International Standards for Building Electronic Health Record (EHR)

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Abstract - The recent progress of ICT (Information Communication Technology) applications in health of our citizens and healthcare make it possible to establish individual EHR within foreseeable time. The goal of EHR is enabling to connect person and health care organizations at point of care. The use of EHR coupled with clinical decision support system in healthcare practice will provide tools for healthcare organizations to achieve errorless, safe, cost effective and quality care.

The consumer focused healthcare is increasingly emphasized and it requires an individual's integrated lifetime health and healthcare database(EHR) in real time from all sites. The integration of clinical data needs interoperable data with national infrastructure that allows the integration of data, access control with data privacy and system security.

In order to build an interoperable EHR, it requires standardized regional collection of individuals' health and care data/information. This standardized approach requires data structure, message development, communication, architecture, clinical documents, semantic content, security and business requirements, etc.

This paper will address relevant definitions of EHR and activities of International Standards Developing Organizations(SDO) with available standards.

I. Introduction

The major issues confronting the healthcare system today are increasing aging population, significant number of medical errors, uneasy access of healthcare information, and increasing cost plus need of consumer focused healthcare information and records[1-4]. The demand for quality, safe healthcare is increasing while resources remain the same level The adoption of contemporary ICT tools can achieve significant improvements in quality and safety of healthcare delivery. This will also contribute to contain healthcare costs in the long term.

Many developed and developing countries in the world pay attention today to the appropriate use of ICT in healthcare. Countries such as the USA, UK, Australia, Canada and others adopted strategic plan for National Health Information Infrastructure (NHII) for next 10 years[2-4]. The objectives for ICT application of developed countries are summarized as :

- To improve access to clinical records;
- To reduce clinical errors and improve safety of patients;
- To improve access to quality information on health for patients and healthcare professionals;
- To improve efficiency of healthcare processes; and
- To contain healthcare costs.

And the Infrastructure to achieve these applications are:

- management of patient identification including:
  - health insurance information;
  - patient identifiers;
  - provider identifiers;
  - healthcare organization identifiers;
  - medical emergency data set; and
  - access control and authentication;
- protection of personal information by using standard Public Key Infrastructure;
- terminology and vocabulary systems for clinical records and drugs; and
- health cards and portals.

The core of the ICT adoption in healthcare to achieve all of these goals is to have universal availability of EHR at the point of care.
The purpose of EHR is listed as follows :

- medico-legal evidence;
- delivery of safe, error free, quality care;
- evaluation of quality of care provided;
- research;
- education;
- public and population health;
- health statistics for policy development;

- health service management; and
- billing, finance, reimbursement.

In this communication, the definition and applicable standards of EHR and activities of International SDOs are briefly discussed.

II. Definition

According to ISO TR 20514: 2005[5], the basic definition of EHR is "a repository of information regarding the health status of a subject of care, in computer processable form." On the other hand, the EHR system(EHRS) is "the set of components that form the mechanism by which electronic health records are created, used, stored, and retrieved." It may include people, data, rules and procedures, processing and storage devices, and communication and support facilities.

For the practical use, the existing Definitions of EHR systems from internationally recognized bodies are listed below.

A. Existing EHR System Definitions
1)   IOM's (Institute of Medicine of US) Computerized Patient Record defined the EHRS in 1991 as [7]:

"The set of components that form the mechanism by which patient records are created, used, stored, and retrieved. A patient record system is usually located within a health care provider setting. It includes people, data, rules and procedures, processing and storage devices (e.g., paper and pen, hardware and software), and communication and support facilities."

2)   IOM Letter Report Key Capabilities of an Electronic Health Record System defined the EHR System in 2003 as including [8]:

"(1) longitudinal collection of electronic health information for and about persons, where health information is defined as information pertaining to the health of an individual or health care provided to an individual; (2) immediate electronic access to person- and population-level information by authorized, and only authorized, users; (3) provision of knowledge and decision-support that enhance the quality, safety, and efficiency of patient care; and (4) support of efficient processes for health care delivery."

3)   ISO/TS 18308: 2003 references the IOM 1991 definition above as well as CEN 13606, 2000 [9]:

(ISO: International Organization for Standardization; CEN: Committee for European Normalisation)

"A system for recording, retrieving and manipulating information in electronic health · records."

4)   ASTM Committee E-31 includes two definitions in the standard, E 1769 – 95 [10]:

(ASTM: American Society of Technology and Materials)

"An assemblage of technical, administrative, operational, communication and computer-based automated functions organized to accept, process, store, transmit and retrieve electronic clinical information for various purposes - such as assistance in health-care delivery and evaluation supports the EHR. It provides practitioner reminders and alerts, and it facilitates access to expert knowledge bases. The operative EHRS shall permit authorized health-care staff to enter, verify, manage, process, transmit, retrieve, view or print, or a combination thereof; any or all of the EHR data. The EHRS shall permit the algorithmic creation of longitudinal electronic healthcare files. The EHRS shall allow authorized user access to EHR data for purposes such as clinical, educational, administrative, financial, quality improvement, utilization review, policy formation, and research, as defined in the authorization agreement with each legitimate user. The EHRS shall protect the data from unauthorized access."

B. Categories of EHRS[5-6]
On the basis of ISO TR 20514: 2005[5], the following sections discuss several different categories of EHRS which may be useful in further defining in context the EHR in terms of the settings in which it is created, stored and used. These systems are given names such as "Local-EHR system (Institutional EHRS)" and "Shared-EHR system."

1)   Local-EHRS (Institutional EHRS)
In most healthcare systems, individual healthcare facilities and community-based healthcare providers maintain their own local patient/consumer healthcare records, whether manual or electronic or a combination of both.

An important characteristic of these records is that they contain detailed health and clinical information on the subject, collected during encounters with that particular health provider. They usually also contain externally sourced material such as diagnostic results and referrals but access to the information in the Local-EHRS is usually restricted to authorized health professionals within the particular facility. This is almost synonymous to conventional manual "medical records system."

2) Shared EHRS

A Shared-EHRS is purpose built to facilitate integrated shared lifetime care within a "community of care" and supports sending and receiving of extracts and integrated workflow. The community of care will most often be within a restricted geographic region, however, it can be national and/or global basis in the future. It will consist of a range of health organizations and clinicians attended by the patient/consumer on a regular or episodic basis. This will typically include one or more primary care clinicians, specialist clinics, hospitals, allied health professionals and alternative/complementary practitioners. In fact National-level Shared-EHRSs are already being planned and built in a number of countries. The lifetime collection of Shared EHR of an individual is the new paradigm EHR (IOM 2003)[8].

3) Personal Health Record (PHR)

It is increasingly common in many countries for the EHR subject of care to also have access to her/his own EHR but the nature and extent of such access (including direct contributions to the EHR by the subject of care) is still unclear.

The key features of the PHR are that it is under the control of the subject of care and that the information it contains is at least partly entered by the subject (consumer, patient).

Although there is a widespread misapprehension in the community, including among health professionals, that the PHR must be a completely different entity from the EHR, there is no reason why the PHR cannot have exactly the same record architecture (i.e. standard information model) as the health provider EHR and still meet all of the patient/consumer requirements

The PHR can then be considered in at least four different forms:

- A self-contained EHR, maintained and controlled by the patient/consumer;

- The same as a. but maintained by a third party such as a web service provider,
- A component of an EHR maintained by a health provider (e.g. a GP) and controlled at least partially (i.e. the PHR component as a minimum) by the patient/consumer, or
- The same as the above. but maintained and controlled completely by the consumer.

4) Population Health Record (Public Health EHR)

A population health record contains aggregated and usually de-identified data. It may be obtained directly from EHRs or created *de novo* from other electronic repositories. It is used for public health and other epidemiological purposes, research, health statistics, policy development, and health service management.

5) EHR for Oriental Traditional Medicine

"Oriental Medicine (e.g. Chinese Traditional Medicine) collectively often called "alternative" or "complementary" medicine in Western countries, are fundamentally different from Western Medicine. This is particularly important in countries where patients/consumers seek health care from practitioners of more than one health model, sometimes for the same illness. The practitioners of these different health models not only use different terms for the same entity but sometimes also use the same term to express different concepts. For example, the terms "kidney" has quite different meanings for Western and Oriental Medicine practitioners, for Oriental Medicine practitioners it means organ kidney and status of emotional/homeostatic control of the subject, as well.

A single EHR, across different health paradigms, could be very beneficial for the holistic care of patients seeking care from practitioners of different health models (more than 50% of the population in many countries)."

6) Dental Care Records

It is also important to be integrated in the EHR.

C. Context of EHR

1) Shared EHR

Effective integrated and shared care requires, at a minimum, timely and efficient shared personal health information, i.e. a shareable EHR, which implies at a minimum, functional interoperability. However, to obtain optimum

information management for integrated health care, it is necessary to have semantic interoperability, through standardization of clinical and other domain concepts using terminologies, archetypes and templates.

For the context of sharable EHR the followings issues should be considered :

- longitudinality;

- granularity;

- consensus logical information model;

- persistence of information;

- completeness of information;

- security and privacy; and

- accessibility.

III. Architecture

All EHRS assume a level of interoperability within and between EHRSs and diverse supported systems. The generic structural components from which all EHRs are built, defined in terms of an information model (ISO/TS 18308:2004) [9].

The systems architecture for EHRS can be highly variable to meet the needs of different health sectors and health disciplines.

IV. Functionality

There are three basic functionalities to support EHRS as listed as followings (HL7 Draft Standard for Trial Use)[11]:

A. Direct Care EHRS

The Direct-care EHRS functions are the subset of EHRS functions that enable hands-on delivery of healthcare and offer clinical-decision support. Users are healthcare providers. The major functionalities are :

- Care management;

- Clinical decision support; and

- Operations management and communication.

B. Supportive EHRS

The Supportive EHRS functions are the subset of EHRS functions that assist with the administrative and financial requirements associated with the delivery of healthcare. *Supportive EHRS functions* also provide input to systems that perform medical research, promote public health, and seek to improve the quality of healthcare delivered Users are the support staff but, under certain circumstances, the healthcare providers might be expected to perform certain

administrative functions.

- Clinical support

- Measurement analysis, research, reporting

- Administrative and financial

C. Information Infrastructure EHRS

The Information Infrastructure EHRS functions are the subset of EHRS functions that a). Provide a framework for the proper operation of the Direct-care and Supportive EHRS functions, and b). Offer EHRS technical capabilities that are essential, yet transparent, to the user. The main users are expected to be performed transparently by EHRS applications on behalf of EHRS end users.

- EHR security

- EHR Information and records management

- Unique identity, registry, and directory service

- Support for health infor4matics and terminology standards

- Interoperability

- Manage business rules

- Workflow management

V. Standards

All EHRS require a level of functional and semantic interoperability within and among EHRS and diverse support systems. There are number of standards developed to ensure the required interoperability for EHR by International SDO. However, developed standards do not meet EHR/EHRS requirements satisfactorily. Standards should ensure interoperability among diverse information systems.

Relevant international SDO with standards applicable to EHRS are discussed in the sections below.

A. ISO/TC215 "Health Informatics"[12]

The Technical Committee(TC) "Health Informatics" of ISO was created in 1998. Its scope is defined as: "Standardization in the field of information for health, and ICT to achieve compatibility and interoperability between independent systems. Also, to ensure compatibility of data for comparative statistical purposes (e.g. classifications), and to reduce duplication of effort and redundancies."
The number of Participating countries is 24, with 14 Observer countries. In 2004, the total number of ISO standards published under the direct responsibility of ISO/TC215 is about 20.
ISO/TC215 liaises with several organizations:

CEN, DICOM, IEEE, ICN, IMIA, UN/ECE, W3C,etc. The work of ISO/TC215 is distributed between 8 Working Groups:

Infrastructure Working Group :
WG 1 Data Structure (EHR)
WG 2 Data Interchange (Messaging and
    communication)
WG 3 Semantic Content
WG 4 Security

Domain Working Group:
WG 5 Health cards
WG 7 Device (Medical Device Interface)

Business Requirement Working Group:
WG 6 Pharmacy and medication business
WG 8 EHR Requirements

1) ISO/TC215 Work List(January, 2005)
Standards and/or Guides Published:
•TR 18307:2001 Health Informatics –
    Interoperability and common messaging and
    communication standards – key characteristics
•TS 17090-1:2002 Health Informatics – PKI
    framework and overview
•TS 17090-2:2002 Health Informatics – PKI
    certificate profile
•TS 17090-3:2002 Health Informatics – PKI
    management of certificate authority
•TS 17117 :2002 Health Informatics –
    Controlled health term structure and high-level
    indicators
•ISO 18104 :2003 Health Informatics –
    Integration of a reference terminology model
    for nursing
•ISO 18812 :2003 Health Informatics – Clinical
    analyser interfacing information system
•TS 21667:2003 Health informatics - Health
    indicators conceptual framework
•TS 18308:2004 Health Informatics –
    Requirements for an electronic medical record
    architecture
•ISO 21549-1:2004 Health informatics - Patient
    healthcard data - Part 1: General structure
•ISO 21549-2:2004 Health informatics - Patient
    healthcard data - Part 2: Common objects
•ISO 21549-3:2004 Health informatics - Patient
    healthcard data - Part 3: Limited clinical data
•ISO 22857:2004 Health informatics -
    Guidelines on data protection to facilitate trans-
    border flow of personal health information
•TR 16056-1:2004 Health informatics –
    Interoperability of telehealth systems and

networks – Part 1: Introduction and definitions
•TR 16056-2:2004 Health informatics –
    Interoperability of telehealth systems and
    networks – Part 2: Real-time systems
•TS 16058:2004 Health informatics –
    Interoperability of telelearning systems
•TR 21089:2004 Health informatics – Trusted
    end-to-end information flows
•TS 17120:2004 Health informatics - Country
    identifier mechanism in healthcare
•ISO 17432:2004 Health informatics - Messages
    and communication - Web access to DICOM
    persistent objects
•TR 20514:2005 Health informatics – EHR
    Definition, scope and context

Major Working Items in Process:

Working Group 1
•A general domain model for health information -
    profiling framework
Working Group 2
•Exchange of information between healthcare
    information systems
•Point-of-care medical device communications –
    Nomenclature
•Point-of-care medical device communications -
    Domain information model
•Point-of-care medical device communication -
    Transport profile - Infrared wireless
•Point-of-care medical device communication -
    Application profiles - Base standard•Point-of-
    care medical device communication - Transport
    profile - Cable connected
Working Group 3
•Vocabulary for terminologic systems
Working Group 4
•PKI overviewof digital certificate services
•PKI certificate profile
•PKI management of certificate authority
Working Group 5
•Healthcards – General characteristics
•Healthcards – Numbering system and
    registration procedure for issuer identifiers

B. DICOM(Digital Imaging and
    Communications in Medicine)[13]
Founded in 1983 by the American College of
Radiologists (ACR) and the National Electronic
Manufacturers' Association (NEMA), the DICOM
Standards Committee is acting as an
internationally acknowledged SDO dealing with
digitized diagnostic image related standards..
DICOM has 22 Working Groups and it has
established working relationships with CEN/ISSS,
ASTM Internet protocol TCP/IP, JIARS(Japan

Industries Association of Radiological Systems), ANSI-HISBB, HL7 and ISO/TC215

C. HL7[14]

HL7 (Health Level Seven, by reference to the 7 layers of ISO/OSI model) was founded in 1987 in the USA.. Their goal was to develop messages consensual formats to facilitate a better interoperability of Hospital Information Systems. In 1994, HL7 was accredited by ANSI as a SDO. Current HL7 standards include :

- Version 2.x (message specifications
- Version 3 and RIM
- CDA (clinical document architecture)
- Arden Syntax (for clinical decision support)
- CCOW(Clinical Context Object Workgroup)

HL7 has 28 International Affiliates.: HL7 also maintains partnership relations with CEN/ISSS and ISO/TC215.

In 2000, XML encoding of version 2 messages has been approved .Specifications of Versions 2.x cover:

D. UN/CEFACT[15]

UN/CEFACT is the United Nations Center for Trade Facilitation and Electronic Business. It is the organization responsible for standardization in the field of EDI and ebXML. Technical Specification, as part of the overall ebXML framework, drawn up by a UN/CEFACT-OASIS joint initiative.

The specification focuses both on human-readable and machine-processable representations of this information. The ebXML is also adopted in CDA.

VI. Conclusions

The EHR is defined and divided into 4 categories, Institutional EHR, Shared EHR (lifetime collection of summarized individual health and clinical information), Personal EHR and Population EHR.

The successful deployment of appropriate EHR requires both functional and semantic interoperability and security and privacy protection with applications of relevant standards such as HL7 CDA, Clinical Decision Support Systems, Evidence-Based Medicine, Individual-Based Medicine. The application of international Health Informatics standards is essential for a successful EHR development.

The international SDOs. should be engaged in further developing necessary standards as soon as possible.

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