



National Resource Centre
for EHR Standards
India

EHR Standards Adoption Starter Guide

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INTRODUCTION

Ministry of Health & Family Welfare (MoHFW), Govt. of India has envisaged establishing an integrated frame work for inter-operability & data exchange to enable Electronic Health Records (EHRs) of citizens to be created, made available and accessible national wide. Creation of EHR System is envisioned with objectives to facilitate continuity of care, better affordability, optional information exchange to support better health outcome, better decision support, big data analytics etc. This effort will place healthcare in India in a transformational path towards realization of nationwide standardization of EHR, thereby achieving seamless access and information exchange across the platform.

For moving towards Integrated Healthcare System, Ministry has released EHR standards for India v2 in 2016 subsequent to the earlier notified EHR standards for India v1 in 2013. The intent is to introduce a uniform system for maintenance of EHR/EMR by the hospitals and healthcare providers and enable unique EHR for each individual in the country. This can bring patient's complete health information together for supporting better clinical decisions, and more coordinated care amongst various care providers.

To facilitate adoption of the entire set of notified EHR Standards in the country, Ministry has engaged Centre for Development of Advanced Computing (C-DAC), Pune to set-up and manage "National Resource Centre for EHR Standards (NRCeS)" for providing assistance in adoption, integration and use of EHR standards effectively in healthcare applications in India.

PURPOSE

In order to make an interoperable and secure healthcare system for better health care to the patient, there is a need to create EHR standards compliant healthcare applications. EHR Standards for India specifies a set of EHR standards and guidelines for implementation and compliance in EHR (or its derivative) applications. Various EHR Standards specified include standards for data structure, exchange, terminology, coding systems, security, data integrity and audit trail, etc. All the standards cater to different functional requirements of a healthcare application. Identification of relevant standard, procurement, getting knowledge, adoption and implementation of these notified standard requires to have strategic approach. It is also recognized that a sustainable and incremental approach for adoption of EHR standards is essential to achieve interoperability. This document is an effort to provide pathway towards development of EHR standard compliant application.

SCOPE

This document provides step-by-step approach towards EHR standard adoption and implementation in healthcare applications (EHR and its derivatives). This document is only for reference purpose. The approach for implementation may vary from application to application based on the requirements, resources, and

scope. This document **does NOT**, in any way, provide or substitute requirements for evaluation, certification or compliance to EHR Standards for India (2016).

INTENDED AUDIENCE

The intended audience for this document includes Healthcare Providers, Central and State Health Departments, Hospital Management, Policy Makers, Healthcare IT professionals, and Medical Software and Device Manufacturers.

GUIDE FOR IMPLEMENTING EHR STANDARDS IN AN APPLICATION

- **Understand Scope and Objective**

First and foremost, define the scope and objective. It is recommended to know the kind and scope of healthcare application for which compliance is sought. Applicability of different standards depends upon the use case and scope of the application e.g., whether it is a full EHR, patient-maintained PHR, encounter-based EMR or catering to need of any clinical specialty. Applicability and selection of standards will largely depend on the scope.

- **Identify Clinical Information**

Identify the type of clinical information being captured, stored and exchanged by the healthcare application. The detailed list of data elements with value-sets if any being captured for each type of clinical information may be prepared. This will help in identifying appropriate applicable EHR standards from the recommendation.

- **Identify Applicable Standards**

In addition to meeting the functional needs of the practice, the guidelines given in the approved EHR Standards for India (2016) helps in identification of relevant EHR standards for adoption of electronic health informatics standards in EHR/EMR and other similar clinical information and documentation systems. With adoption of these standards properly, the data capture, storage, view, presentation, and transmission will be standardized and hence interoperability of both the data contained and its meaning in the records can be achieved. So, identification of the significant EHR standards that need to be adopted and implemented is vital. *In this regard, NRCeS provides free consulting/advisory services for strategic approach and advice on the most valuable ways to enhance the effectiveness of the system implementation and adoption to both the government and private sector including Central and State Governments, Public and Private Sector companies, Multi-lateral funding agencies, Investors and Developers.*

Figure 1 shows prioritization of EHR standards adoption in primary, secondary and tertiary level

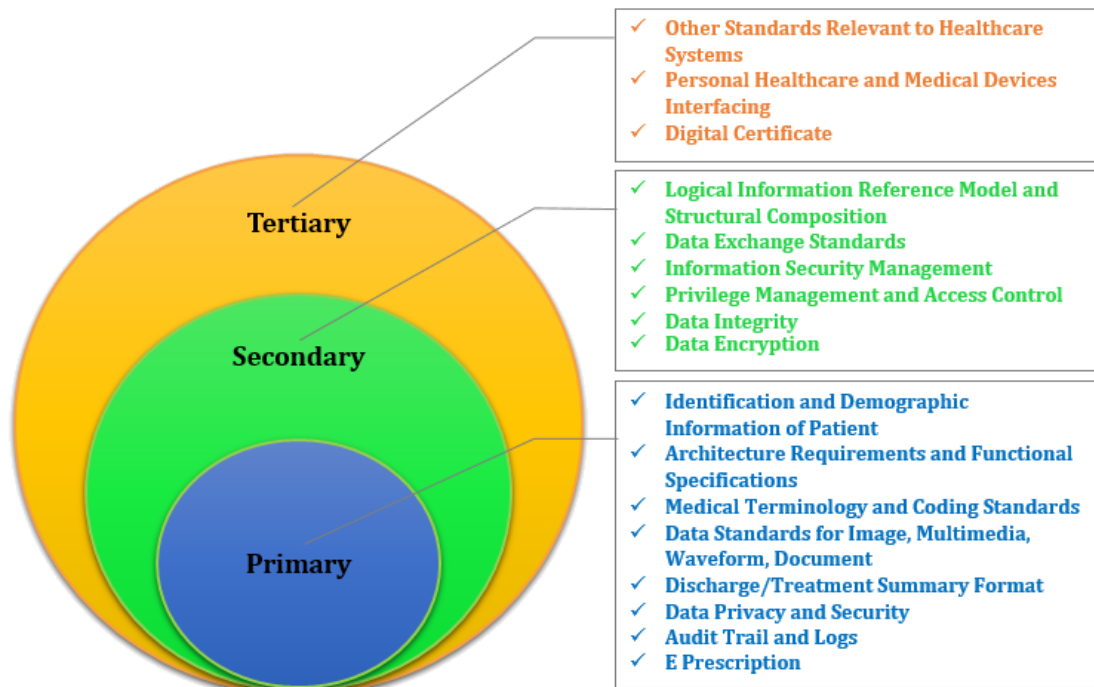


Figure 1. Prioritization of EHR Standard Adoption

- **Refer to Standard Specifications**

Standards are available for purchase from Bureau of Indian Standards (BIS) or directly from ISO or other owner Standard Development Organizations (SDOs). The resources and information about getting standards are available through respective SDOs. The list of standards with their accessibility related details are provided in Table 1.

Sr. No.	Category	Standard	Accessibility
1	Identification & Demographics	ISO/TS 22220:2011 Health Informatics – Identification of Subjects of Health Care	Paid
2		MDDS – Demographic (Person Identification and Land Region Codification) version 1.1	Free
3	Patient Identifiers	UIDAI Aadhaar	Free
4		Local Identifier	Free
5		Government Issued Photo Identity Card Number	Free
6	Architecture Requirements	ISO 18308:2011 Health Informatics – Requirements for an Electronic Health Record Architecture	Paid
7	Functional Requirements	ISO/HL7 10781:2015 Health Informatics - HL7 Electronic Health Records-System Functional Model Release 2 (EHR FM)	Paid

Sr. No.	Category	Standard	Accessibility
8	Reference Model and Composition	ISO 13940 Health informatics - System of Concepts to Support Continuity of Care	Paid
9		ISO 13606 Health informatics - Electronic Health Record Communication (Part 1 through 3)	Paid
10		openEHR Foundation Models Release 1.0.2	Free
11	Terminology	SNOMED Clinical Terms (SNOMED CT)	Free for use within India
12	Coding System	Logical Observation Identifiers Names and Codes (LOINC)	Free
13		WHO Family of International Classifications (WHO-FIC) including ICD, ICF, ICHI, ICD-O	Paid
14	Imaging	Digital Imaging and Communications in Medicine (DICOM) PS3.0-2015	Free
15	Scanned or Captured Records	JPEG lossy (or lossless) with size and resolution not less than 1024px x 768px at 300dpi	Free
16		ISO/IEC 14496 - Coding of Audio-Visual Objects	Paid
17		ISO 19005-2 Document Management - Electronic Document File Format for Long-Term Preservation - Part 2: Use of ISO 32000-1 (PDF/A-2)	Paid
18	Data Exchange	ANSI/HL7 V2.8.2-2015 HL7 Standard Version 2.8.2 - An Application Protocol for Electronic Data Exchange in Healthcare Environments	Free
19		ASTM/HL7 CCD Release 1 (basis standard ISO/HL7 27932:2009)	Free
20		ISO 13606-5:2010 Health informatics - Electronic Health Record Communication - Part 5: Interface Specification	Paid
21		DICOM PS3.0-2015 (using DIMSE services & Part-10 media/files)	Free
22	Other Relevant Standards	Bureau of Indian Standards and its MHD-17 Committee	Paid
23		ISO TC 215 set of standards	Paid
24		IEEE/NEMA/CE standards for physical systems and interfaces	Free

Sr. No.	Category	Standard	Accessibility
25	Discharge/ Treatment Summary	Medical Council of India (MCI) under regulation 3.1 of Ethics	Free
26	E-Prescription	Pharmacy Practice Regulations, 2015 Notification No. 14-148/ 2012- PCI as specified by Pharmacy Council of India	Free
27	Personal Healthcare and medical Device Interface	IEEE 11073 health informatics standards and related ISO standards for medical devices	Paid
28	Data Privacy and Security	ISO/TS 14441:2013 Health Informatics – Security & Privacy Requirements of EHR Systems for Use in Conformity Assessment	Paid
29	Information Security Management	ISO/DIS 27799 Health informatics - Information Security Management in Health using ISO/IEC 27002	Paid
30	Privilege Management and Access Control	ISO 22600:2014 Health informatics - Privilege Management and Access Control (Part 1 through 3)	Paid
31	Audit Trail and Logs	ISO 27789:2013 Health informatics - Audit trails for Electronic Health Records	Paid
32	Data Integrity	Secure Hash Algorithm (SHA) used must be SHA-256 or higher	Free
33	Data	Minimum 256-bits key length	Free
34	Encryption	HTTPS, SSL v3.0, and TLS v1.2	Free
35	Digital Certificate	ISO 17090 Health informatics - Public Key Infrastructure (Part 1 through 5)	Paid

It may be noted that purchasing a standard may not be necessary if organization or its consultants/developers/contractors already have access/license of the same. As far as SNOMED CT is concerned, India is a member country of SNOMED International which allows free use of SNOMED CT in Indian Territory on acquiring appropriate license from National Release Center of the country. Few useful resources and information about standards are also available at NRCeS website.

- **Acquire Knowledge**

In order to standardize existing/new healthcare application for compliance towards recommended EHR standards, there is a common effort required to understand detailed specification of each standard. Towards this, it is

essential to develop the skills/ knowledge base to adopt the standards as quickly as possible. A lot of resources are available regarding each notified EHR standards. Respective Standard Development Organizations (SDOs) also provide knowledge resource in terms of guidelines, specifications, eLearning, education and training, workshops/conferences, etc. Training presents a prime opportunity to expand the knowledge base of the user community in the country. NRCeS also provides Education and Training services to healthcare professionals, vendors, implementers, policy makers, departments, educational institutes, organizations, consortiums, associations, etc. for sensitization, understanding and quick adoption of EHR Standards.

- **Identify stages/phases for Standard Adoption from Applicable Set**

In an application development lifecycle, it is important to know that interoperability and standardization can be achieved at different levels. It is also recognized that a sustainable and incremental approach is essential towards adoption of standards. So one has to prioritize the identified EHR standards and strategize while implementing in to the healthcare systems in different stages/phases. This approach will allow implementer to evolve application to standard compliance.

- **Identify Application Modules/Models/Forms for Integration**

Every EHR/EMR or any other clinical information system is designed by considering the specific requirement and need. Towards implementation of any standard, whether partially or fully, it is recommended to implement it in stage/phase wise. It is important to recognize the target areas from same or different modules of a healthcare system before the actual implementation starts. The identification of these target areas may depend on severity, or critical requirement where particular standard has to be implemented on priority. Such areas/modules may be considered in first stage/phase.

- **Identify Readily Available Software/Tools/SDKs**

For enabling standard adherence through integrating in existing healthcare applications, each implementer/vendor requires to learn, design, and implement the integration layer in their respective applications. Readily available standard compliant open source tools / software APIs helps in quick and easy integration with minimal changes required in the application with minimal essential understanding of standard. Such tools /APIs help in reducing complexity, cost, time of integration for standard adherence.

Few readily available free and open source tools/ SDKs from NRCeS for standards compliance include:

- C-DAC's Toolkit for SNOMED CT (CSNOTk)
- SNOMED CT to ICD-10 mapping APIs
- C-DAC's Medical informatics SDK for ANSI/HL7 v2.8.2
- C-DAC's Medical informatics SDK for DICOM PS 3.0 2015

- **Learn and Take Assistance from Experts**

At times, a guidance/ assistance is required while developing an application in order to check if the integration progress is in the correct direction or not, get the solution of a problem in case something gets stuck. *So, it is advised to get the expert assistance in order to implement the standards in the application as it may provide different perspective towards implementation. NRCeS at C-DAC Pune assists in strategizing correct approach, providing know-how, and troubleshooting in integration of EHR Standards.*

- **Get the Work Evaluated**

After integrating standards in application, it is vital to get it reviewed by someone in order to validate whether it is standard compliant or not. It is recognized that, in order to standardize these applications across the platform and to ensure their functioning at the same level, thereby assuring interoperability, a common mechanism to certify these applications towards EHR standard compliance is required.

Hence, it is advised to get the application certified and validated for standard compliance. There are few individual standard certification programs available through different agencies and SDOs. Ministry of Health & Family Welfare (MoHFW) and Ministry of Electronics and Information Technology (MeitY), Govt. of India are also working towards development of EHR Standards for India (2016) Certification Scheme and Guidelines to ensure standard compliance across healthcare applications in the country. EHR applications will be validated against the published implementation guidelines for notified EHR standards for India.

NOTE

In evidence of any material error, change, correction, concerns or assistance regarding this document, you are requested to immediately report it at: nrc-help@cdac.in

REFERENCE

- 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>

GLOSSARY

Electronic Health Record

Electronic Health Record (EHR) is a longitudinal electronic record of patient health information generated by one or more encounters over a lifetime in any care delivery setting which includes patient demographics, progress notes, problems, medications, vital signs, past medical history, immunizations, laboratory data and radiology reports; and can be accessed instantly and securely by authorized users.

It is a record in digital format that is theoretically capable of being shared across different health care settings. In some cases, this sharing can occur by way of network-connected, enterprise-wide information systems and other information networks or exchanges.

Primary purpose is the support of continuing, efficient and quality integrated healthcare and it contains information which is retrospective, concurrent and prospective. Standards are essential to maintain structural and semantic interoperability of records for capture, storage and retrieval. Other benefits of EHR are:

