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Languages of Health Informatics
A Survey of Standards

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ABSTRACT

Integration of Information and Communication Technology (ICT) in healthcare has been a much talked about topic in the last decade. Much effort is being put into integrating new technologies to improve the delivery of care, public health and other related administrative tasks. Although almost everybody agrees that this change is necessary and would bring positive changes to the healthcare system, the actual implementation in the field has seen mixed results. A number of factors make an implementation successful or unsuccessful; interoperability is one of the factors which is often seen to have a major impact[1]. Standards play a crucial role in enabling interoperability.

One of the main objectives of eHealth is to provide healthcare professionals with ICT tools and systems to enable collection, management and sharing of healthcare related information. As stated earlier, interoperability among these systems is necessary for them to be adopted and yield real value. Standards form the backbone of all such ICT tools, ensuring syntactic and semantic interoperability. Standards also cut down the cost of development of systems and tools if used in an appropriate manner[2]. Thus, it is important to have a good understanding and knowledge about standards to be able to do any successful work in eHealth tool and system development and integration.

Although a number of standards are available which solve interoperability issues to a great extent, developing standards based healthcare ICT solution has a number of challenges[3, 4]:

1. No one standard serves all use cases. Standards are usually designed for a specific purpose and have to be used in combination to create a useful system.
2. Competing standards exist that serve the same purpose.
3. There is a lack of easily available information resources about standards to help implementers understand and choose between standards.
4. There is a lack of proper specifications regarding testing of conformance to standards.

This paper presents a survey of health informatics standards, including an overview, current status and comparison of current popular standards. The main objective of this study is to do a survey of health informatics standards to help developers of eHealth systems make informed decisions about when, where, what, and how to use standards.

Keywords: Health informatics, standards, DICOM, HL7, SNOWMED, electronic health records, interoperability

EHRS, INTEROPERABILITY AND STANDARDS

Electronic Health Record System (EHRS) and interoperability are two important keywords and topics of discussion whenever talking about the use of Information and Communication Technology (ICT) in healthcare. Both these topics rely on the ability to share data, and standards form the core of that ability. To understand and appreciate the complexity involved in the sharing of healthcare data, it is important to know what information is being exchanged and why.

EHRS

The use of information technology in healthcare is not a new phenomenon nor is the idea of having standards to make these systems interoperable. The origin of most of the current popular standards can be traced back to late 1980s or even earlier than that. Yet there have been some changes in the industry in the last decade, in the way information technology is being and would be used in the future. These changes have made the use of standards more important than ever before.

The use of ICT in healthcare until about the beginning of the 21st millennium was mainly limited to sharing data within institutions. The increasing cost of healthcare, and learnings available from successes with ICT in other domains, led to a realization that there was a need for a similar change in healthcare applications that would lead to better care and medical research at a lower cost. Use of standards became more important than ever before to achieve this goal. Many countries have started or are starting projects to make patient medical data available electronically anytime and anywhere as needed[5]. In Canada, this project is being led by Canada Health Infoway at the federal level in a major effort to develop a high level ICT architecture and standards. Each province in turn is working to develop its own infrastructure based on CHI's guidelines. This infrastructure is planned to serve as the back bone of Electronic Health Record Systems (EHRS) in Canada that will allow sharing of healthcare data throughout the country.

INTEROPERABILITY

Interoperability is defined as the ability of two or more systems to inter-operate through the exchange of information. Interoperability has two levels: syntactic interoperability and semantic interoperability[6, 7]. Syntactic interoperability is the ability to exchange data, and semantic interoperability is the ability to interpret the data exchanged in a meaningful manner (i.e. to be capable of not just receiving data but also understanding or interpreting it in the manner intended by the sender). Lack of syntactic and semantic interoperability limits the advantages of ICT in healthcare to a great extent. The use of health informatics standards is a way of ensuring both syntactic and semantic interoperability, especially when the systems involved are developed and maintained by different vendors or organizations. Building EHRS systems that will exchange data at a provincial or federal level requires that all systems involved are both syntactically and semantically interoperable.

STANDARDS

The ability of humans to communicate using spoken and written languages is one of the most complex traits that we have developed over the long course of evolution. This ability has allowed human beings to evolve into complex beings and to advance in many fields, ranging from art and literature to science and technology. Although this is a farfetched analogy, it might help us understand the need for and the complexity of informatics standards.

Languages provide names for everything in a way that means the same thing to everybody understanding the same language. It also allows us to communicate complex ideas to one another in a meaningful way. As technology has advanced and computing systems have become an integral part of our way of working, it is important for these computing systems to have that same ability, even though humans remain end consumers of the information being communicated.

As mentioned earlier, concepts of interoperability deal with the same ability. It is standards that provide systems with languages to make interoperability possible.

STUDY DESIGN AND METHODOLOGY

This study is a survey of standards in health informatics. The standards included in the study are the standards upon which pan-Canadian standards are based[8]. These include:

1. Systematized Nomenclature of Medicine -- Clinical Terms (SNOMED CT®)
2. Health Level 7 (HL7)
3. Logical Observation Identifiers Names and Codes (LOINC)
4. Digital Imaging and Communications in Medicine (DICOM)
5. Integrating the Healthcare Enterprise (IHE) Profiles

This study also briefly covers other popular standards, either competing with the above standards or serving a purpose not served by any of the above standards.

The survey of health informatics standards covers the following, for each standard included in the study:

1. A brief history and origin
2. The purpose served
3. Technical overview
4. Resources available for implementers
5. Usage in the industry

David A Grimes and Kenneth F Schulz[9] describe "*a good descriptive research, like good newspaper reporting, should answer five basic "W" questions—who, what, why, when, and where—and an implicit sixth question, so what?"* This study tries to answer all these questions for each of the standards studied.

A literature review was done to collect the literature related to standards. Various search engines were used, including Pub Med, Compendex and Google Scholar, and provincial and federal eHealth websites as well as other information resources were consulted, including the official websites for standards. Key terms used, in various combinations, were "health information standards", "health informatics standards", "healthcare interoperability", and specific names of standards "SNOMED CT", "LOINC", "HL7", "DICOM","IHE" (using both the abbreviations and the expanded names).

SNOWMED CT

Systemized Nomenclature of Medicine – Clinical Terms (SNOMED CT) is a comprehensive collection of clinical terms. SNOMED CT provides the core general terminology for the electronic health record (EHR) which can be used to represent clinically relevant information consistently, reliably and comprehensively[10].

History

SNOMED CT was formed in 1999 jointly by United Kingdom's National Health Service (NHS) and the College of American Pathologists (CAP). SNOMED CT was developed by converging SNOMED RT (Reference Terminology) and Clinical Terms Version 3 (Read Codes CTV3). SNOMED RT was developed by CAP and contained over 120,000 interrelated healthcare concepts. CTV3 was developed by NHS and consisted of approximately 200,000 interrelated terms designed to store structured information about primary care encounters[11].

In April, 2007 the intellectual property rights for SNOMED CT were transferred from CAP, leading to the formal creation of the International Health Terminology Standards Development Organisation (IHTSDO).

IHTSDO

IHTSDO is an international not-for-profit standards development organization. IHTSDO was formed in April 2007 by its Charter Members, consisting of health sector organizations from nine countries (Australia, Canada, Denmark, Lithuania, New Zealand, Sweden, The Netherlands, The United States and The United Kingdom). IHTSDO's head office is located in the IT University in Copenhagen, Denmark. IHTSDO owns and administers the rights to SNOMED CT and related terminology standards. It also develops, maintains, promotes, and enables the adoption of SNOMED CT around the world[12].

Basic Components

Concepts

A SNOMED CT concept is a clinical idea or meaning that never changes, and it is identified by a unique numeric identifier (conceptID). Each concept also has a unique human readable Fully

Specified Name (FSN). Concepts in SNOMED CT can have varying levels of granularity ranging from general (for example, procedure) to specific (for example, excisional biopsy of lymph node) or somewhere in between (for example, biopsy of lymph node)[13]. Support for multiple levels of granularity allows SNOMED CT to be used to represent clinical data at a level of detail that is appropriate for a specific use case.

Descriptions

Descriptions are the human readable term(s) assigned to a SNOMED CT concept. Each description has a unique numeric DescriptionID assigned to it. SNOMED CT has three types of descriptions: (1) Fully Specified Name (FSN) which uniquely describes a concept and conveys its meaning, (2) Preferred Term which is the common word or phrase used by clinicians for that concept in the given language and (3) Synonym which represents a term, other than the FSN or Preferred Term, that can be used to represent a concept in a particular language or dialect.

Relationships

Relationships link concepts to other concepts in SNOMED CT. Four kinds of relationships that can be used to link concepts in SNOMED CT are: (1) Defining relationships, which define the meaning of concepts. These are pre-coordinated concepts; (2) Qualifying relationships which may be used in clinical systems to modify the meaning of terms using post-coordination; (3) Historical Relationships link currently active concepts to retired or inactive concepts; and (4) Additional relationships that allow distributional or non-definitional information. The most commonly used relationship in SNOMED is the IS A relationship[14].

Hierarchies

SNOMED CT concepts are organized into hierarchies (see Table 1). The root, named "SNOMED CTConcept" is the supertype of the top-level concepts and all the concepts beneath them. The lower a concept is in a hierarchy the more specific (or granular) it is. Currently, all the concepts are classified under nineteen top level concepts[13].

Table 1 : Hierarchies in SNOMED CT

Name	Description	Example(s)
Clinical finding	Represent the result of a clinical observation, assessment or judgment and include both normal and abnormal clinical states.	Normal breath sounds
Procedure	Represent any type of activity performed for the delivery of healthcare.	Appendectomy

Observable entity	Represents a question or procedure which can produce an answer or a result. Properties to which value(s) can be assigned	Left ventricular end-diastolic pressure, Color of nail
Body structure	All normal as well as abnormal anatomical structures	Mitral valve structure, Adenosarcoma
Organism	All organisms of significance in human and animal medicine, including causes of diseases.	Streptococcus pyogenes
Substance	Active chemical constituents of drug products, food and chemical allergens, adverse reactions, toxicity or poisoning information, and physicians and nursing orders	Insulin, Endorphin
Pharmaceutical/biologic product	All drug products	
Specimen	Entities usually obtained from a patient for examination or analysis	Specimen from prostate obtained by needle biopsy
Special concept	Inactive concept codes	
Linkage concept	Concept that can be used as a Relationship Type	
Physical force	Physical forces that can play a role in causing an injury	Friction
Event	Occurrences (other than procedures and interventions)	Flood, Travel
Environment or geographical location	Types of environments as well as named locations such as countries, states, and regions.	Intensive care unit, California
Social context	Social conditions and circumstances significant to healthcare	Occupation, Caregiver
Situation with explicit context	Concepts which Express something about who is subject of the record, when the event	No family history of stroke

	took place, absence (or presence) of a finding and if a procedure was done or not	
Staging and scales	Assessment scales and tumor-staging systems	Glasgow coma scale
Physical object	Natural and man-made objects	Military vehicle, Latex rubber gloves
Qualifier value	Concepts used as values for SNOMED CT attributes that are not contained elsewhere in SNOMED CT	Left
Record artifact	Entities created for the purpose of referring to other parts of electronic patient records	

Current Status and Tools

SNOMED CT is continuously updated to keep up with developments in healthcare around the world. The current release of SNOMED CT has more than 311,000 active concepts with more than 1.3 million relationships[13].

SNOMED CT is distributed in the form of tab-delimited text files that can be imported into a relational database. The core tables of the database are the Concepts table, the Description table and the Relationships table.

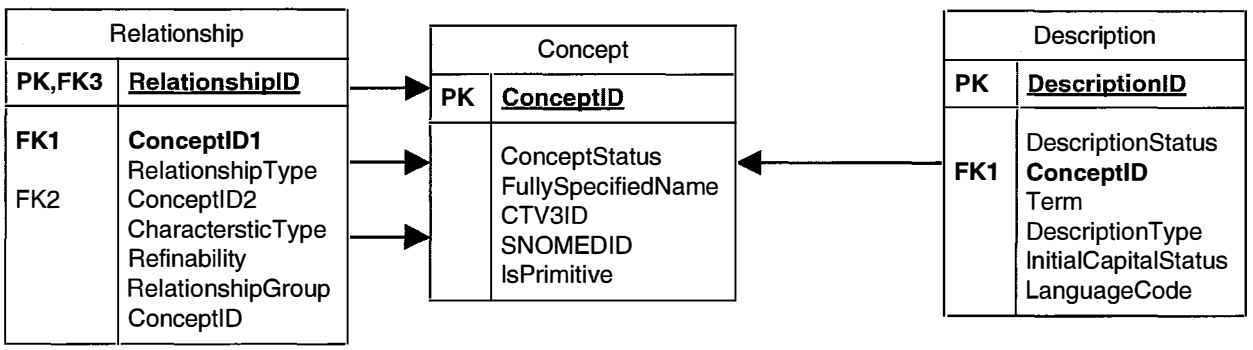

Figure 1 : SNOMED CT Table Structure

The association between concept and a set of Descriptions and a set of Relationships is defined through the ConceptId which is the primary or foreign key in the three tables. This format of release provides an easy way for implementers to include SNOMED CT in clinical applications.

SNOMED CT has been widely adapted to be used in various kinds of clinical applications like EMRs (Electronic Medical Record systems) and decision support tools[15]. It is also used for

research and education purposes. In most cases SNOMED CT is used within other applications for specific purposes. A few applications are available which allow searching and browsing SNOMED CT concepts. One of the most commonly used such applications is the CliniClue® Xplore [16].

In 2009, IHSDO introduced an open source tool called the SNOMED CT Modular Workbench. The IHTSDO Workbench includes a set of tools that allow users to author terminology, map terminology to other code sets, undertake workflow and process automation, search, browse and classify terminology. This tool is intended to allow organizations from around the world to use the same tools to maintain their terminologies and coding systems[17].

LOINC

Logical Observation Identifiers Names and Codes (LOINC) is a database providing a set of universal names and identifier codes for laboratory and clinical test results.

History and Ownership

LOINC was initiated by the Regenstrief Institute in 1994. Regenstrief Institute is a non-profit medical research organization associated with Indiana University, Indianapolis, Indiana. Regenstrief Institute serves as the home for LOINC and the copyrights for LOINC are owned by Regenstrief Institute, Inc. and the LOINC Committee.

The project to develop LOINC was initiated in February 1994 with the goal of developing a coding system that covers at least 98% of laboratory tests known at that time. The project was started because at that time a growing number of laboratories were transmitting laboratory results to their clients electronically, using standards like HL7. Most such laboratories identified tests in the messages through code values developed internally; this made it difficult for the receiving system to comprehend the results unless they adopted the coding system of the sender or mapped it to their own internal coding system. This could be a resource intensive exercise, especially if one was receiving results from multiple sources[18]. Thus, the LOINC database was created to provide universal identifiers to be used in HL7 messages. Specifically, LOINC identifiers were used for the observation identifier field (OBX-3) of the HL7 observation reporting message.

Structure

As mentioned before, the LOINC database provides a set of universal names and identifier codes for laboratory and clinical test results. Each record in the LOINC database corresponds to a single test result. LOINC defines names in terms of five or six major axes (see Table 1).

Table 2 : LOINC Axes Based Naming Structure

Part	Name	Description	Example
1	Component/ analyte	Name of the analyte/component used	Potassium, hemoglobin, hepatitis C antigen.
2	Property measured	Kind of property of observation or measurement	A mass concentration, enzyme activity (catalytic rate).
3	Timing	Time aspect of the measurement or observation (i.e. whether the observation applies to a moment in time or is an average or amount taken over a period of time)	24 hours
4	System(Sample)	The type of sample or organ examined	Urine, blood, chest
5	Scale	The type of scale: i.e. whether the measurement is quantitative (a true measurement) ordinal (a ranked set of options), nominal, or narrative.	Nominal: e.g., E. coli; Staphylococcus aureus) Narrative: dictation results from x-rays
6	Method	Method used to produce the observation, but only when different methods give clinically significant different results	

A fully specified LOINC name is described formally using the following syntax.

<Analyte/component>:<Propertymeasured>:<time aspect>:<system(sample)>:<scale>:<method>

The colon character, ":", is part of the name and is used to separate the main parts of the name[19].

The first main part of the LOINC name can be further divided up into three subparts: (1) the principal name (2) the challenge or provocation and, if relevant, the time delay, substance of challenge, amount administered and route of administration; and (3) any standardization or adjustment. The first subpart, the principal name, can contain multiple levels of increasing taxonomic specification, separated by dots (.). These subparts are represented using the following syntax:

<[analyte].[subclass].[sub-subclass]> ^

<[time delay] post [amount] [substance] [route])> ^

<adjustment>

The third and fourth parts of the name (time aspect and system/sample) can also be extended with a second subpart, separated from the first by a carat. A time aspect modifier can indicate the sub-selection or integration of the observations taken over the defined period of time (maximum, minimum, mean, etc.). In the case of a system, the modifier indicates the source of the sample if it is not the patient (e.g., blood donor and fetus)[19].

Current Status and Tools

The most recent release of LOINC (version 2.38, Released December 2011) contains 68,350 terms[20]. The Regenstrief Institute maintains the LOINC database and makes it available in two different file formats: (1) A tab delimited ASCII Text file that contains all of the fields of the LOINC table, with each record of the database on a separate line. Each record is terminated by CR/LF, and each field is delimited with a tab character. Non-null text fields are enclosed in double quotes (“); (2) LOINC ACCESS database; The official LOINC database is available as an ACCESS file called LOINC.MDB, created by Microsoft Access™ 2007[19]. It is freely available with permission to use the database for any purpose without charge or written permission. The Regenstrief Institute also provides a mapping utility called the Regenstrief LOINC Mapping Assistant (RELMA®). RELMA allows users to search through the LOINC database and assists in mapping local codes to LOINC codes[21].

In Canada, Canada Health Infoway has adopted a subset of LOINC, which is constrained to include only observations applicable to Canadian laboratories. This adapted standard is known as the pan-Canadian LOINC Observation Code Database (pCLOCD)[8].

HL7

Health Level Seven International (HL7) is a not-for-profit standard development organization, accredited by the American National Standards Institute (ANSI). The “Level 7” in the name refers to the highest level of the Open System Interconnection (OSI) model of the International Organization for Standardization (ISO). The OSI model divides the functionalities of communications software and hardware into seven layers, or levels. HL7 primarily focuses on the issues related to the seventh, or application, level[22]. The name HL7 is used both for the organization and the standards produced by it.

History

HL7 was formed in 1987 with an initial focus on enabling exchange of information related to admissions, discharges and transfers (ADT) within hospitals. The first version of the standard (HL7 v1.0) was released in the last quarter of 1987 as an Application Protocol for Electronic Data Exchange in Healthcare Environments. The next version, HL7 v2.0, was published the

following year, 1988. This version included major extensions to support orders and reports for tests and treatments and some related patient accounting systems. These extensions were based on the ASTM (American Society of Testing and Materials) E.1238.88 standard. The first widely used version, HL7 v2.1, was published in 1991. The HL7 organization was officially accredited by ANSI in 1994[14].

HL7's vision is to create the best and most widely used standards in healthcare. HL7 has been working towards providing standards for the exchange, integration, sharing, and retrieval of electronic health information to support clinical practice, and the management, delivery and evaluation of health services[23]. Starting with 12 members in the first meeting more than two decades ago, HL7has come a long way. It now has 2,300+ members, including approximately 500 corporate members who represent more than 90% of the information systems vendors serving the healthcare industry.

HL7 v2.x

HL7 version 2 is currently the most widely used healthcare interoperability standard in the world. The HL7 V2 standard was created mostly by clinical interface specialists. It was designed to provide a framework in which data could be exchanged between disparate clinical systems. The core concept behind HL7 V2 can be explained as follows. Occurrence of external events, known as trigger events, is recognized by healthcare computer applications. An application sends a specific message, based on that trigger event, through the network to one or more receiving applications[24]. It is also important to note that HL7 does not specify the communication protocol for transmission of messages. It only specifies the trigger events and the relevant message.

To understand HL7 v2 it is important to understand the message syntax and data types. Message syntax specifies the overall structure of messages. Each message is composed of sequenced segments, which contains fields, also sequenced. These fields have specified data types. Data types are the building blocks of the fields. The data types can be simple or complex. Simple data types have a single value whereas complex data types have multiple components. These components themselves have data types which can in turn be simple or complex (see Figure 2).

The HL7 v2 standard provides adopters with an interface framework which covers about 80 percent of its scope. It also provides the ability to negotiate the remaining 20 percent of needs on a case by case basis. The standard achieves this goal by

- Defining HL7 encoding rules, groupings, cardinality, and the default character set (i.e. ASCII)
- Supporting case specific variations in data interchanges by allowing optional fields, with additional messages
- Evolving and adapting the standard through experiences from real-world usage of the standard
- Supporting batch processing of messages in a file

- Working with other standard development organizations and considering the relationship of HL7 standards with other standards and protocols such as DICOM, X12 and protocols published by ASTM and IEEE.

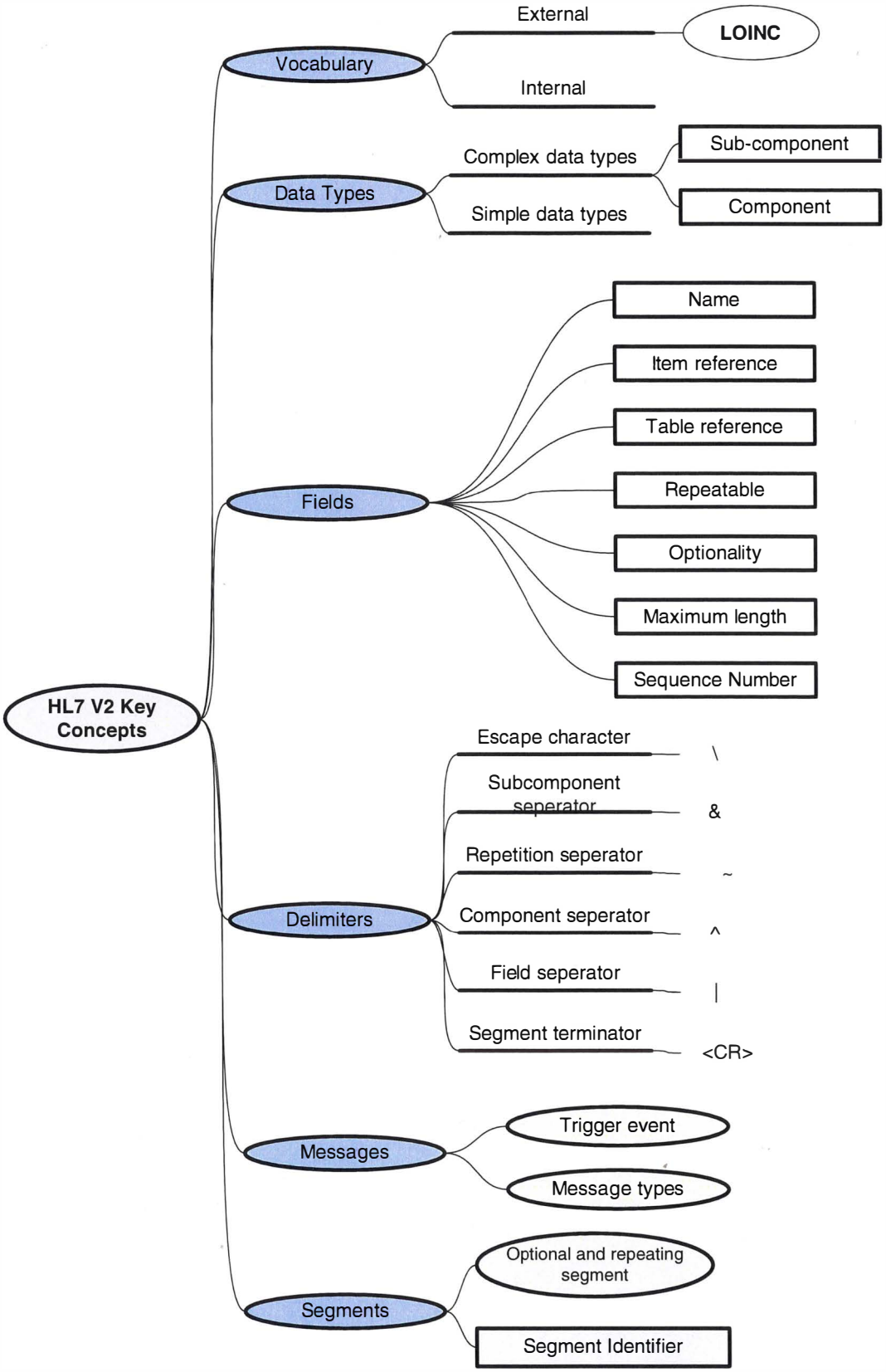

Figure 2 : HL7 V2 Key concepts adapted from Benson 2010[14]

Current status and Tools

HL7 v2 has been around for more than 2 decades. It is being used by 95% of US healthcare organizations, and more than 35 countries have HL7 v2.x implementations. The latest update to the version, HL7 v2.7, was published in 2011[25].

An important characteristic of the HL7 version 2 standards is that they are all backward compatible. This means that an older application built on an older HL7 v2.x standard can receive and process messages from newer applications using newer HL7 v2.x standards without producing errors. This is possible because the v2 standard allows applications to ignore message elements they do not expect.

As mentioned earlier, HL7 v2 standards have been around for a long time and have been adopted in the industry in a large scale. Thus, a number of tools are available in the market, either free or proprietary, which enable adopters to integrate the standard into their applications. Two of the most famous such tools are listed below:

- HAPI: HL7 application programming interface (HAPI) is an open-source, object-oriented HL7 2.x parser for Java. The project that developed HAPI was initiated by the University Health Network, Toronto, Canada[26].
- Messaging Workbench Tool: The Messaging Workbench is a multipurpose productivity tool for HL7 V2.x implementers. It facilitates rapid development of HL7 v3 based applications. It also includes an online message validation service and message generator for testing purposes[27].

HL7 v3

The success of HL7 v2 is largely attributed to its flexibility. Although this flexibility makes it adaptable to most use cases, it also makes it almost impossible to verify conformance. Also, v2 was developed in an ad hoc and unplanned manner[14, 24, 28]. In 1992 a task force was established to develop a new version of the standard using a methodological approach. This methodological approach, based on object-oriented development principles, has been called the Message Development Framework (MDF). The primary goal for HL7v3 was to offer a standard that is definitive and testable[24]. HL7v3 presented a new approach towards clinical information exchange based on a model driven methodology that produces messages and electronic documents expressed in XML syntax.

HL7 v3 RIM

The Reference Information Model (RIM) forms the backbone of HL7v3. RIM specifies the grammar and building blocks of the language (nouns, verbs, etc.), relationships and data types for v3 messages. The core of RIM consists of six main classes and the relationships between them. The core RIM is represented in Figure 3.

The main components of RIM are[14, 28, 29]:

Entity: Entity is one of the main backbone classes in the RIM. Entity is any living thing such as people, animals, plants, etc., nonliving things such as places, chemical substances etc., and abstract things such as organizations. Entities have two main structural attributes: (1)*classCode* which states the type of thing it represents and (2)*determinerCode* which helps distinguish between individual instances and a collection or kind.

Role: Role (as suggested by the name) assigns roles to entities giving them competencies to perform specific actions. Examples of common roles are patient, practitioner, home, etc.

Act: Act is something which happened or may happen, for example observation, procedure, etc. One of the important structural attributes is *moodCode*. *moodCode* is similar to the tense of a verb, indicating whether the Act has happened, is a request for something to happen, a goal or a criterion. *StatusCode* is another important attribute associated with Acts. *StatusCode* specifies the state of an act, such as New, Active, Completed, Cancelled or Aborted. The rules related to transitions between these states are specified using state-machine diagrams.

Participation: Participation defines how a Role is involved in an Act. Examples of participation include performer, subject, location, author, etc. (of an act).

Role Link: Role Link is a relationship between roles such as those that appear in an organization chart or family.

Act Relationship: Act Relationship links acts together. The various types of links include composition, documentation, fulfillment, etc.

RIM also specifies a comprehensive set of attributes, with specified Data Type, associated with the classes. RIM was designed as a universal model which would be applicable to any use case in healthcare. Its abstract nature and the ability to extend RIM make it usable in any conceivable information exchange scenario in healthcare.

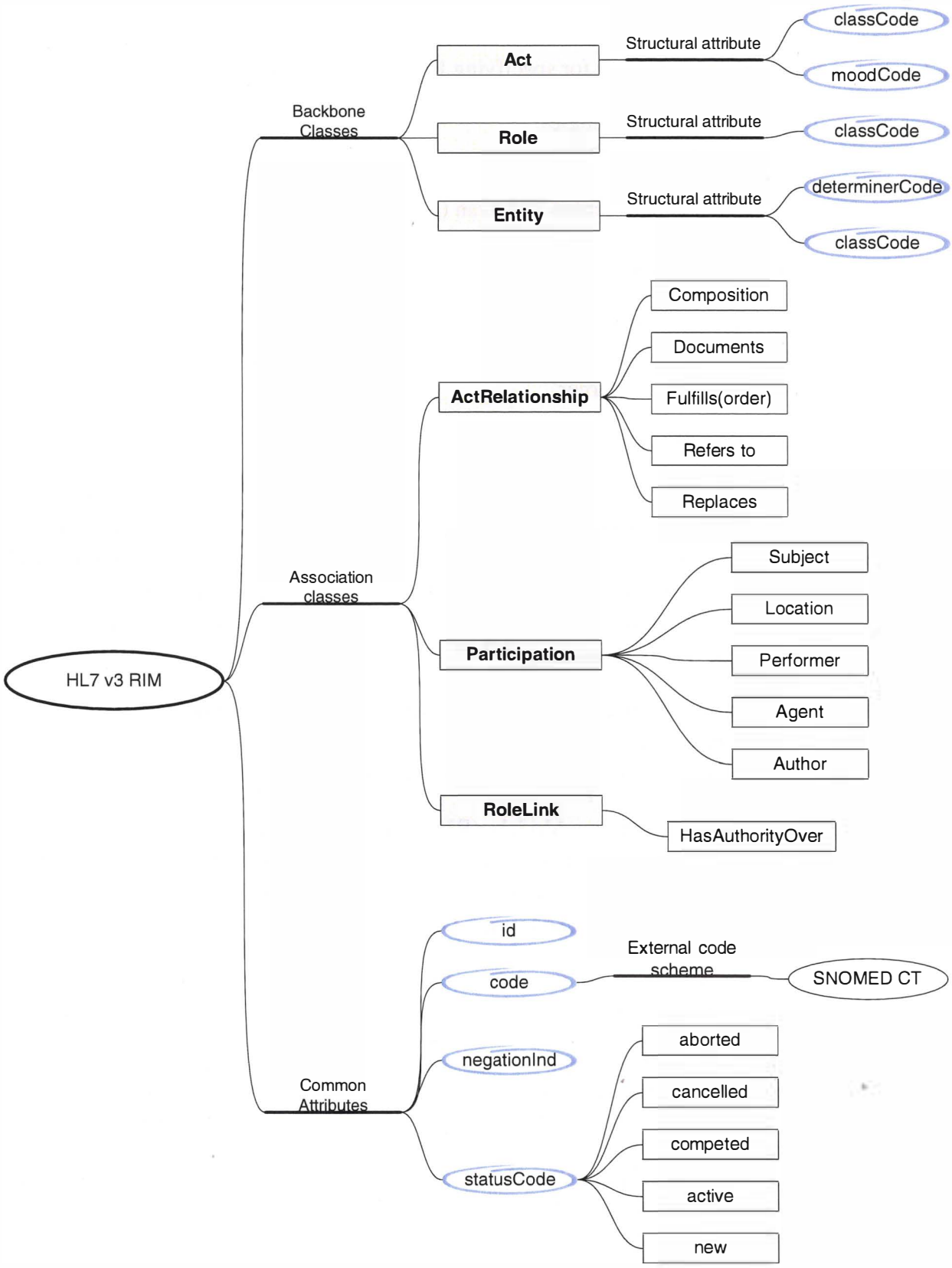

Figure 3 : Core RIM Structure adapted from Benson 2010[14]

Diagram Notation

HL7 uses a special graphical notation for specifying Information Models in HL7v3.

- Entities are green rectangles.
- Roles are yellow rectangles.
- Acts are represented as red rectangles.
- Participation is represented as a cyan (light blue) pentagon.
- ActRelationship is represented as a pink (salmon) arrow shaped pentagon.
- RoleLink is represented as a light yellow pentagon.

The direction of the arrows in pentagons indicates the meaning of the association (source to target). ActRelationship and RoleLink may have a recursive relationship which is indicated by a "pig's ear" box with a notched out corner[14].

Constrained Information Models

The approach taken towards development of HL7v3 was very different from HL7v2 and most other standards. The objective was not just to develop a set of specifications for the messages but to develop a framework for the development of standards. RIM was developed as a central model which can be constrained or refined to drive the format to represent the information needed for the given use case. HL7v3 recognizes a hierarchy of such models with decreasing level of flexibility (or increasing level of constraints) [14, 28, 29].

DMIM: Domain Messaging Information Model (DMIM) is a general model defined for a subject area. A DMIM cannot be serialized and thus cannot be implemented as it is. It provides a common point of reference between all the further specialized models within that domain.

RMIM: Refined Message Information Models (RMIMs) are constrained information models derived from a DMIM. The important difference between DMIMs and RMIMs are (1) RMIMs have a defined single point of entry and (2) they are serializable. RMIMs can also be expressed in a tabular format known as Hierarchical Message Descriptions (HMD).

There are various ways to constrain the information models mentioned earlier. The most commonly used ways in HL7v3 are[14]:

1. Omission: Omitting the optional classes or attributes in a model.
2. Cloning: The classes contained in an information model can be used in multiple ways. Cloning refers to making a clone of a class in an information model and then constraining it in the constrained information model.
3. Multiplicity and Optionality: Most associations and attributes in the RIM are optional and allow for an unlimited number of repeats. These can be constrained by making them mandatory or limiting their repeatability.
4. Data Type Constraint: HL7v3 data types have a hierarchical structure with varying levels of complexity. This allows constraining a data type to a different

level of complexity in a derived model. For example the data type GTS (General Type Specification) can be constrained to IVL<TS> (Time Interval) or TS (Time stamp).

5. Code binding: This type of constraint involves limiting the set of values in a set.

Another important concept in HL7v3 information models is Common Message Element Types (CMET). CMET is a reusable module which can be used in multiple messages. Use of CMETs speed up the process of developing messages, while maintaining a level of consistency between specifications.

HL7 CDA

The origin of HL7 Clinical Document Architecture (CDA) can be traced back to 1996. Extensible Markup Language (XML) was gaining a lot of popularity around that time and was being applied in various different domains to represent complex information in a structured manner. Every instance of an XML file is referred to as a document, which led people to think about the use of a document based paradigm for standards based representation of healthcare data[14]. This interest was also inspired from the desire to unlock the large amount of clinical information which was stored in format free text clinical notes[30].

In early 1996, a group of physicians initiated work on the concept of structured markup, used in XML, in clinical documents. The first draft of the specification was called the Kona Architecture and was developed in 1997. Since then the basic ideas have been refined and developed along with the HL7v3 framework and RIM[14].

CDA is part of the HL7v3 family of standards that derive their machine processable meaning from HL7 RIM. CDA is a document markup standard that specifies the structure and semantics of "clinical documents".

The Architecture

The "Architecture" in CDA refers to a hierarchy. HL7 envisions that a complete CDA will include a hierarchical set of document specifications. Thus the architecture can be thought of as a set of hierarchically related XML Document Type Definitions (DTD) or schemas[30]. Thus far, two levels in the CDA hierarchy have been released and work on the third release is in progress.

CDA Level 1 has a header and a body. The header contains basic meta-data primarily conveying the context in which the document was created and intended to enable retrieval of the document. The body contains the informational statements that make up the actual content of the document. The body is human readable text or images.

CDA Level 2 allows the body to be composed of either a single unstructured blob, like Level 1, or one or more structured sections. Each of these sections contains a narrative block that can be rendered in a human readable form[31].

Work on CDA Level 3 is still in progress. CDA Level 3 would allow each of the sections in the body to include machine processed entries at a higher level of granularity. This would allow it to have the benefits of both human readable and machine processed documents[14].

Technical Overview

As mentioned before, a CDA document has a header and a body. The header contains the contextual information and the body contains the factual information that makes up the actual content of the document.

The header has four logical components[14, 30]:

- Document information: containing document identification, confidentiality status, and relationships to other documents and orders.
- Encounter data: describes the setting in which a document encounter occurred; it includes an encounter identifier, a time stamp, and a location.
- Service actors include author(s), authenticator(s), those intended to receive a copy of the document and healthcare providers who participated in the service(s) being documented
- Service targets include the patient and other significant participants (such as family members).

The CDA body is either an unstructured blob or StructuredBody. An unstructured blob may contain any kind of human readable data in the form of text (txt, rtf, html or pdf) or images. StructuredBody is used for including XML-encoded data. It serves as a root node for one or more sections. Each section contains a human readable narrative block, called Section.text. This narrative block is intended to convey the meaning of that section in a way that can be rendered in a human readable manner. Each section can contain any number of entries. These entries are in the form of clinical statements. Clinical statements are a structured computer processable representation of clinically (or clinically relevant) information, such as observations, medication administrations, and adverse events. The clinical statement pattern also allows the representation of relationships between entries. The common types of relationships allowed are: has component, has reason, evaluates (goal), is manifestation of[14, 31].

DICOM

Digital Imaging and Communications in Medicine (DICOM) is one of the most popular standards in healthcare. It is the most widely accepted and adopted standard in the diagnostic imaging domain, enabling the integration of various imaging modalities and information systems.

History and Origin

The introduction of computed tomography (CT) in 1970s, followed by other digital diagnostic imaging modalities and increasing use of computers in healthcare brought an era of change in

healthcare, especially in the domain of medical imaging. The American College of Radiology (ACR) and the National Electrical Manufacturers Association (NEMA) recognized the need for a standard to enable integration of devices manufactured by various different vendors. They formed a joint committee in 1983 to develop a standard with the following objectives[32]:

- Promote communication of digital image information, regardless of device manufacturer
- Facilitate the development and expansion of picture archiving and communication systems (PACS) that can also interface with other systems of hospital information
- Allow the creation of diagnostic information data bases that can be interrogated by a wide variety of devices distributed geographically
- For connecting displays and similar devices to medical imaging equipment from different manufacturers

The first version of the standard was published in 1985, named ACR-NEMA Standards Version 1.0. This was followed by two revisions; the first one was published in October 1986 and second in January 1988. Version 2.0 of the standard was published in 1988. It included version 1.0, the published revisions, and additional revisions. It also included command support for display devices, a new hierarchy scheme to identify an image and data elements for increased specificity when describing an image. These versions already included the main definitions related to terminology, data structures and data encoding[32-36]. The main drawback of the first two versions was that they both relied on point-to-point connections for message transmission. This posed a problem with modern communication networks which do not use absolutely dedicated channels, and connections to a network required additional hardware and software.

In 1993 a new revision of the standard was released. This revision was named DICOM 3.0 and forms the basis of the DICOM standard of today. This revision included some major enhancements to the previous ACR-NEMA standards[32, 35], as follows:

- It was applicable to a networked environment, and supported operations using the industry standard networking protocol TCP/IP.
- It was applicable to an off-line media environment. The ACR-NEMA standards did not include specifications for a file format or choice of physical media or logical file system. DICOM added specifications to support storage and operations in an offline environment using industry standard media such as CD-R (Compact Disc-Recordable) and MOD (Magneto-optical drive) and logical file systems such as ISO 9660 and the PC File System (FAT16).
- DICOM added specifications, through the concept of Service Classes, for the semantics of commands and associated data. It specified how devices should react to commands and data being exchanged.
- It specified levels of conformance. DICOM explicitly describes how an implementer must structure a Conformance Statement to select specific options. This was a great addition and facilitated the adoption of the standard in the industry, as it provided a

formal and common method for a vendor to specify the parts of the standard the product is conformant too. This made it easier for vendors to integrate their systems.

- It was structured as a multi-part document. This facilitated the evolution of the standard by simplifying the addition of new features and updating existing ones. The structure was based on ISO directives which define how to structure multi-part documents.
- It introduces explicit Information Objects for images, graphics, waveforms, reports, printing, etc.
- It including specifications for the use of Unique Identifiers (UIDs) an established technique for uniquely identifying any Information Object. This facilitated defining relationships between Information Objects in an unambiguous manner as they are acted upon across the network.

Structure and Technological Overview

The DICOM standard enables interoperability in the domain of medical imaging by specifying[32-35]:

- A set of protocols to be followed to enable network communications between devices.
- The syntax and semantics of commands and associated information which can be exchanged using these protocols.
- A set of media storage services, a file format, and a directory structure to facilitate access to the images and related information stored on removable media.
- Information that must be supplied with a system claiming to be conformant to the standard.

The DICOM standard consists of the components outlined in Table 3[32, 33]:

Table 3 : Structure of the DICOM Standard

	Name	Description
PS 3.1	Introduction and Overview	Provides an overview of the goals and structure of the standard.
PS 3.2	Conformance	Consists of two main parts: - Conformance requirements: specifies the general requirements which must be met by any implementation claiming conformance. - Conformance Statement: defines the structure of a Conformance Statement, specifying the information which must be present.
PS 3.3	Information Object Definitions	Specifies a number of Information Object Classes consisting of a description of its purpose and the Attributes which

		define it.
PS 3.4	Service Class Specifications	Defines a number of Service Classes. A Service Class associates one or more Information Objects with one or more Commands to be performed upon these objects. Service Class Specifications state requirements for Command Elements and how the Commands are applied to Information Objects.
PS 3.5	Data Structure and Encoding	Specifies how to construct and encode the Data Sets resulting from the use of Information Objects and Services Classes. It also specified the support of a number of standard image compression techniques (e.g., JPEG lossless and lossy). It also addresses the encoding rules needed to construct a Data Stream to be conveyed in a Message (see PS 3.7).
PS 3.6	Data Dictionary	The centralized registry which lists all DICOM DataElements available to represent information and a list of uniquely identified items that are assigned by DICOM. For each element it specifies: • A unique tag, consisting of a group and element number • A name • Value representation (character string, integer, etc) • Value multiplicity (how many values per attribute) For each uniquely identified item it specifies: • Unique value (numeric with multiple components separated by decimal points and limited to 64 characters) • Name • Type • Part of the DICOM Standard it is defined in.
PS 3.7	Message Exchange	Specifies the service and protocol used by an application to exchange Messages over the communications support services (see PS 3.8). It specifies the rules to establish and terminate associations and rules that govern the exchange of Command requests and responses.
PS 3.8	Network Communication Support for Message	Specifies the communication services and the upper layer protocols necessary to support an efficient and coordinated communication between DICOM applications in a networked

	Exchange	environment.
PS 3.9	Retired	Specifies the services and protocols used for point-to-point communications in a manner compatible with ACR-NEMA 2.0.
PS 3.10	Media Storage and File Format for Data Interchange	Specifies a general model for the storage of medical imaging information on removable media. It includes a DICOM file format and a layered model for the storage of medical images and related information on storage media.
PS 3.11	Media Storage Application Profiles	Specifies application specific subsets of the DICOM Standard applicable to the exchange of medical images and related information on storage media for specific clinical uses.
PS 3.12	Media Formats and Physical Media for Data Interchange	Specifies a structure for describing the relationship between the media storage model and a specific physical media and media format. It also contains specific physical media characteristics and associated media formats facilitating the interchange of information between applications in medical environments.
PS 3.13	Retired	Specifies the services and protocols used for point-to-point communication of print management services.
PS 3.14	Grayscale Standard Display Function	Specifies methods for calibrating display systems for consistent presentation of images on different display media (e.g. monitors and printers).
PS 3.15	Security Profiles	Specifies security and system management profiles defined by referencing externally developed standard protocols, such as DHCP, LDAP, TLS and ISCL.
PS 3.16	Content Mapping Resource	Specifies templates for structuring documents as DICOM Information Objects and sets of coded terms for use in Information Objects.
PS 3.17	Explanatory Information	Informative and normative annexes containing explanatory information
PS 3.18	Web Access to DICOM Persistent Objects	Specifies how to request a DICOM persistent object in form of an HTTP URL/URI request.

	(WADO)	
PS 3.19	Application Hosting	Specifies an Application Programming Interface (API) to a DICOM-based medical computing system. This allows programs written to that standardized interface to just 'plug-in'.
PS 3.20	Transformation of DICOM to and from HL7 Standards	Specifies transformations of DICOM data to and from HL7 standards.

DICOM is a large and complex standard. It involves several layers in relation to the OSI network Model. DICOM is independent of the physical network connection. It defines an upper layer protocol that is used over the TCP/IP protocol. Network services are used for transferring information. In these services the roles of the provider (Storage Class Provider, SCP) and the user of the functionality (Storage Class User, SCU) are distinguished. For example, when sending ultrasound images from the originating modality to a PACS the ultrasound modality is the SCU and PACS is the SCP. These services can differ for specific DICOM objects. For example, systems which are designed to be used exclusively for analysis of CT images do not accept ultrasound images. For a successful information exchange between two DICOM systems a function agreement is necessary. Both stations have to support the same service (e.g. image transmission) and object (e.g., CT), but with complementary roles. This combination is known as Service-Object Pair Class (SOP Class) [35].

DICOM defines detailed data structures for medical images and associated data. Information Object Definitions (IODs) are the central components of the data structures. Each attribute in these structures has a well-defined meaning and is divided into several logical groups. For example, group 10 is reserved for patient data.

Current status and Tools

DICOM is one of the most popular standards in healthcare and has been adopted in the medical imaging domain on a large scale. Although it is a large and complex standard it has been able to keep up with the latest developments in the industry. It is currently developed and maintained by 26 working groups catering to developments in different branches of medicine, different modalities, and other technical aspects of the standard.

One of the reasons for the success of DICOM as a standard is its wide scale adoption by the manufacturers of the imaging modalities. These are often large multinational companies and these lead the adoption of standards. Also, the modalities are the main sources of data (images) which are used by other systems in the medical imaging ecosystem.

Although adopted on a large scale by industry, because of the complexity of the standard most of the applications implementing the standard are proprietary and expensive. A few well known open source implementations which are often used for education and research purposes are[37]:

- ClearCanvas: ClearCanvas offers a suite of open source products including PACS, WorkStation and a web based DICOM viewer[38].
- Osirix: OsiriX is a free open source DICOM viewer. It was developed in Objective-C for the Mac OS X operating system. OsiriX is also able to receive images transferred by DICOM communication protocols from any PACS or medical imaging modality[39].
- Dcm4chee: Dcm4che is an open source implementation of DICOM in Java[40].
- Dcmtk: DCMTK is a collection of libraries and applications implementing large parts of the DICOM standard. It includes software for examining, constructing and converting DICOM image files, handling offline media, and sending and receiving images over a network connection. DCMTK is available as open source software written in a mixture of ANSI C and C++ [41].

IHE

Integrating the Health Enterprise (IHE) holds a special position among the standards development organizations. IHE is not a standards development organization in itself. IHE is an initiative by healthcare professionals and the industry to improve the way computer systems in healthcare share information. IHE promotes the coordinated use of established standards such as DICOM and HL7 to address specific clinical needs, in support of optimal patient care[42].

Origin and History

The IHE initiative started in 1998 as a joint effort of the Radiological Society of North America (RSNA) and the Healthcare Information Management Systems Society (HIMSS) [43]. RSNA had been a promoter of DICOM as the universal standard for medical imaging, and HIMSS strongly advocated the use of HL7 as the standard for enabling information exchange across the whole healthcare ecosystem. IHE was started with the initial objective of improving integration of imaging data into hospital IT infrastructure using HL7 and DICOM standards.

As stated earlier, IHE's objective was not to create new standards but to promote coordinated use of existing standards to improve the way various healthcare systems share information. Standards like DICOM and HL7 are created with a specific objective of addressing a defined set of interoperability issues in healthcare systems. There is some amount of overlap in the functionalities and in many cases they complement each other. There is also a certain amount of flexibility offered by these standards in order to adapt to case specific needs. Also, some of the information standards often do not specify lower level details related to protocols to be used for exchange of messages, as this would restrict the way standards can be used. These factors led to vendors creating products implementing slightly different flavours of the same standards, resulting in integration issues in the field. Thus the IHE initiative was undertaken by vendors,

healthcare providers, IT professionals, regulatory agencies, and independent experts who collaborated voluntarily to resolve these interoperability issues. IHE accomplished this by releasing frameworks and profiles specifying how to use established standards to solve certain real world issues in an as unambiguous manner as possible[44, 45].

Process

IHE brings together various stakeholders involved in the development of health information technology to provide solutions to integration issues from the industry. The development process followed by IHE can be summarized as follows[42]:

1. Clinical and technical experts define critical use cases where information needs to be shared.
2. Technical experts create detailed specifications to address these use cases using established standards.
3. Industry implements these specifications.
4. IHE tests vendor systems at events called Connectathons.

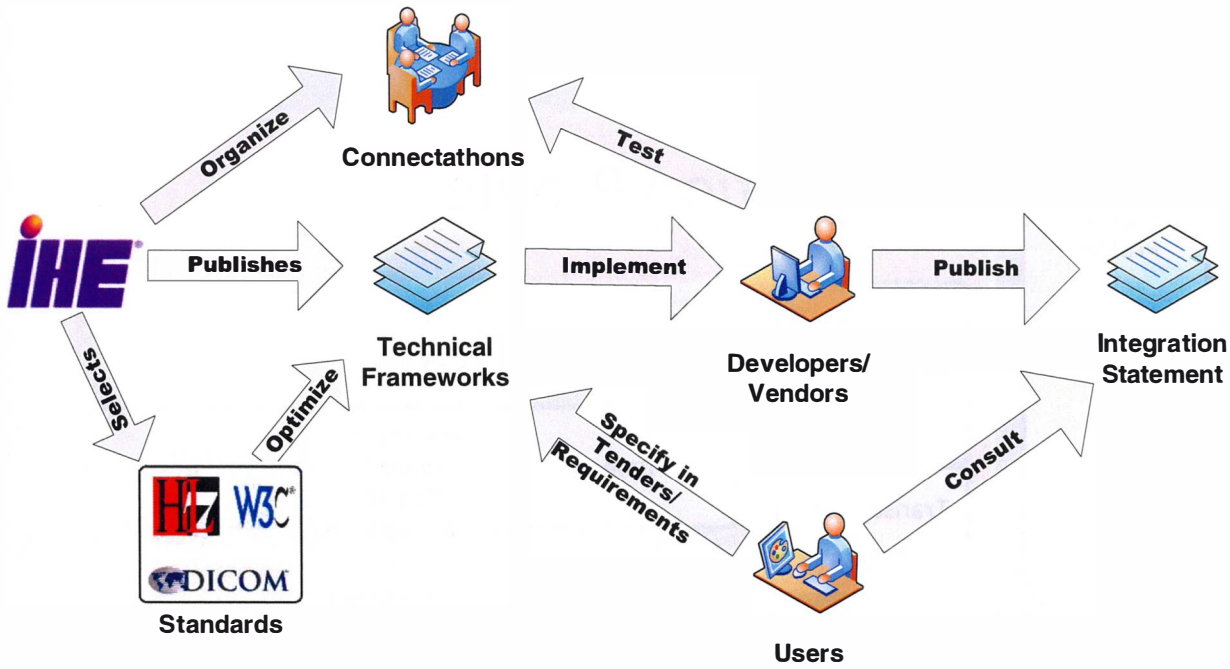

Figure 4 : IHE Development Process adapted from IHE International 2011

Structure

IHE is organized into a number of clinical and operational domains. Each domain is a functional subdivision of IHE that covers a particular subject area. Domains have a technical and a planning committee who follow the four step process stated earlier to address the interoperability issues in their domain. Currently nine domains are active within IHE[42]:

- Anatomic Pathology
- Eye Care
- IT Infrastructure
- Laboratory
- Patient Care Coordination
- Patient Care Devices
- Quality, Research and Public Health
- Radiation Oncology
- Radiology

Each domain develops and maintains its own set of Technical Frameworks. IHE Technical Frameworks are a resource for the stakeholders involved in the development of healthcare information systems. They define specific implementations of established standards to address specifically the interoperability use cases.

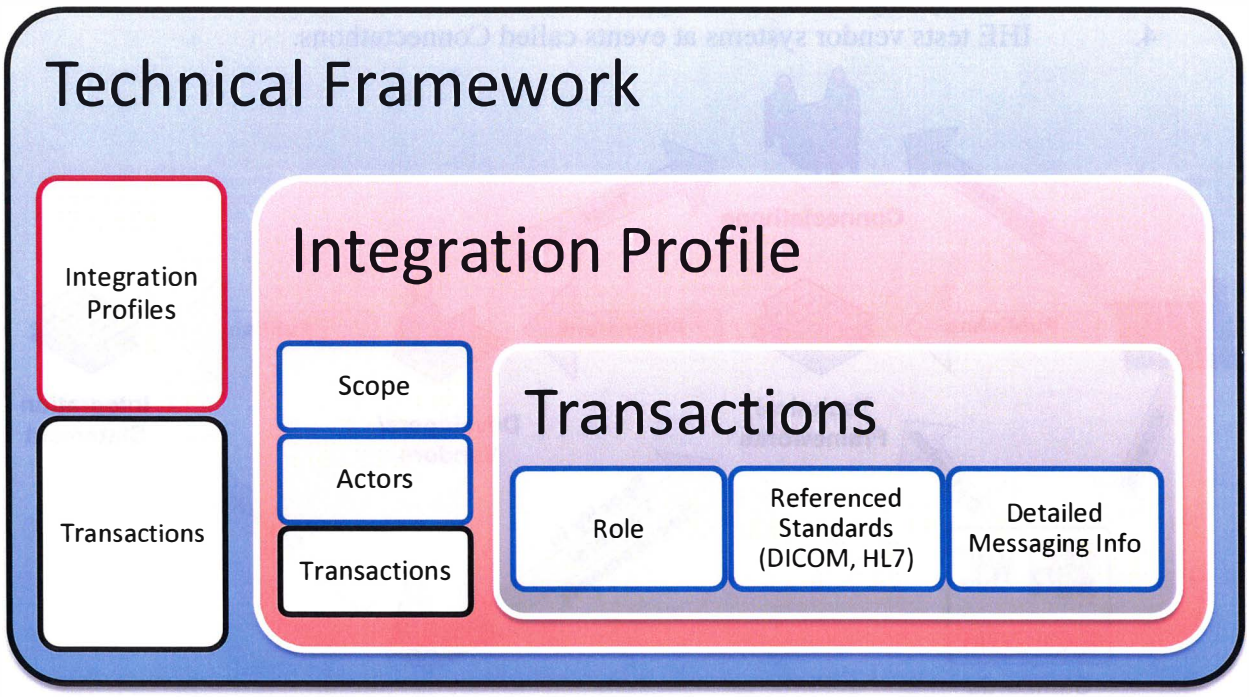

Figure 5 : Organization of IHE Technical Framework adapted from IHE International 2011[37]

An IHE Profile, also known as an Integration Profile, describes a clinical workflow in terms of what information is needed and exchanged. It also describes how to use established standards to accomplish the same. It is a resource for purchasers and vendors, providing a common language to discuss the integration needs of a healthcare system[42, 46]. The profiles are described using Actors and Transactions. An Actor may be either a person or a system collaborating with other actors to accomplish a particular use case. A transaction is a complete unit of information exchanged between actors[47]. An IHE technical framework is a detailed documentation of profiles and associated actors and transactions. It is a tool used by developers, and provides them

with detailed specifications to implement established standards in order to build interoperable and easy to integrate health information systems.

IHE also conducts large scale interoperability testing events known as Connectathons. A Connectathon offers vendors a unique opportunity for testing their compliance with IHE profiles. During Connectathons, systems integrate with complementary systems from multiple vendors, performing all of the transactions required for the selected roles in the selected IHE Profile. Connectathons have received enthusiastic responses from participating vendors; it provides them with a unique opportunity to test their systems. The first Connectathon was held in 1999 and it has become an annual event since then. This year's connectathon included more than 150 systems from over 100 participating organizations and more than 3500 successful tests of IHE Integration Profiles were performed and verified[42].

DISCUSSION

Recent efforts to build EHRS (and Health Information Exchanges) have brought about an era of change in the way ICT is and could be used in healthcare. Before this it was only (or mainly) important to be able to share medical data within an institute or even within a department. Now information is expected to be made available for almost all authorized users. This change was not just in terms of scale of the systems. Some other important aspects of this evolution that are worth noting are:

1. Usually healthcare institutes have their own internal networks, so the information remained within their own networks in most cases. Now it has become imperative to share information outside the institute's network. This leads to new security and privacy issues to be dealt with.
2. When the information is being shared within an institute there are a limited number of integration points and a limited number of systems involved. Also, in many cases institutes use systems from a single vendor which integrate well, even without the proper use of standards.
3. When the information is used mainly within an institute or organizations, it's at times easier to work with their own vocabulary.

Facing these changes and the accompanying challenges has made the use of standards more important than ever before. This also raises questions of whether the existing standards can support all the needed use cases and whether they can keep up with changes in the technology.

Interoperability Standards

As mentioned before, standards form the back bone of interoperable eHealth applications. It is important to clearly understand what makes these standards so important and how different standards fit together to create interoperable systems.

Standards are important and beneficial from the perspective of both the healthcare providers and the vendors supplying the eHealth products. A few such benefits are[2]:

- Standards reduce costs of development;
- Standardized products are easier to update or replace;
- Standardized products make integration of products from different suppliers easier;
- Standards allow healthcare institutions to iteratively extend their IT capabilities;
- Standardized products can reduce errors and make healthcare services safer.

To make use of standards to their full potential, it is important to understand the purpose served by each standard, and how they fit together.

Standards can be broadly classified into two categories: communication standards and terminology standards[2].

Communication standards are also known as syntactical standards as they offer syntactical interoperability. These standards ensure correct transmission of data between two systems. Standards like HL7 v2, HL7 v3 and DICOM offer standards to ensure syntactical interoperability but their capabilities are not limited to that. They offer semantic interoperability features to a limited extent and also specify how to integrate them with other standards to achieve higher levels of semantic interoperability.

Terminology standards offer the ability to name, classify and encode data in a consistent manner, so that different systems can interpret the data in the same way. These standards ensure semantic interoperability between systems. Terminology standards like SNOMED and LOINC are also important because they provide coding systems which are easy to use and integrate into a computing system.

The Health Level Seven EHR Interoperability Work Group[48] identified a third type of interoperability known as process interoperability. Process interoperability ensures coordination between business processes that may be followed in two different organizations. IHE, although it is not a standard development organization, offers solutions that can ensure process interoperability.

Making the choice

As the adoption of ICT in healthcare progresses, developers of the systems and policy makers have to choose which standards to adopt, and how to go about it. Below is a list of recommendations which might be useful in helping stakeholders to make that choice:

- With the rapid development of public EHR systems that will eventually link healthcare systems in larger and larger regions, it would be beneficial to adopt the

standards recommended by regional governing organizations (like Canada Health Infoway).

- Domain specific terminology standards, like LOINC, offer certain advantages over broader terminology standards like SNOMED CT, providing more specific information in a single code, with smaller subsets of codes to be supported.
- Broad terminology standards, like SNOMED, offer capabilities to give more specific information via post-coordination (using SNOMED CT expressions). Also, it is easier to expand the scope of applications and integrate them with other systems in the future.
- Many resources are available to make the adoption of standards easier and cheaper. It is important to do an extensive survey of such resources before choosing a standard.
- Look at the history of the development and intended purpose of standards. Some standards were developed with a specific purpose but are also applicable in other use cases. It is important to consider the development history of a standard, as it gives an idea about which direction the standard might head in the future and whether it aligns with future plans for the specific application or system. This would also help while making a choice between standards that offer similar capabilities.
- Mapping between standards. Many standards development organizations work together to provide mappings to other standards. It is beneficial to determine if a mapping exists among standards being considered, as it would affect future integration with systems using other standards.

Limitations

The intention of this study was to provide an introduction and overview of standards being used in the Canadian eHealth domain. A few limitations to the study are:

1. A subset of health informatics standards are used in the Canadian healthcare system. A number of other standards being used outside Canada like ICD (International Classification of Diseases), which were not included in the study.
2. Considering the complexity of these standards, it is hard to provide in such a brief document a comprehensive overview of relevant standards.
3. Although some of these standards have been around for more than two decades, industry and academic interest in the topic is still limited. Thus, a limited amount of literature is available which addresses relevant aspects of the topic.
4. Details relating to use of standards are often missing or hidden in eHealth research publications, making it difficult to find literature on specific aspects of the topic.

CONCLUSION

Achieving universal interoperability in the world of eHealth is no easier than building the Tower of Babel. It can only be achieved if all the systems involved understand each other. Standards do provide a language to these systems but, as in the human world, there is no single universal language in the world of health informatics.

With the rapidly changing technology and the increasing amount of healthcare information being collected in electronic format, standards continue to become ever more important. Standards, like any other language system, are complex, but they continue to evolve in order to provide the necessary tools needed to communicate healthcare information.

"We shall not cease from exploration
And the end of all our exploring
Will be to arrive where we started
And know the place for the first time."
From "Four Quartets"

T.S. Eliot

GLOSSARY OF TERMS

ACR	American College of Radiology
ANSI	American National Standards Institute
ASTM	American Society for Testing and Materials
CDA	Clinical Document Architecture
DICOM	Digital Imaging and Communications in Medicine
EHRS	Electronic Health Record System
EMR	Electronic Medical Record
HL7	Health Level Seven
ICT	Information and Communication Technology
IHE	Integrating the Healthcare Enterprise
IHSTDO	International Health Terminology Standards Development Organisation
ISO	International Organization for Standardization
LOINC	Logical Observation Identifiers Names and Codes
NEMA	National Electrical Manufacturers Association
RIM	Reference Information Model
SNOMED CT	Systematized Nomenclature of Medicine -- Clinical Terms
XML	Extensible Markup Language

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