (ePHI)

- 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.
- <u>All technologies used for accessing, transmitting, or receiving PHI electronically are covered under e-PHI</u>
  - Media containing data at rest (data storage) like personal computers with internal hard drives, external portable hard drives, magnetic tape, removable storage devices
  - Data in transit, via wireless, Ethernet, modem, DSL, or cable network connections, Email, File transfer

Way Ahead

- MoH&FW moved ahead with facilitating the adoption of EHR Standards, as next steps:
  - SNOMED CT made available free-for-use in India
  - Set-up of National Release Center (NRC) for widespread adoption and support of SNOMED CT in country
  - National Resource Centre for EHR Standards (NRCeS) to support adoption and implementation of EHR Standards for India
- For any queries, assistance, implementation support related to EHR Standards for India (2016) contact NRCeS at nrc-help@cdac.in

References

- ELECTRONIC HEALTH RECORD (EHR) STANDARDS FOR INDIA (2016), Standards Set Recommendations v2.0, *e-Health Division, Department of Health & Family Welfare, Ministry of Health & Family Welfare, Government of India* http://www.mohfw.nic.in/sites/default/files/17739294021483341357.pdf

Thank **You**

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