Semantic Interoperability in electronic health record: a standardised approach

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The main objective of this study is to compare two major international standardisation approaches that enable semantic interoperability in electronic health record (EHR) , to identify harmonisation efforts between the two approaches and to suggest possibilities on future harmonisation.

Archetypes and HL7 are the two major approaches in current Electronic Health Record development, but their approaches to semantic interoperability are very different. Many countries, organisations, and companies have adopted the overlapping approaches. It is very difficult for systems adopting different approaches to communicate. Harmonisation is one possible way other than replacing each other to settle this issue.

The thesis first presents overviews on semantic interoperability in information system, electronic health records and international interoperability standards. Then, detail studies in the two approaches are conducted by reviewing articles and international standards. A set of prerequisites of semantic interoperability is used to evaluate the approaches. Finally, differences between the two approaches and harmonisation efforts are identified.

The result suggests that both approach are sufficient to support semantic interoperability. Despite their incompatibility harmonisation efforts have appeared to alleviate the problem. Further harmonisation is essential and experiences may be adopted from other industries.

Key words and terms: Electronic Health Record, semantic interoperability, HL7, Clinical Document Architecture, archetype, openEHR, ISO 13606.

Contents

1. Introduction

Electronic health record (EHR) provides a digital way to document health record of the patients. Semantic interoperability is one of the key factors to provide continuing, efficient and high quality EHR systems. [Karlra, 2006; ISO/TR 20514, 2005; Begoyan, 2007].

Electronic health (eHealth) has been developed for decades, research focus has changed from concept proven to quality assurance. EHR systems are in use in most developed and even in many developing countries [Merruko, 2013]. However, demands for interoperability between electronic health systems have arisen during these years. Enabling interoperability is a prerequisite for collaboratively providing health service and exchanging health data in distributed locations.

Currently, electronic health systems can exchange electronic health record following some prevalent messaging standards such as HL7 (health level 7) version 2. Syntactic interoperability has been achieved in a way that data and message can be transmitted between electronic health systems as long as they follow the same standard. However, current EHR systems are very unlikely to "understand" the information from other electronic health records. One of the most important reasons is that there is no true semantic interoperability between the electronic health records. Attributes, terms, concepts or data of the same name may have different meaning and interpretation in different systems, and the information system itself cannot discern them.

Although considerable research has been devoted to discussion of semantic interoperability of Electronic Health Record, rather less attention has been paid to detail review of technical specifications on this topic. Some studies [Blobel et al., 2010; Mandl and Kohane, 2012] consider the challenges for achieving semantic interoperability and problems of current EHR systems based on previous research and experiences. Merruko [2013] has studied and reviewed plenty of case studies and reports on real world practices with open source EHRs. Reviews [Karlra, 2006; Begoyan, 2007; Blobel, Engel, and Pharow, 2006; Blobel and Pharow, 2009] on published electronic health standards have been conducted. These studies may not provide sufficient review on this topic and adequate guidelines to enable semantic interoperability.

1.1. Research Questions and Motivation

The reason for choosing this topic was my personal interest in eHealth . Healthcare is a promising field to enable and support well being of mankind. The expectation of making contribution to better health services for people motives me to conduct this

research. The purpose is to provide better understanding of semantic interoperability in current EHR systems and recommendations for future EHR systems.

In this research, following questions are studied:

- How is semantic interoperability enabled in EHRs today?
- How to enable better semantic interoperability in EHRs in the future?

1.2. Research methods and process

The research is conducted by literature review. The literature review covers semantic interoperability, EHRs and EHR interoperability standards.

Materials used in this research include articles, standard documentations, open source specifications and open source project materials. Articles have been acquired from databases in Web of knowledge and by Google Scholar. Some standards are not open access and require fee to acquire, therefore they have been e replaced by reviews on these standards. Health care product is usually proprietary and very expensive. It was not feasible for this study to acquire materials of commercial EHR products. Open source projects might be a replacement, but they were not considered comprehensive enough for the whole domain. Use of materials in relation to research questions in different study phases is presented in Table 1.

The research is conducted in three phases as an incremental process. In each phase, a research question is answered. The review on related concepts and issues is conducted in first phase. In the second phase, approaches for semantic interoperability in EHR systems are discussed to review on current development. In the third phase, the two approaches are compared and analysed to produce a conclusion and future suggestion.

Phases	Materials	Method	To answer
1	Articles, Standards	Literature review	What is semantic interoperability and EHR?
2	Articles, Standards, Open source materials	Literature review	How is semantic interoperability enabled in EHR systems?
3	Articles, Standards, Open source materials	Literature review	What can be done in order to provide better semantic interoperability in EHR systems?

Table 1. Use of materials in the three phases of the research

2. Semantic interoperability

2.1. Introduction

This chapter presents an overview on semantic interoperability. In general, semantic interoperability refers to common and precise understanding of information. In the context of eHealth semantic interoperability enables more future opportunities in health services as intelligent decision support and integrated care planning require semantic interoperability as their prerequisite because it enables local processing of shared data [Schloeffel et al., 2006].

Distributed health services for patients also require semantic interoperability, to ensure that the electronic health record of the patients can be shared in different locations and reused by different professionals.

Enabling semantic interoperability among information systems requires significant attention to details than enabling interoperability among people [Graybeal, 2009]. For example, it is very common to use translation when people are from different countries and they don't speak the same language. Good translation between languages requires semantic interoperability that ensures that the meaning is accurately expressed without misunderstanding. It is very difficult to achieve this goal with machine translator considering the complexity of cultural difference and uncertainty of human behaviour. Furthermore, machine translators are scarcely used in official occasions and they are not capable to replace human translators in near future.

2.2. Definition

Interoperability is defined as an "ability of two or more components to exchange information and to use the information that has been exchanged" [IEEE, 1991]. International Organisation for standardisation (ISO) defines semantic interoperability as "ability for information shared by systems to be understood at the level of formally defined domain concepts" [ISO/TR 20514, 2005]. In other words, semantic interoperability is a means to ensure that the information exchanged between systems makes sense [Heiler, 1995].

In order to understand the essence of semantic interoperability, a deeper look is concentrated on the underlying prerequisite - what is the basis for semantic interoperability.

There are different classifications of interoperability, as well as various interoperability levels in literature and standards. Considering various forms of perspective on heterogeneity in information systems and differences in machine-readable aspects of data representation, Ouksel and Sheth [1999] developed a

classification, which includes four levels of interoperability: semantic, structural, syntactic and system interoperability. However, they hardly discuss these four levels in detail. ISO [ISO/TR 20514, 2005] defines the two main levels of interoperability: functional and semantic interoperability. They are classified by whether machine could understand the information that is exchanged between systems. In addition to the four levels of Ouksel and Sheth [1999], Blobel et al. [2010] put organisations/service interoperability in their classification, but organisational or business is no the main concern of basic point-to-point information exchange.

In the following, a common three levels classification of interoperability in information systems (Table 2) is discussed. The levels are classified based on whether the information can be understood by actual users or machines:

a) **Syntactic interoperability**: The information between different components, systems or organisation can be exchangeable. It does not require special involvement of human [IEEE, 1991]. From the perspective of language, syntax can be considered as the grammar to convey semantics and structure. [Garde et al., 2007].
b) **Functional interoperability**: The semantics of the information or knowledge provided is explicit and can be analysed by domain experts [Garde, et al., 2007]. In other words, the end users should understand the meaning of the information exchanged between information systems.
c) **Semantic interoperability**: Apart from realizing functional interoperability, Grade et al. [2007] believe that it requires that the information system understands the semantics of information request and those of requesting information. The information requester and the information provider should have a common understanding of the "meaning" of the exchanging information [Heiler, 1995]. The information shared by systems should be understood at the level of formally defined domain concepts so that information is computer processable by the receiving system [ISO/TR 20514, 2005].

Interoperability Levels	Information can be understood by human	Information can be understood by machine
Syntactic Interoperability	no	no
Functional Interoperability	yes	no
Semantic Interoperability	yes	yes

Table 2. Interoperability levels

Semantic interoperability is not an all-or-nothing concept [ISO/TR 20514, 2005]. The degree of semantic interoperability depends on the level of agreement on terminology [ISO/TR 20514, 2005]. A higher level of agreement on ontology ensures a higher level of semantic interoperability as long as syntactic and structural interoperability are realized.

There is no definitive classification of interoperability levels but the levels presented here are used for further discussion below regarding EHR and EHR system (EHR-S).

2.3. Semantic interoperability in ontology – from data to understanding

Semantic interoperability plays an essential role in ontology, promoting common understanding among information systems.

The concepts of data, information and knowledge should be explained first, because they are fundamental concepts in information science [Virtanen, 2014]. It is difficult to find a definitive explanation to these concepts. However, according to Virtanen [2014], typically data is defined as 'a set of discrete, objective facts about events as structured records of transactions'. He uses a general definition of information suggested by Floridi [2011]. Virtanen [2014] describes the definition as following:

I is an instance of information if and only if:

1. *I* consists of one or more data;
2. the data in *I* are well-formed;
3. the well-formed data in *I* are meaningful;

From the second requirement of the definition, data in information are organized in a way that complies to the syntax of the chosen system [Virtanen, 2014]. The third requirement suggests that based on the well-formed syntax, the data within should be understandable. In other words, the data must contain semantics of the chosen system [Virtanen, 2014]. There is no generally accepted definition of knowledge, but there is classical philosophical definition, which sees knowledge as "justified true belief". In order to adequately process the information, human require knowledge to provide 'good' solution [Virtanen, 2014]. The knowledge in specific domain is represented in ontology that is "an explicit specification of a conceptualization" [Gruber, 1993].

Machines can manufacture products from raw materials. With same raw materials, some machines can produce the same products. These machines may not be the same and they could be different in types and models. The outcomes of these machines are the same nonetheless. Similarly, from the perspective of human cognition, in order to extract the meaning of a piece of information, people need to use their

knowledge to understand the information. In order to perceive the identical understanding, either people possess the same knowledge or the ontology handles the information in the same way by some means.

The interoperability levels discussed in the previous section correspond with the concept of data, information and knowledge: syntactic interoperability is achieved when the information complies with a commonly acceptable syntax. Functional and semantic interoperability require the same content of the information is preserved no matter where it is processed with knowledge. In the circumstance of people having different knowledge, one's own knowledge should be semantically interoperable to obtain the same content from the information from others (functional interoperability). The same pattern is applied on information systems when information system (machine) is able to process and understand information (semantic interoperability).

3. Electronic Health Record (EHR)

3.1. Introduction

The general purpose for EHR is to document and present patient data, care planning, care actions and care outcome. Besides its basic function of storing health record, the record can be further utilised for other purposes such as education and research. Promising future can be seen with the extensive use of EHR such as intelligent decision support.

EHR is widely used in developed countries and even in some developing countries. One of the widely acknowledged and used EHR related application is Picture Archiving and Communication System (PACS) with the standard of Digital imaging and communication in medicine (DICOM). However, PACS is very specific to the field of digital imaging and the EHR in this thesis is studied at more generic level and not limited to a single sub-domain of health care.

In this chapter, definition of EHR, the purpose of EHR, and definition of EHR systems are presented. The importance of semantic interoperability is also discussed.

3.2. Definition of EHR

Electronic health record is one of the most widely used applications in eHealth domain. According to ISO [ISO/TR 20514, 2005] EHR is a “repository of information regarding the health status of a subject of care, in computer processable form”.

Based on this generic definition, other common terms are used to refer to the EHR in the standard, including electronic medical record (EMR), electronic patient record (EPR), computerized patient record (CPR), electronic health care record (EHCR), electronic client record (ECR), virtual EHR, Personal health record (PHR), Digital medical record (DMR), clinical data repository (CDR), computerized medical record (CMR), population health record. However, EHR is primarily considered as electronic health record for integrated care (ICEHR), which is defined as [ISO/TR 20514, 2005]: “repository of information regarding the health status of a subject of care, in computer process-able form, stored and transmitted securely and accessible by multiple authorized users, having a standardized or commonly agreed logical information model that is independent of EHR systems and whose primary purpose is the support of continuing, efficient and quality integrated health care” .

Integrated care is usually delivered through multi-speciality and multi-disciplinary teams over an extended peroid of time [ISO/TR 20514, 2005]. Kodner & Spreeuwenberg [2002] discuss various meanings of the buzzword integrated health or

integrated care from different viewspoints. Some forms of electronic health record cannot be considered as ICEHR. For example, DICOM is not an ICEHR because its scope is only limited to digital imaging even though it contains information that can be used for integrated care. The EHR we study in this thesis is the ICEHR.

Figure 1 below demonstrates a categorisation of electronic health records. Basic generic EHR is classified into two categories of shareable and non-shareable EHR. Integrated Care EHR (ICEHR) is derived from shareable EHR by adding two of the most essential characteristics of the EHR: the ability to share health information, the primary role of the EHR in supporting continuing, efficient and quality integrated health care [ISO/TR 20514, 2005].

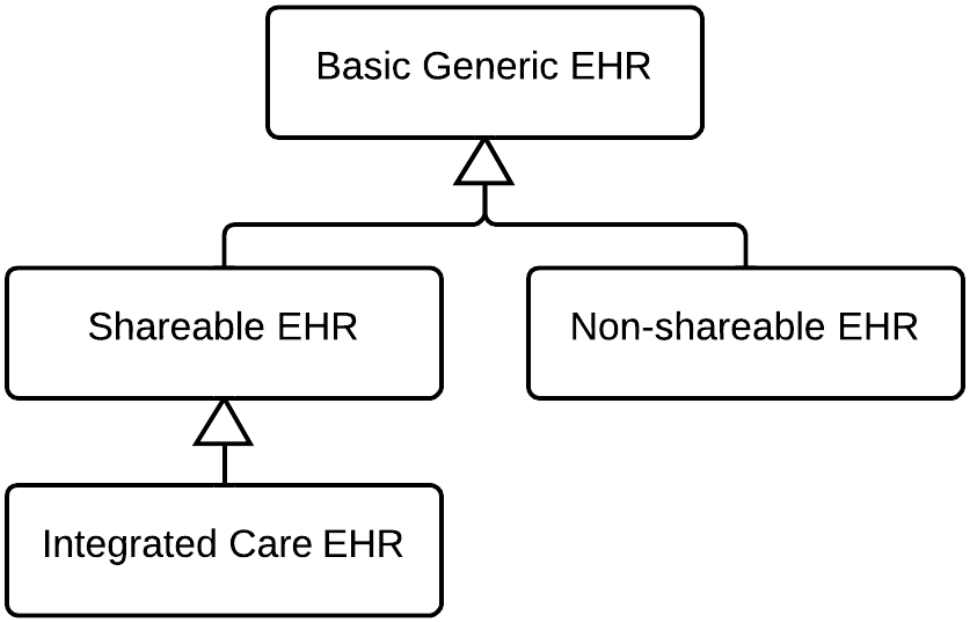

Figure 1. Specialisation of the basic-generic EHR [ISO/TR 20514, 2005, p. 7]

3.3. Purpose of EHR

Similar to the purpose of traditional paper-based health record, the primary purpose of the EHR is to "provide a documented record of care that supports present and future care by the same of other clinicians" [ISO/TR 20514, 2005]. Cooperation and collaboration among clinicians requires this document to be a media for patient's care [ISO/TR 20514, 2005]. The stakeholders of the primary use of EHR are only the patient and the clinicians [ISO/TR 20514, 2005]. EHR is primarily used between patient and clinicians. The primary purpose of EHR is very limited and EHR can be used for other purposes.

Other uses of EHR are derived from the primary use. ISO/TR 20514 [2005] considers these other purposes as secondary. The standard listed some secondary uses: medico-legal, quality management, education, research, public and population health, policy development, health service management and billing/finance/reimbursement. For educational purpose [ISO/TR 20514, 2005] health professionals and clinicians can be trained with sample EHRs. However, there are other purposes not listed in the ISO standard. Schloeffel et al. [2006] mentioned intelligent decision support and care planning as added-value applications of the EHR.

3.4. Core EHR, Extended EHR and their difference

The ICEHR is classified into the Core EHR and the Extended EHR in standards [ISO/TR 20514, 2005; ISO 18308, 2011]. These standards mention three important concepts in information system: information, knowledge and inference. The term information and knowledge are discussed in previous chapters and inference refers to use of knowledge to infer or deduce additional information about an entity or an individual [ISO/TR 20514, 2005].

The core EHR is essentially concentrated on primary purpose of the EHR and it is mainly concerned with clinical information [ISO/TR 20514, 2005], whereas the extended EHR includes the core EHR and additional functions, which are categorized into the secondary purposes discussed earlier. The extended EHR contains clinical information and the inference of information by the use of knowledge [ISO/TR 20514, 2005]. The extend EHR may contain information and knowledge, while the core EHR only contains information [ISO/TR 20514, 2005].

3.5. Where is the EHRs used?

The organisation of health services varies in different countries and cultures, but in general it is divided into primary care, secondary care, tertiary care [Häyrinen, Saranto, & Nykänen, 2008]. According to a glossary published by World Health Organisation (WHO) [2004], primary care is “basic or general health care focused on the point at which a patient ideally first seeks assistance from medical care system”. Primary care services are usually provided in the community e.g. in Finland [Häyrinen, Saranto, & Nykänen, 2008]. Secondary care is provided by a specialist facility, usually with a referral from the primary care [Häyrinen, Saranto, & Nykänen, 2008; WHO, 2004]. Tertiary care is highly specialized services in a major hospital [Häyrinen, Saranto, & Nykänen, 2008]. Health service can also be divided depending on whether it is in private sector and public sector.

EHRs are used in such varying and different environments that it is very difficult to make EHRs interoperable among health care services in different levels, sectors and departments.

3.6. Users of the EHRs

The users of the EHRs are very heterogeneous. In the review conducted by Häyrinen, Saranto and Nykänen [2008], they identify the EHR user groups: health care professionals, administrative staff, and patients. Among the health care professionals, there are physicians, nurses, radiologists, pharmacists, laboratory technicians and radiographers [Häyrinen, Saranto, & Nykänen, 2008]. Patients may be granted access and participation to the EHRs, but this depends on different medical settings and on the national legislations. Furthermore, people related to the subject of care can also be the users such as parents of minors [Poter et al., l, 2000]. There are other health care professionals, which are not listed in the review, such as students, and researchers who also use EHRs in education system [Elliott, Judd, & Mccoll, 2010].

The EHR used by health care professionals, administrative staff and patients are different in context, and currently the heterogeneity seems to be insurmountable. According to the discussion on the concepts of data, information, and knowledge, the three groups are very unlikely to possess a similar knowledge to understand the information in the EHR. It is very challenging for a patient who knows little about health care to understand what a health professional writes in an EHR, especially with a specific medical terminology that it very unlikely to seen in daily life. Enabling semantic interoperability in EHRs should contribute to solve this problem.

3.7. EHR systems

As it is mentioned earlier EHR systems use EHR to support health care service. There are plenty of EHR related systems using generic EHR running all around the world. For instance, Hospital Information System (HIS), which deals with health information mainly concerned with the needs of hospital, can be seen even in many developing countries. Picture Archiving and Communication System (PACS) are widely used in Teleradiology for medical imaging.

The definition of EHR system can be found in many standards [CEN/ISO EN13606, 2008; ISO 18308, 2011; ISO/TR 20514, 2005], research [Karlra, 2006] and organisation [HL7, 2004]. EHR system is a “system for recording, retrieving and manipulating information in electronic health records” [ISO/TR 20514, 2005]. The definition is used in both United States and Europe research. Other definitions can be

found from US National Academies, Institute of Medicine (IOM) [Dick, Steen, & Detmer, 1997; Committee on Data Standards for Patient Safety, 2003].

EHR systems can be categorized into Local-EHR system, shared-EHR system, and EHR directory service system [ISO/TR 20514, 2005], but it is not standardized. Local-EHR system is usually maintained by individual health facilities and community-based health providers, while shared-EHR system is to facilitate integrated shared care within a community of care [ISO/TR 20514, 2005]. EHR directory service system does not contain EHR but a set of links to distribute EHR nodes [ISO/TR 20514, 2005]. Table 3 demonstrates the different characteristics in the three EHR systems.

EHR system type	Local-EHR system	Shared-EHR system	EHR Directory Service
Scope and purpose	Individual local health providers	Local care communities Regional or national	National Trans-national
Type of EHR	Non-shareable ICEHR	ICEHR	Index to ICEHR
Type of data	Detailed local data	Shared data	Meta-data index
Granularity of data	Fine	Coarse (selected or summary data)	N/A
Contributors and access to EHR	Local health providers	Local care community or extend community (regional/national)	N/A
Custodian/maintainer	Health Care Facility	Local health authority	Public health departments or similar

Table 3 EHR system summary characteristics [ISO/TR 20514, 2005, p. 24]

The EHR (ICEHR) enables the possibility of sharing information, whether information is sharable depends on many other factors. Hence, local-EHR system can also contain ICEHR as long as it complies with the definition of ICEHR, which is discussed previously.

The widely shared and interoperable EHR should not depend on the EHR systems technology [ISO/TR 20514, 2005]. The functional requirements of EHR systems depend on demands of the stackholders. No matter what kind of EHR system it ‘lives’

in, the 'future-proof' EHR should be interoperable among numerous different EHR systems.

3.8. Semantic interoperability as a requirement of the EHR system

Semantic interoperability is a very important requirement for advanced EHR systems. According to Sommerville and Sawyer [1997], requirements are:

"Specification of what should be implemented. They are descriptions of how the system should behave, or of a system property or attribute. They may be a constraint on the development process of the system."

Typically, requirements can be functional or non-functional. Functional requirements specify what the system and its component should do. Non-functional requirements are those who describe the constraint of a system. As it is mentioned above, interoperability is a non-functional requirement that depicts the level of ability of a system to exchange information between other systems.

By enabling semantic interoperability, the EHR system can support better functionality in processing information of the EHR. Häyrinen, Saranto and Nykänen [2008] identify the studied and used components of EHR system: referral, present complaint, past medical history, life style, physical examination, diagnoses, tests, procedures, treatment, medication and discharge. The features of these components are supported by semantic interoperability. Usually these components are built into an EHR system, in which each component shares a common ontology. In other words, components within an EHR system usually understand the information in the same way. However, when information is exchanged between two different EHR systems, semantic interoperability becomes very important because the two systems may have different internal approaches for these features. Relying on the standard approach, the SCIPHOX project which mainly focus on discharge and referral data exchange in Gemany enables a high degree of "shared semantics" and realizes "a compromise between local specialization and global generalization". [Heitmann, Schweiger, & Dudeck, 2003]

Semantic interoperability also contributes to the implementation of quality requirement. Hoerbst & Ammenwerth [2010] identify and investigate some quality requirements in EHR: transparency and honesty, reliability, efficiency, usability and accessibility, maintainability and portability. CEN/ISO 13606 is designed to enable semantic interoperability in the electronic health record communication [CEN/ISO EN13606, 2008]. In implementing security, Sucurovic [2007] comments that the two-layer (dual model) methodology in part3 of CEN/ISO 13606 is sufficient to define access right precisely thus contributes to security.

3.9. Enabling semantic interoperability of EHR

Four prerequisites to achieve semantic interoperability are specified in ISO/TR 20514 [2005]:

1. **A standardized EHR reference model**, i.e. the EHR information architecture, between the sender (or sharer) and receiver of the information.
2. **Standardised service interface models** to provide interoperability between the EHR service and other services such as demographics, terminology, access control and security services in a comprehensive clinical information system
3. **A standard set of domain-specific concept models**, i.e. archetypes and templates for clinical, demographic and other domain-specific concepts;
4. **Standardized terminologies** that underpin the archetypes. Note that this does not mean that there needs to be a single standardized terminology for each health domain but rather, terminologies used should be associated with controlled vocabularies.

The first two are also required by functional interoperability [ISO/TR 20514, 2005]. Many approaches, including HL7, ISO 13606, openEHR, follow and utilise these four prerequisites in enabling semantic interoperability in EHR and EHR systems.

3.10. Discussion

Semantic interoperability is an essential quality and requirement of the future-proof EHR and EHR systems. It is the prerequisite of the implementation of a national-wide and further international EHR systems.

Semantic interoperability promotes common understanding on the EHR. As it is discussed, ontology (knowledge of specific domain) should be interoperable to some extent in order to achieve the original understanding of information from an EHR. Interoperability can be enabled in different levels, in different scopes and among different users. The interoperability can be achieved on syntactic, functional and semantic levels. In semantic level, machine should be able to understand the semantics of the EHR. The scope can be local, community, provincial, state, national, or international. Different health professionals may have different ontologies in their own health domain.

Extended uses of the EHR require semantic interoperability to preserve and extract the accurate meaning of the EHR. The requirements of EHR systems are not limited to the features of the core EHR. Semantic interoperability ensures the information are correctly understood and precisely inferred to secondary uses. Extended

uses can be functional (invoicing, education, etc.) or non-functional (security, access control, usability, etc.) requirements in the EHR systems.

4. Standards and organisation that contributes to semantic interoperability

4.1. Introduction

In last decades electronic health information systems have been under a continuously development. Many organisations and researchers have put countless efforts in promoting eHealth. US-based Health Level 7 (HL7) and Europe-based openEHR are among the most influential and active organisations currently around the world. Standards, specification and documentation developed by the two organisations are widely used all around the world. Although they share the same goal as promoting interoperability in eHealth domain, differences between their outcomes (specifications, standards, etc.) seem impede the interoperability among EHRs and EHR systems across the approaches of these two organisations.

In this chapter, the organisation, development, goals and focuses of HL7, openEHR and ISO Technical Committee 215 Health Informatics (ISO/TC 215) are first introduced. After the introduction, a series of standards under the influence of HL7 and openEHR are selected according to their relationships to semantic interoperability. This chapter only provides introduction to these standard, further details are discussed in other chapters.

4.2. HL7 organisation, openEHR community and ISO/TC 215

The official website of HL7 [HL7, 2015] defines HL7 as:

"Founded in 1987, Health Level Seven International (HL7) is a not-for-profit, ANSI-accredited standards developing organisation dedicated to providing a comprehensive framework and related standards for the exchange, integration, sharing, and retrieval of electronic health information that supports clinical practice and the management, delivery and evaluation of health services. HL7's 2,300+ members include approximately 500 corporate members who represent more than 90% of the information systems vendors serving healthcare."

Excluding the propaganda, the organisation is mainly focused on producing a comprehensive framework and standards that can be applied in electronic health information and are commonly used in the world. Currently HL7 standards are grouped into 7 sections [HL7, 2015]: Primary Standards, Foundational Standards, Clinical and Administrative Domains, EHR profiles, Implementation Guides, Rules and References, and Education & Awareness. These standards are not totally available to public and

some parts of these standards require a subscription fee. HL7 also organizes meetings, training, conference, workshops and related activities around the world.

As it is introduced in its official website [openEHR Foundation, 2014]: "openEHR is a virtual community working on interoperability and computability in e-health. Its main focus is electronic patient records (EHRs) and systems."

The focuses of the two organisations are mainly on electronic health domain though HL7 seems to reside in a larger sphere of health care information system. The common goal of the two organisations is to promote interoperability. There is a set of organisations within openEHR as well, which include four programs: Specification Program, Clinical Models Program, Software Program and Localisation Program.

Unlike HL7, openEHR is a community because its specifications are free and open to public and everyone can participate in the community without a charge. OpenEHR is not a standardisation body so it does not produce standard. However, many international standards [CEN/ISO EN13606, 2008; ISO/TR 20514, 2005] are highly influenced by this organisation. In addition, the community also develops implementations of EHR in different programing languages, while HL7 only provides specific guidelines for implementation.

The peak standardisation body for EHR and other health informatics standards [Health Level Seven, 2004] created in 1998 is ISO/TC 215 which has published 129 standards at the time of this research. Work groups related to this research are listed:

- ISO/TC 215/CAG 1 Executive council, harmonization and operations
- ISO/TC 215/WG 1 Architecture, Frameworks and Models
- ISO/TC 215/WG 2 Systems and Device Interoperability
- ISO/TC 215/WG 3 Semantic content

HL7 and openEHR have strong influence on ISO technical committee on health informatics (ISO/TC 215) and its published and developing standards. The work groups of ISO/TC 215 develop some de novo standards (e.g. ISO 18308 – Requirements for an EHR Architecture), but they also used and adopted many other existing standards from other national (e.g. CEN/EN 13606) and international standards (e.g. HL7 standards, DICOM) as at least a starting point for an ISO standard [Health Level Seven, 2004]. CEN and HL7 have special agreements with ISO that their existing standards can be fast-tracked to become ISO standards. For example, CEN/ISO 13606 are adopted from its original standard EN 13606 that is based on openEHR methodology from Europe and Reference information model (RIM), as the core of HL7 version 3, is published as ISO/HL7 21731.

4.3. The international standards related to interoperability of EHR

There are hundreds of standards and specifications in the health informatics domain. Notably, According to Begoyan [2007], European Standardisation Committee (CEN) and its Interoperability working group IV within Technical Committee 251 (CEN/TC 251) list the standardisation bodies responsible for EHR: International Standardisation Organisation (ISO), European Committee for Standardisation (CEN), Health Level seven (HL7), and Digital Imaging and Communications in Medicine (DICOM). OpenEHR has a significant influence on the development of EHR standards by the first three international standardisation development organisations [Schloeffel, Beale, Hayworth, Heard, & Leslie, 2006].

The following standards are selected for this study because they are most related to interoperability of EHR and systems: EHR Definition, Scope and Context (ISO/TR 20514), Electronic Health Record Communication (ISO 13606), Requirements for an EHR Architecture (ISO 18308), HL7 version2, and HL7 version3.

4.3.1. ISO 18308 Requirements for an EHR Architecture

This standard "defines the set of requirements that shall be met by the architecture of systems and services processing, managing and communicating electronic health record (EHR) information" [ISO 18308, 2011]. The purpose of the standard is to ensure that "EHRs are faithful to the needs of healthcare delivery, are clinically valid and reliable, are ethically sound, meet prevailing legal requirements, support good clinical practice and facilitate data analysis for a multitude of purposes" [ISO 18308, 2011]. The standard analyses EHR business objectives, and defines the requirement for the representation of clinical information, communication and interoperability requirements, ethical and legal requirements, and fair information principles.

The standard contributes to the governance of EHR information within EHR systems [ISO 18308, 2011]. It is expected that the standard does not specify the full set of requirements of an EHR system. According to the discussion of Core EHR and extended EHR in this research, the requirements in ISO 18308 reflects the primary uses of the EHR and some of its secondary purposes. It is difficult to define the whole set of requirements because the derived uses of EHR are widespread in the health domain.

It is "intended to be used when designing the architecture of health information services that incorporate or interact with EHR systems or repositories" (ISO 18308, 2011). A conformance statement [Beale, ISO 18308 Conformance Statement, 2006] of this standard was produced by openEHR in order to describing conformance of openEHR architecture to the standard. A separate and complementary standard

ISO/HL7 10781, the HL7 EHR-S functional model, which defines the requirements of individual EHR systems [ISO 18308, 2011], is discussed in the later sections.

4.3.2. ISO/TR 20514 Electronic health record-Definition, scope and context.

ISO/TR 20514 standard (Technical report) defines generic EHR and ICEHR, discusses the scope of EHR (Core EHR and extended EHR) according to ISO 18308, and describe the context of the EHR in the health domain. Additionally, a brief discussion of EHR systems is included as supplement information. As one of the de novo standard produced by ISO/TC 215, the standard was written in a generic and impartial way that does not specifically refers to archetype methodology of openEHR or HL7 standards. Some details of the standard are discussed in the previous chapter.

4.3.3. ISO/HL7 10781 Electronic Health Record-System Functional Model

The topic of this standard has changed from the one of the previous two standard from EHR to EHR systems (EHR-S). HL7 functional model is intended to provide a summary understanding of functions that are possibly presented in an EHR-S and consistent description of system functionalities [HL7, 2004; HL7, 2015]. In other words, it provides not only a systematic documentation of possible EHR system functional requirements but also the method to produce and document these requirements. The standard use a hierarchy that ensure the requirements are well organized and extendable at the same time.

The standard documents some requirements that support semantic interoperability. For example, in section T1.4 of the requirement list in the functional model, A Function named Standard Terminology and Terminology Services is identified, which support the consistency of human and machine interpretation of shared data and reports [HL7, 2014].

4.3.4. ISO 13606 Electronic Health Record Communication

EN/ENV 13606 is the pre-standard of the CEN 13606 standardised by CEN/TC 251. ISO/TC 215 later adopted CEN 13606 and the standard becomes ISO 13606. EN 13606 Association currently supports the maintenance of the CEN/ISO 13606 standard. ISO 13606 is a set of standards that is designed to achieve semantic interoperability in the electronic health record communication [ISO 13606-1, 2008]. The goal of the standard is to “define a rigorous and stable information architecture for communicating part or all of the Electronic Health Record (EHR) of a single subject of care (patient)” [ISO 13606-1, 2008]. Currently, the standards are published separately in five parts in ISO:

- ISO 13606-1:2008 Part 1: Reference model

- ISO 13606-2:2008 Part 2: Archetype interchange specification
- ISO 13606-3:2009 Part 3: Reference archetypes and term lists
- ISO/TS 13606-4:2009 Part 4: Security (Technical Specification)
- ISO 13606-5:2010 Part 5: Interface specification

The standard uses a generic technical approach that is based on the practical experience obtained from its precedent ENV 13606 and HL7 version 3 [ISO 13606-1, 2008]. Originated from openEHR, the Dual Model approach (Reference Model and Archetype) is adopted from ENV 13606 [2008] in a generic form that is compatible with HL7 v3. Part 4 addresses those security issues pertaining to EHR communications. Part 5 describes the information architecture, which enables interoperable communications between systems and services that request or provide EHR data [ISO 13606-5, 2010].

4.3.5. ISO/HL7 27931 HL7 version 2 Messaging standard

Arguably the most widely implemented standard for healthcare in the world is HL7 [Health Level Seven, 2015], HL7 version is still under support and development after its first approval by ANSI in 1996 [HL7 version 2.7, 2011] despite of the advent of HL7 version 3. HL7 not only provides the standard itself, but also the implementation guides and other support documents. Although American National Standards Institute (ANSI) has approved the latest version of the standard, ISO only adopted version 2.5. Its significant influence is not limited to USA because it has been used in more than 35 countries [Health Level Seven, 2015].

HL7 v2 is designed to make sure that the communication is feasible, but it does not guarantee that the clinical information in EHR is semantically interoperable. According to the standard [HL7 version 2.7, 2011], the purpose of HL7 v2 is to “serve as a way for inherently disparate applications and data architectures operating in a heterogeneous system environment to communicate with each other”. It ensures syntactic interoperability but not the higher levels of interoperability. HL7 version 3, using a different approach, tries to promote interoperability to a higher level in health domain.

4.3.6. ISO/HL7 21731 HL7 version 3 -- Reference Information Model

Regarded as the backbone [Smith & Ceusters, 2006], critical component and cornerstone [Health Level Seven, 2015] of the whole HL7 version 3 standard Reference Information Model (RIM) is the root of all information models and structures

developed as part of the version 3 development process [Health Level Seven, 2015]. Approved by ANSI in late 2003the RIM was adopted and published as an ISO standard in September 2006 [HL7, 2015].

A set of HL7 versions is produced on the basis of HL7 RIM, including HL7 Clinical Document Architecture. The RIM, along with Data Types and Vocabularies are the foundation for all information modelling within HL7. In order to describe the larger picture of HL7 methodology, details and content of this standard are discussed later in this chapter.

4.3.7. ISO/HL7 27932 HL7 Clinical Document Architecture, Release 2

Listed as the primary standard by HL7 and approved by ISO and ANSI HL7 Clinical Document Architecture (CDA) is a document markup standard that specifies the structure and semantics of a clinical document for the purpose of exchange between healthcare provider(s) and patients (Health Level Seven, 2015; Dolin, et al., 2006). According to Dolin, et al. [2006] HL7 CDA Release 1 is the first specification derived from HL7 Reference Information Model and its second release has evolved from Release 1 with its basic model unchanged.

HL7 CDA is not a standard for messaging. The exchange of HL7 CDA document is not specified in the standard, but it can be exchanged using HL7 message or other transport solutions [Dolin, et al., 2006]. HL7 CDA document is a form of information that includes clinical data, and CDA itself is the structure that encapsulates the data. The exchange of HL7 message is not limited to HL7 v2 or v3 messaging (Dolin, et al., 2006).

The details of this standard are discussed with the analysis of the HL7 version 3 methodology along with HL7 Reference Information Model, HL7 Data Types and other related HL7 v3 standards.

4.4. Discussion

The topic of semantic interoperability is discussed, considered and supported in these international standards. In ISO 18308 and ISO/HL7 10781 (HL7 FM), semantic interoperability is discussed and analysed as one of the requirements in EHR and EHR systems. Partially supported by HL7 v2, it is also the goal and purpose of CEN/ISO 13606 and ISO/HL7 27932 (HL7 CDA).

It is exhilarating that considerable efforts have been invested into this topic. However, overlaps and potential conflicts on these standards may impair semantic interoperability. It seems that there is no obvious conflicts between ISO originated standards and adopted standards. ISO 18308 and ISO/HL7 10781 (HL7 FM), both

describe requirements related to semantic interoperability, but their focus are concentrated on different entities: EHR and EHR-S. It is more noticeable that there are potential conflicts among ‘adopted’ standards when they are not so generic. For example, Oemig and Blobel [2011] address the issues of incompatibility between HL7 v2 and v3. The overlap of HL7 CDA and ISO 13606 is very obvious and HL7 is commented as approximately a subset of CEN 13606 (predecessor of its ISO version), with some minor differences [Schloeffel, Beale, Hayworth, Heard, & Leslie, 2006]. In order to discover potential conflicts and overlaps, especially among ‘adopted’ standards, the underlying methodologies have to be studied and revealed.

5. The Archetype Methodology

5.1. Introduction

The term archetype is mentioned, discussed, used, referred to and defined in many international standards (e.g. ISO 13606, ISO 20514, ISO 18308, HL7 version 3) and countless literature. In these standards the methodology is a recommended way of implementing EHR and EHR systems. Among the literature Beale [2002] provided a detailed discussion on the archetype methodology and a dual-model architecture in information system with actual examples in health and medicine. The methodology itself is constantly developing and evolving, and there are many variations adopted, developed, documented by different organisation, groups and people (e.g. openEHR, ISO, CEN).

In the first part of this chapter, the theoretical background of the methodology is introduced. The methodology is analysed, discussed and demonstrated. In the second part, architecture of current openEHR specification project is represented in order to demonstrate the methodology. In the final part, the latest standardisation of archetype methodology ISO 13606 is discussed and reviewed.

5.2. An earlier archetypes methodology

The archetype methodology is developed, extended and standardised in many standardisation entities (e.g. CEN, ISO, openEHR). Beale [2002] presented a systematic definition of the early archetype methodology. It is reviewed to present the purpose and the fundamental idea of this methodology.

5.2.1. Theoretical Background: information system and concepts

There are many definitions of information systems. In general, information systems collect, create, process, retrieve and manage information related to the real worlds. In order to present of the archetype methodology, Beale [2002] suggested that the purpose of information system is “the creation and processing of instances of concepts”.

The “concepts” here are described as entity types understood by the system [Beale, 2002]. In other words, real world entities are classified into different categories and the classifications are used by information system to process data. The “instances” here mean “occurrences of such types” [Beale, 2002] or simply data. According to the definition of information previously discussed in this thesis, the instances of concepts should be well formed and meaningful. Information systems are programmed to manage the data as information, which should be organized and understandable by the system and human.

5.2.2. The Single-model Methodology

Conventionally, when developing information systems, the domain concepts, which the system is to process, are hard-coded into its software and database models [Beale T. , 2002. Currently, a lot of systems are constructed in this way even with the advanced object-oriented techniques such as Unified Modelling Language (UML) [Beale, 2002]. As demonstrated in Figure 2 the system is first modelled with real world scenarios with domain concepts currently in use. The system is then implemented with the current model. For example, a *Person* class with a field called *Gender* is implemented in a software system. The developers first believed that there were two genders in the society, so they set the data type of *Gender* as *Sex* and allowed values of *Gender* as only male and female and programed this into the software system.

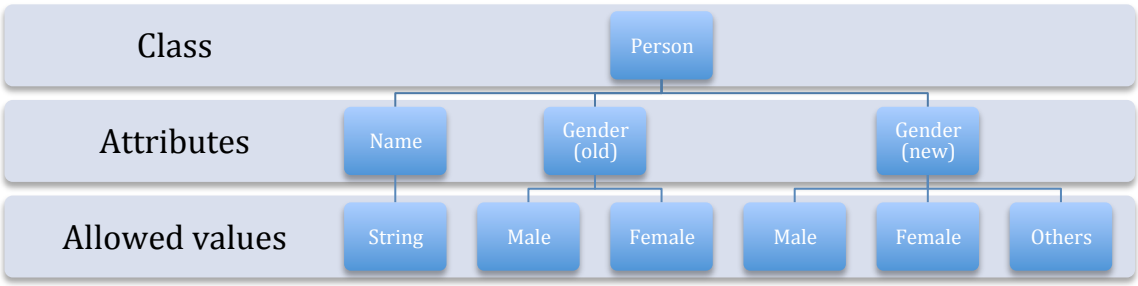

Figure 2 the changes of Gender field in Person class

In runtime system, the model is predetermined and the system can only process instances of the original concepts. Continuing from previous example, new understanding of Gender emerges, in which gender should not be limited to male and female. The concept of *Gender* has changed. A new allowed value of *Gender* is required in the software system. The developers have to update the *Person* Model and there is no other way but to update the *Sex* data type by coding the changes and redeploy the software. In Single Model methodology, changes in domain concepts cannot be implemented in runtime, so it leads to rebuild and redeployment of the system.

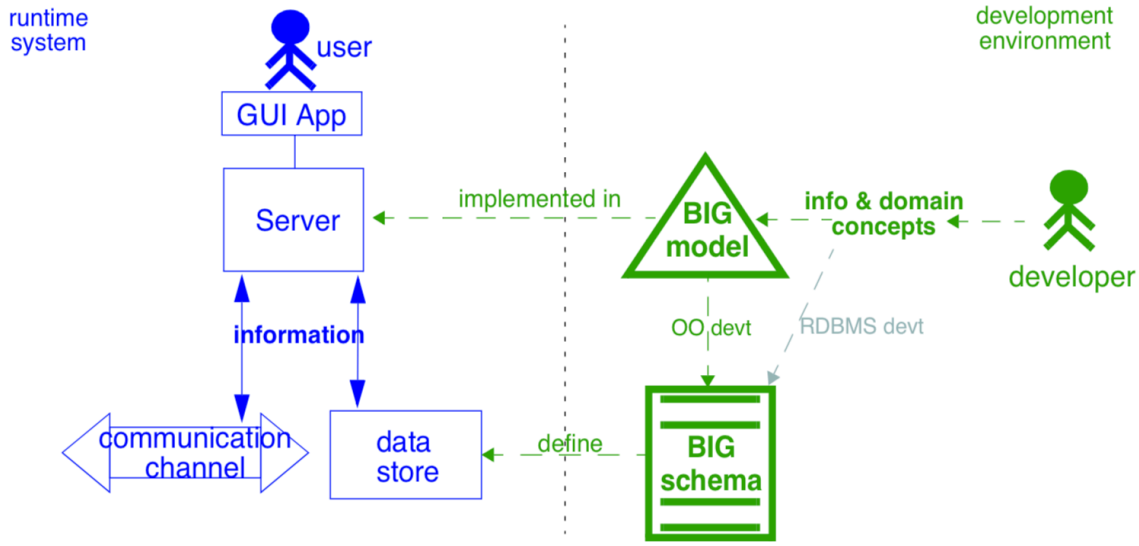

Figure 3 Single-model development [Beale T. , 2002, p. 11]

One of the problems of this approach identified by Beale [2002] is that interoperability is difficult to achieve. Old and new systems are using a different model. Different system must maintain the compatibility with other systems either by adapting their models or continually upgrading software converter or bridges [Beale, 2002]. There are possibilities for single model systems to achieve interoperability, but the level of interoperability generally degrades over time, because the systems have to follow differing local requirements [Beale, 2002] and changing concepts.

5.2.3. The Dual-model Methodology

In order to overcome the shortcomings of single-model methodology, the dual-model methodology was designed based on the core idea of "the separation of domain and technical concerns in information systems" [Beale, 2002]. Figure 4 illustrates an interoperable knowledge methodology, or dual-model methodology.

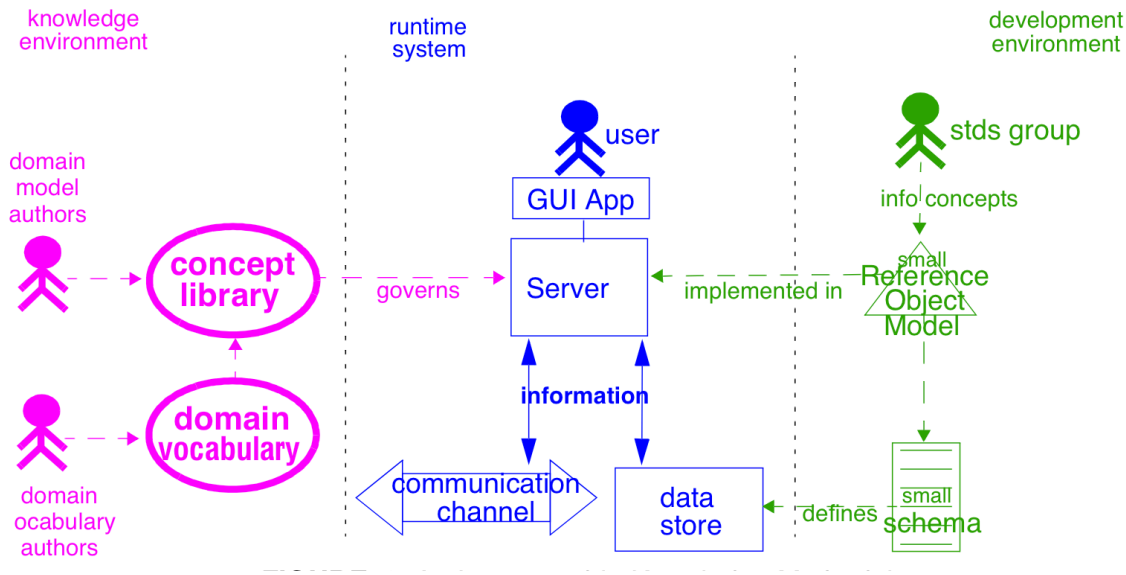

Figure 4 an interoperable Knowledge Methodology [Beale, 2002, p. 17]

In the development environment on the right side of the figure, a small reference object model (ROM) has replaced the hard-coded model in the single model methodology [Beale, 2002]. In the knowledge environment, domain concepts are maintained in a concept library separated from the software code by domain experts other than software developers [Beale, 2002]. Figure 5 below illustrates a possible ROM for *Person* class continuing from previous section. This model represents the basic and generic *Person* class with allowed values unspecified and support of other unknown fields. This abstract model should be implemented into software and the actual *Person* class from Figure 2 are used in runtime to specified attributes, data types and allowed values. The changes of *Gender* concepts in *Person* class can be updated by replacing the actual class with a new one. The actual class is called archetype in this methodology.

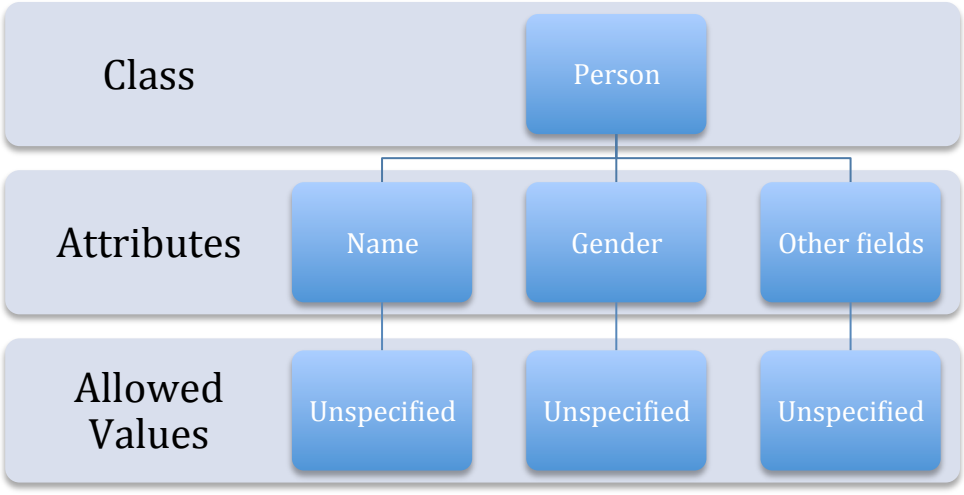

Figure 5 an abstract model of Person class in dual-model methodology

The methodology ensures that the information system can be implemented without domain modelling [Beale, 2002]. First, there is no direct dependence between domain concepts and ROM [Beale, 2002]. The ROM defines a basic structure of the data used in a system and domain concepts are formalized in archetypes, which are constraint models that correspond to ROM [Wollersheim, Sari, and Rahayu, 2009]. Second, domain experts govern the domain concepts by creating and changing the knowledge inherent in archetypes. The results of this process, archetypes, are used by the software system at runtime. Thus, the changes in domain concepts (knowledge) no longer result in rebuild and redeployment of the system.

5.3. Archetype Methodology in openEHR

Beale's contribution later turned into the specification programme of openEHR [Beale & Heard, 2007]. The organisation of openEHR was introduced in previous chapter. In this section, a deeper look into the specifications of openEHR is demonstrated.

5.3.1. Architecture of openEHR

The deliverables of the specification program are requirements, abstract specifications, implementation technology specifications, computable expressions and conformance criteria [Beale & Heard, 2007]. The abstract specification includes:

- Reference Model (RM): this model should be implemented in the software
- Archetype Model (AM): this model is used in runtime.
- Service Model (SM): this model includes basic services in health information environment.

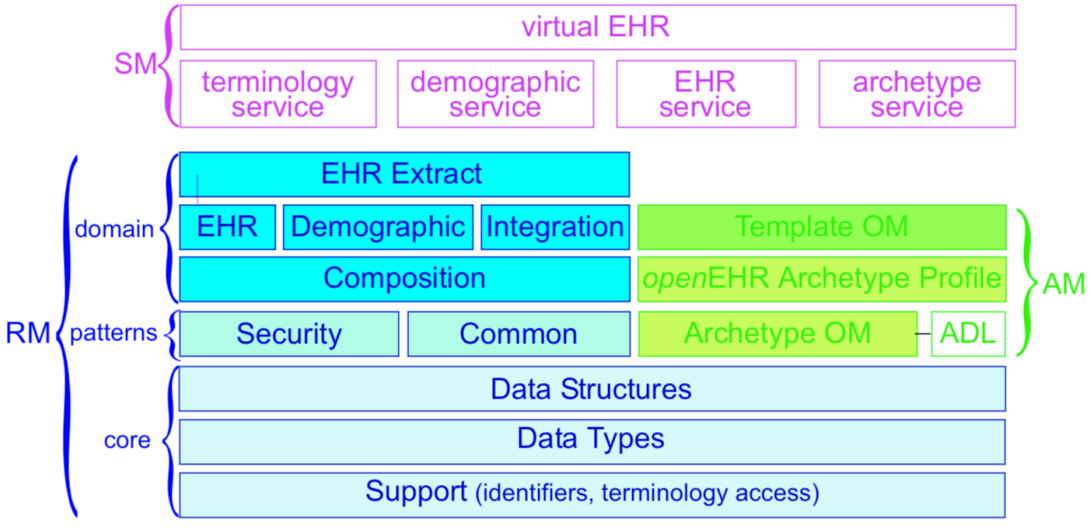

Figure 6 openEHR Package Structure [Beale and Heard, 2007, p. 21]

5.3.2. Dual-model in openEHR

Dual-model methodology is used in openEHR specification programme. Reference Model is implemented in software. The methodology makes it possible for clinician to send and receive medical information complied with the Reference Model [Garde, Knaup, Hovenga, and Heard, 2007]. Thus, it ensures syntactic interoperability [Garde et al., 2007]. Archetype Model enables semantic interoperability. An Archetype, instance of Archetype Model, represents domain knowledge that gives constraints to the medical information. It ensures that the information is understood in the same way.

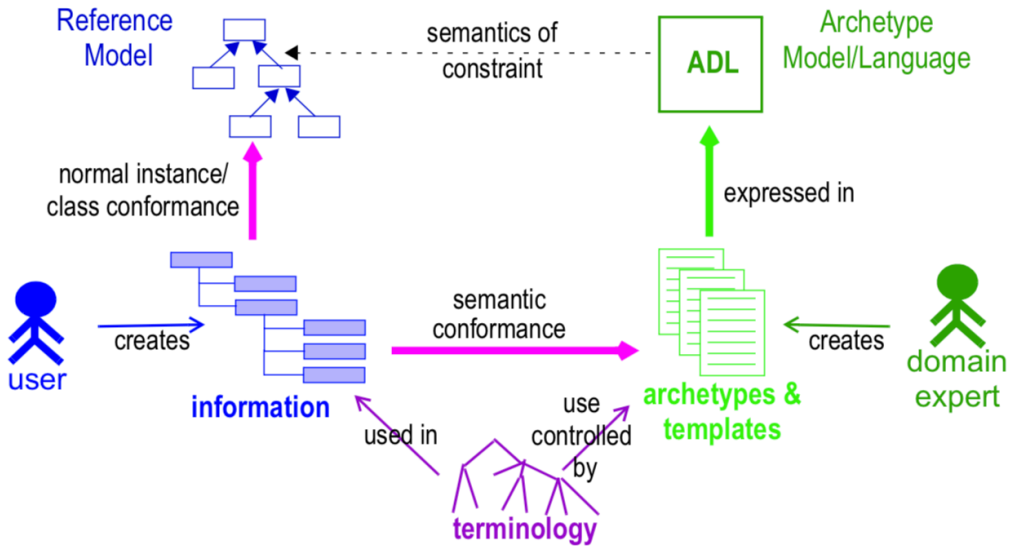

Figure 7 Archetype Meta-architecture [Beale & Heard, 2007, p. 16]

5.4. Archetype methodology in ISO 13606

ISO 13606 is the latest standardisation of archetype methodology at international level. There are noticeable differences in terms and definitions in representing the archetype methodology. ISO 13606 is based on a similar dual model as the earlier ones: a Reference Model that supports the information, and an Archetype Model to define knowledge (domain concepts) [Muñoz, et al., 2011]. ISO 13606 separates the openEHR specification in different parts. Security is solely taken out to discuss as the main focus in part 4 of ISO 13606. Some of the names of classes, attributes and data types are changed. ISO 13606 reorganizes openEHR classes, putting them into four packages: EXTRACT Package, DEMOGRAPHICS Package, SUPPORT Package and PRIMITIVES Package.

5.4.1. The Dual Model in ISO 13606

Part 1 of the standard (Reference Model) defines "basic generic components that support information and the relationships between those components" [Muñoz, et al., 2011]. A set of classes is used to represent these basic components and some other classes to support the hierarchy of the data structure. The Main classes are:

EHR_EXTRACT: the representation of part or all of the health record information related to the subject of care for the purpose of exchange [ISO 13606-1, 2008].

RECORD_COMPONENET: super-class of the main building block classes (FOLDER, COMPOSITION, SECTION, ENTRY, CLUSTER and ELEMENT) that used to construct the EHR_EXTRACT.

FOLDER: an optional class at the highest level of the hierarchy within the EHR_EXTRACT (ISO 13606-1, 2008). It groups COMPOSISTIONs by many conditions in various contexts [ISO 13606-1, 2008] such as episode of care and compartments of care [Muñoz, et al., 2011].

COMPOSITION: the set of medical information resulted from a single clinical encounter or record documentation session [ISO 13606-1, 2008; Muñoz, et al., 2011].

SECTION: medical information under one clinical heading reflecting flow information [ISO 13606-1, 2008].

ENTRY: single clinical statement.

CLUSTER: data structure organizing nested multi-part data such as tables, time series [ISO 13606-1, 2008].

ELEMENT: the leaf node of the EHR hierarchy, consist of a single data value [ISO 13606-1, 2008].

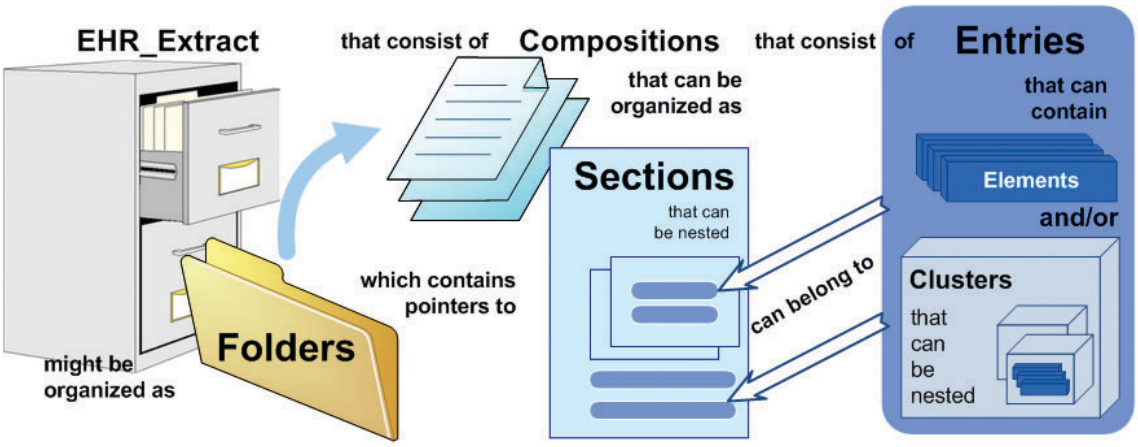

Figure 8. Component relationships of the ISO 13606 Reference Model [Muñoz et al., 2011, p. 14]

The Reference Model defines the basic components and hierarchical relationships between them [Muñoz, et al., 2011]. In other words, the possible ways of organizing EHR data is defined. This allows EHR systems to interpret information of this hierarchy. Thus, EHR data in this form is syntactically interoperable between systems conformed to the standard. However, this does not guarantee semantic interoperability because the Reference Model does not contain and define any knowledge (domain concepts).

The other part of the dual model is defined in part 2 of the standard (Archetype Model). Archetypes are:

"effectively pre-coordinated combinations of named RECORD_COMPONENT hierarchies that are agreed with a community in order to ensure semantic interoperability, data consistency and data quality" [ISO 13606-2, 2008].

An archetype represents part or all of the knowledge in a specific domain under specific contexts. In the Reference Model, there are attributes to specify the conformance of archetype to which RECORD_COMPONENT within an EHR_EXTRACT [ISO 13606-2, 2008].

Archetypes are not defined in ISO 13606, but archetypes should conform to the stable Archetype Model. The Archetype Model and the Reference Model are represented in the standard using Open Distribution Processing (ODP) Information Viewpoint Model [ISO 13606-2, 2008]. Archetype Definition Language (ADL) from openEHR as an optional archetype interchange format is also specified [ISO 13606-2, 2008].

Part 1 of ISO 13606 (Reference Model) defines attributes and their data types of classes in the References Model but does not give any specifications in allowed values of these attributes. Part 3 (Reference archetypes and term lists) specifies a normative set of (coded) term lists that define controlled vocabulary for these attributes [ISO 13606-3, 2009]. It also provides an informative set of reference archetypes originated from HL7 and openEHR. These reference archetypes are represented with mappings of original information to the ISO 13606 Reference Model.

In conclusion, the Reference Model defines the components of an EHR. An archetype specifies a way to organize these components. The term lists give detail constraints on data values in defining archetypes.

5.4.2. Other parts in ISO 13606

Security is one of the crucial issues in developing an EHR system. The EHR data interchanged between systems should be precise, complete and intact. Part 4 (Security)

describes a methodology for specifying the rights and privileges necessary to access EHR data and other general security requirement applying to EHR communications [Muñoz, et al., 2011].

The previous parts of the standard specify how clinical information is organized and specified in an EHR for the purpose of exchange, but the media of how EHR should be exchanged is also very important. In part 5 [ISO 13606-5, 2010], a set of interfaces for requesting access to the information and resolving the request are specified. These interfaces provides:

- An instance of EHR_EXTRACT (defined in part 1)
- One or more ARCHETYPE(s) in a formal language such as ADL
- EHR_AUDIT_LOG_EXTRACT (revision history)

The first interface provides health information in the form of EHR_EXTRACT. If the communicating systems use same set of archetype, which means they have the same knowledge, the systems can exchange EHR_EXTRACT syntactically and semantically. However, if the systems are not using the same archetypes, the semantics of the information in EHR_EXTRACT may not be understood by the receiving system. Sending archetypes in use before EHR_EXTRACT can solve this problem because the receiving system can use the archetypes provided by the sending system to interpret the information.

The interfaces here are provided without specifying or restricting particular engineering approaches to implement these as messages or as service interfaces.

6. The HL7 Methodology

6.1. Introduction

Among the standards produced by HL7, HL7 Clinical Document Architecture, Release 2 (CDA R2) is latest published approach to semantic interoperability in health information exchange. It is "a document markup standard that specifies the structure and semantics of clinical documents for the purpose of exchange" [Dolin, et al., 2006]. CDA is not a messaging standard like HL7 version 2. A CDA document including text, image, sounds or other multimedia content can be transferred within a message, but it does not bind to a specific message or service type [Dolin, et al., 2006]. HL7 CDA uses a different term to describe clinical information: clinical document. A clinical document is a documentation of clinical observations and service, with following characteristics: persistence, stewardship, potential for authentication, context, wholeness (integrity) and human readability [Dolin, et al., 2006]. HL7 CDA does not specify any internal structure of systems that handle, create, exchange or manage health information.

As a member of the HL7 version 3 family, CDA is developed from HL7 Reference Information Model (RIM) in the HL7 Development Framework (HDF), which control the development process [Dolin, et al., 2006]. The following artefacts are used to define CDA in the process:

- HL7 Reference Information Model (RIM)
- HL7 V3 Data Types
- HL7 Vocabulary Domains
- HL7 CDA Refined Message Information Models (R-MIM)
- HL7 CDA Hierarchical Description (HD)
- HL7 CDA XML Implementation (CDA Schema)

CDA can be constrained by additional rules defined in HL7 Templates. It is a similar pattern as archetypes constraining reference model in archetype methodology. HL7 Templates Standard is still under development at the time of this thesis, but a draft standard has been published in 2014 for trial use.

In this chapter, the aforesaid artefacts are reviewed for better understanding of the approach in defining the specification and uses of HL7 Templates in CDA. HL7 version 2 and other standards of HL7 version 3 including HL7 Development Framework (HDF) are excluded in reviewing because of the limits of the thesis.

6.2. HL7 Reference Information Model

As the "backbone" of the whole HL7 version 3 standards, all other version 3 standards are based on the RIM [Dolin, et al., 2006]. CDA, Release 2 is derived from HL7 RIM, Version 2.07. RIM is an abstract model comprised of six core classes:

- **Act**: actions that are executed and documented in health care activities (e.g. observation, medication, supply);
- **Participation**: role-playing entities in specific acts (e.g. author, performer, subject, witness) [Blobel, Engel, and Pharow, 2006]
- **Entity**: physical objects or the actors in health care domain (e.g. living subject, organisation, materials) [Blobel, Engel, and Pharow, 2006]
- **Role**: the roles that entities play in acts (e.g. patient, clinician)
- **ActRelationship**: relationships between acts
- **RoleLink**: relationships between roles

RIM defines the most generic classes in health care domain. HL7 CDA Refined Message Information Models (R-MIM) contains specializations that constraint the base classes in RIM for the purpose of clinical document exchange.

6.3. HL7 V3 Data Types and HL7 Vocabulary Domains

CDA, Release 2 uses the HL7 V3 Data Types, abstract specification and XML-specify data type representation. Every data element has a data type. Data types define the meaning (semantics) of data values that can be assigned to a data element. HL7 Data Types define "the structural format of the data carried within an RIM class's attribute and influence the set of allowable values an attribute may assume" [Dolin, et al., 2006]. The Data Types standard only defines semantics, independent from representational and operational concerns or specific implementation technologies. CDA use HL7 XML Implementation to represent data values.

For an attribute in a RIM class, the set of allowed values is called a vocabulary domain [Bakken et al., 2000]. For example, the vocabulary domain of a *gender* field can be Male, Female, and Unknown. The standard of HL7 Vocabulary Domains defines the set of allowed values of attributes in RIM. The purpose of using vocabulary domains in CDA is to strengthen the semantic understanding and computability in CDA documents [Bakken et al., 2000].

Lvl	Type, Domain name and/or Mnemonic code	Concept ID	Mnemonic	Print Name	Definition/Description
1	L: (FT)	16037	FT	Full-time	Employment in which the employee is expected to work at least a standard work week
1	L: (PT)	16038	PT	Part-time	Employment in which the employee is expected to work less than a standard work week

Table 4 EmployeeJobClass in HL7 Vocabulary Domains

The CDA supports external terminologies in its vocabulary domains. CDA vocabulary domains can use HL7-defined concepts in HL7 Vocabulary Domains, or other HL7-recognized coding systems such as Logical Observation Identifiers Names and Codes (LOINC) or Systematized Nomenclature of Medicine--Clinical Terms (SNOMED CT) [Dolin, et al., 2006]. This feature is realised by assigning a coding strength to each vocabulary domains in CDA [Dolin, et al., 2006]. The coding strength can be "Coded, No Extension" (CNE), in which case, only HL7-defined value sets are allowed; or "Coded, With Extension" (CWE), in which case, other values from external source may be used [Dolin, et al., 2006]. In order to use external terminologies, developers set additional allowed values of attributes in vocabulary domains with CWE coding strength.

6.4. HL7 CDA Refined Message Information Model

HL7 CDA R-MIM is one of the version 3 specifications that derived from the base HL7 RIM. The refinement process includes specialisation of HL7 RIM classes. HL7 V3 Data Types and HL7 Vocabulary Domains are also used in the CDA R-MIM development process. The specialisation may specify more restrictive attribute cardinality (HL7 Data Types) or further constraint on allowed vocabulary values (HL7 Vocabulary Domains) [Dolin, et al., 2006]. The CDA R-MIM is a graphical representation of CDA specification using HL7 conventions and notations.

The definitive description of the CDA R-MIM is included in the CDA, Release Two. A summarising description of a clinical document in CDA R-MIM is provided: "A CDA document is comprised of a header and a body. The header identifies and classifies the document; provides information on authentication, the encounter, the patient, and the provider; and sets the context for the document as a whole. The body contains the clinical report, and is conceptually divided up into nested sections, each containing a narrative block to be rendered along with structured entries and external references" [Dolin, et al., 2006]. It is interested that the class *ClinicalDocument* in CDA has a similar structure as the class *Composition* in Archetype methodology.

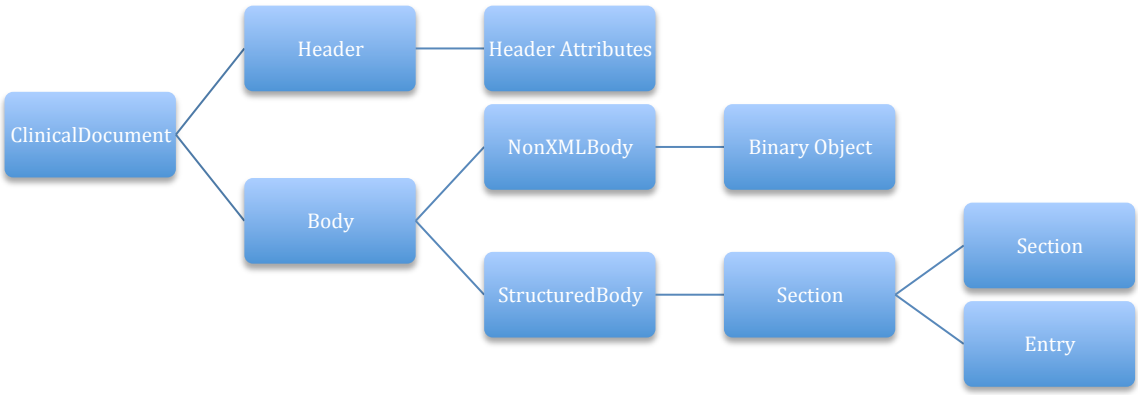

Figure 9 A simplified structure of the class ClinicalDocument

6.5. HL7 CDA Hierarchical Description and CDA XML Implementation

Derived from the graphical representation of CDA (R-MIM), CDA Hierarchical Description (HD) represents the specification in a tabular form and it defines the structure of a CDA document without dependency on any implementation technology (Dolin, et al., 2006). The definitive source for CDA conformance rules is CDA HD. The CDA conformance rules implemented in XML by HL7 XML Implementation Technology are called the CDA schema. CDA schema contains computable files written in XML.

CDA schema is used when CDA document is created and exchanged to assure that the documents created technically conform to the CDA rules. The information within a CDA document is created from the authoring system (e.g. electronic health records, medical devices) that generates the clinical information. The authoring system has to validate against CDA schema when creating the CDA document to ensure that

receiving system can acquire the document in the correct syntax conforming to CDA rules.

6.6. HL7 Templates

It is mentioned previously that CDA documents can be further constrained by HL7 Templates. It is worth mentioning that HL7 Template is different from openEHR Template that defines a tree of openEHR archetypes developed and used locally [Beale and Heard, 2007]. HL7 Templates is one of the HL7 Version 3 artefacts that can be used by other HL7 standards [Heitmann, et al., 2014]. It is not designed to be a standard inside the CDA but a framework that serves the whole HL7 version 3, while the current focus is mainly on CDA [Heitmann, et al., 2014]. The current HL7 Templates standard is still a trail version and is under ballot.

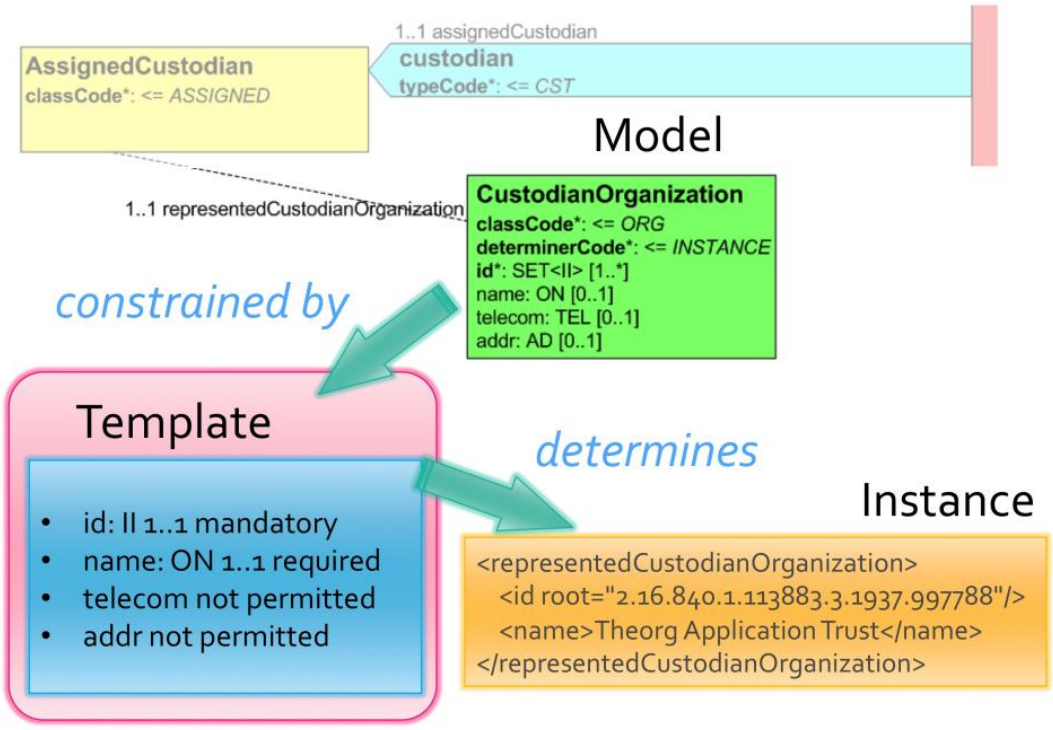

Figure 10 HL7 Model constrained by Template and Model Instance determined by Template [Heitmann, et al., 2014, p. 15]

A CDA document should be first validate against CDA schema, and additional constraints can be applied by conforming to one or more templates. Figure 10 illustrates the role of Template in creating an instance of a HL7 class. The structure and content of a conformant CDA document is determined by the template definition [Heitmann, et al., 2014]. Using the example in Figure 10, the *CustodianOrganization* class is defined in CDA R-MIM and additional constraints are specified in the template. Instances of the *CustodianOrganization* class must validate against *CustodianOrganization* model first

and conform to this template in this system. The example template specifies that *telecom* and *addr* is not permitted in the instances. The resulting instance does not contain information on the two attributes. In conclusion, the *CustodianOrganization* class is static but templates can be applied to further control instances.

7. The comparison of the two approaches from the semantic interoperability perspective

7.1. Introduction

In previous chapters the archetype methodology and HL7 CDA methodology were discussed and reviewed respectively. They share a similar goal of enabling semantic interoperability in health, medical or clinical information. It is obvious that the two approaches are developed in different scope, processes, organisations and many perspectives, but similarities can also be found.

In this chapter, the four prerequisites to enable semantic interoperability are used to evaluate the two approaches, some similarities of the two approaches are identified and current progress of harmonization is introduced. The comparison here is not complete due to many uncovered technical details from standards of both approaches and limits of this master thesis.

7.2. How they fulfil the prerequisites of semantic interoperability?

The two approaches use EHR and clinical document respectively to describe health, medical or clinical information they are using. It is safe to say clinical document is a subset of EHR. EHR and clinical document have similar characteristics such as security, persistence and stewardship. EHR includes all health information regarding a subject of care [ISO/TR 20514, 2005]. But clinical document only contains information related to clinical observations and service [Dolin, et al., 2006]. The internal structure of the Composition in Reference Model of openEHR corresponds closely to the levels in ISO 13606 and HL7 CDA [Beale & Heard, 2007]. Clinical document can be considered to be equivalent to Composition in archetype methodology according to the internal structure discussed previously.

The four prerequisites can be found in both approaches. It is very likely that archetype methodology can comply with the prerequisites because the prerequisites are defined in ISO/TR 20514 [2005] , which is referred by ISO 13606. Although HL7 CDA uses a completely different architecture and cannot fulfil the all prerequisites by itself, however some components of CDA as well as those of the whole HL7 standards can be used as alternatives.

7.2.1. A standardized EHR reference model

The Reference Model (ISO 13606-1, 2008) developed from the Reference Model of openEHR is definitively a standardized EHR reference model.

Reference Information Model (RIM) in HL7 version 3 seems to fit in this prerequisite but RIM is too abstract that it does not provide specific medical information architecture. HL7 CDA Refined Message Information Model (R-MIM) is another possible model to satisfy this prerequisite because it is derived from RIM and it represents the architecture of a clinical document that contains medical information.

7.2.2. Standardised service interface models

The Interface specification [ISO 13606-5, 2010] defines a set of interface for requesting health information, such as EHR. Some services such as querying an EHR or requesting the populations of EHRs are beyond the scope of the ISO 13606. It is not a complete set of service interface models providing health information.

HL7 version 3 message standards can be regarded as standardized service interface models. HL7 CDA does not contain any service or message specification, but exchanging CDA document in HL7 messages (version2 and version 3) is discussed in the standard. In HL7 version 3, CDA documents can be carried in any message that can exchange documents such as HL7 V3 Medical Records messages [Dolin, et al., 2006].

7.2.3. A standard set of domain-specific concept models

Achetypes can be considered as a standard set of domain-specific concept models. In archetype methodology, archetype conformed to the Archetype Model in ISO 13606 represents knowledge (concepts) in a specific domain [ISO 13606-2, 2008]. However, OpenEHR Template, which is a set of archetypes used locally, is not included in Archetype Model in ISO 13606 so it is not standardized.

Domain concepts are modelled in HL7 version as the Domain entries in HL7 Version 3. For example, HL7 Version 3 Standard: Blood, Tissue, Organ: Donation, Release 1 (2013) specifies the syntax and semantics (meaning) of information presented in the context of Blood, Tissue and Organ Donation. Some of these standards are accepted by ANSI while others are only trail version or under ballot.

7.2.4. Standardized terminologies

Both approaches have their own set of standardized terminologies. For ISO 13606, terminologies for Reference Model are defined in part 3 [ISO 13606-3, 2009], while terminologies in a specific domain are determined by an archetype. For HL7 Version 3, HL7 Vocabulary Domains specify terminologies used in RIM, and other version 3 standards including CDA.

References to external terminologies are available in both approaches. In ISO 13606, Archetype Model [ISO 13606-2, 2008] supports reference to external

terminologies as a constraint, so the external terminologies are specified in archetypes. In CDA, external coding system (e.g. SNOMED CT, LOINC) may be used to encode concepts in CDA documents by specifying *code* attributes with CWE coding strength in *Section* or *Observation* class.

7.3. Discussion

There are many discrepancies between Archetype methodology and HL7 methodology. It is impossible to identify all of them. Some of the differences which the author of this thesis discovered are listed:

Scope: Archetype methodology has a narrower scope than HL7 methodology. HL7 version 3 is designed for whole health domain and HL7 CDA focus on clinical document exchange under the big picture without addressing exchanging method. Archetype methodology shares a similar scope as CDA but its subject is EHR.

Architecture: The architectural differences between the two approaches are evident. Archetype Methodology uses a Dual-Model to separate technical and domain concerns. In an archetype-based system, Reference Model is implemented in software and archetypes used by the system are developed and maintained by health domain experts. While HL7 version 3 uses a multi-model approach aiming for a solution for the whole health information domain. HL7 Models are developed based on HL7 RIM in the process of HL7 Development Framework (HDF) for different purposes in different domains. These models are standardized in HL7 version 3, including domain specific models.

Terminologies: As previously discussed, the internal terminologies of two approaches are different though both support referencing to other terminologies, but their ways to achieve this is very different.

Domain Knowledge governance: Domain knowledge is managed in different ways between two approaches. Archetype approach enables creating and changing the knowledge in archetype by domain experts [Garde et al., 2007]. Archetypes need to be standardized for semantic interoperability between health areas and specialist fields, even between various organisations (Garde, Knaup, Hovenga, & Heard, 2007). Archetypes can be modified for local needs and conventions. However, HL7 specifies domain knowledge in standards (HL7 Normative Edition), which aims for global use with the ability to change according to local or regional requirements [Health Level Seven, 2015]. Domain knowledge is internationally specified in HL7 standards and some specifications can be chosen and modified for local uses. On the other hand, using archetypes is more flexible because archetypes can either be developed locally or adopted from standardised archetypes and

further customised. Archetypes can be used in runtime, while HL7 normative standards have to be implemented in software.

Implementation: Implementing the two approach is very different. HL7 standards are complicated with detailed specification but ISO 13606 is rather abstract. HL7 specifies details in domains in medical system such as HL7 Version 3 Standard: Blood, Tissue, Organ: Donation, Release 1 (2013). ISO 13606 does not define any archetypes, which means no domain knowledge is specified by the standard. W hen developing archetype-based system, archetypes are either locally developed or adopted from standardised archetypes. While implementing HL7-based system, developers have to choose from the version 3 standards that satisfy local requirements, and the chosen standards can be adapted for local uses [Health Level Seven, 2015].

Efforts have been put on harmonisation of the two approaches. ISO technical committee of health information (ISO/TC 215) promotes and tackles harmonization at the international level [Health Level Seven, 2014]. Among those standards related to ISO/TC 215, ISO 13606-1 [2008] includes mapping to HL7 version 3 in its Reference Model. ISO 13606-3 [2009] also provides some ISO 13606 archetypes examples mapping from HL7 version 3 classes. Standardisation developing organisations (SDO) also work together for better interoperability between standards. The Joint Initiative on SDO Global Health Informatics Standardisation [The Joint Initiative Council, 2015], working closely with ISO/TC215, CEN/TC251, HL7, DICOM and many other SDOs, aims to address and resolve issues of gaps, overlaps and counterproductive standardisation efforts. HL7, openEHR and EN 13606 Association, participate in the Clinical Information Modelling Initiative (CIMI). CIMI develops a central model repository (CIMI, 2015) that aims to provide consistent and correct health information models, Figure 11. In the repository, Models can be translated into different model formats, such as ADL, XML, and JSON. It provides a possibility of translating HL7 models into archetypes.

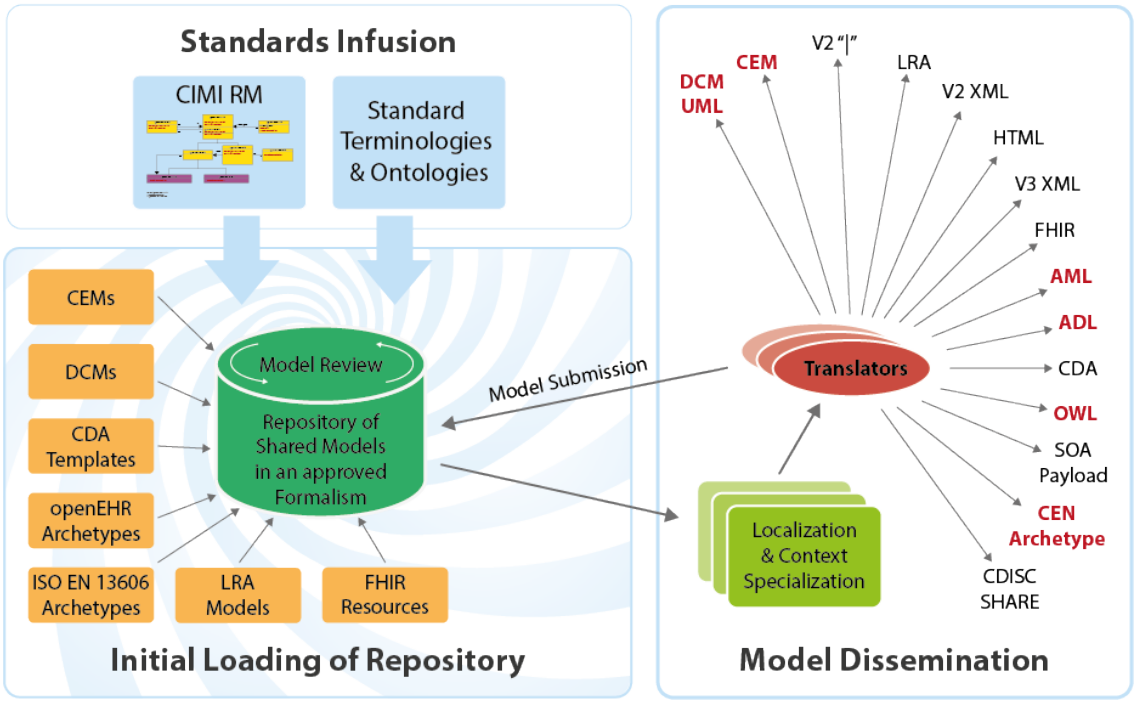

Figure 11 CIMI Model Development lifecycle (CIMI, 2015)

7.4. Conclusions

The very different approaches of Archetype methodology and HL7 methodology provide promising solutions to semantic interoperability of electronic health record. The prerequisites of semantic interoperability [ISO/TR 20514, 2005] can be fulfilled by the two approaches. Despite the various differences in architecture, terminology and knowledge management, the discrepancy can be alleviated and the two approach can cooperate with the continuously efforts on harmonization.

Although currently the two major approaches can respectively support semantic interoperability, it is difficult to determine which one is superior. The adoption of approach is influenced by many factors (policy, culture, health system, etc.) and further determined by local requirements. For example, HL7 standards are developed according to the western medicine practices, so it is obviously a ready-to-use option for health provider in the United States and other countries with similar medical system. However, HL7 cannot satisfy requirements of many other health and medical system, such as oriental medicine. Archetypes approaches with its flexible domain knowledge governance are more capable of tackle various and heterogeneous local requirements.

Higher level of semantic interoperability requires further harmonization of the two approaches. The identified differences demonstrate that currently the two approaches are incompatible. The current harmonisation is focus on a consistency of knowledge between the two approaches. Because t it is difficult to determine which one is superior, it is unlikely that one of the approaches will dominate in the near future.

There is no real semantic interoperability when existing systems using different approaches cannot cooperate.

Experiences may be found in similar scenarios in other industries. Various standards (e.g. EDGE, CDMA2000, W-CDMA, TD-CDMA and UMTS) of third generation (3G) of mobile telecommunications technology didn't hinder the prevalence of 3G technologies. For example, the technology that support phone call to numbers of other operators may be useful for harmonisation of the two approaches.

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