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Towards best practice in the Archetype Development Process

By

Alberto Moreno Conde

Supervisor:

Damon Berry

Trinity College Dublin

Center for Health Informatics

Department of Computer Science

DECLARATION

Student Name: **Alberto Moreno Conde**

Student Number: **08261630**

Number of Words: **≈ 25 000**

I declare that the work described in this dissertation is, except where otherwise stated, entirely my own work, and has not been submitted as an exercise for a degree at this or any other university.

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SUMMARY

The Archetype Development Process (ADP) is a technique where clinicians participate in order to define the structure of composite clinical concepts as they are used in an EHR system and the relationships between them. This process involves many actors with different backgrounds who collaborate to achieve a consensus in the definition of these clinical concepts. This dissertation aims to evaluate current initiatives based on archetypes and proposes actions to promote best practice in the Archetype Development Process.

This research proposes the Continuous Improvement Cycle as a process for quality management in the ADP. This is an iterative process composed by four stages (Plan-Do-Check-Act) to achieve the continuous refinement of the development process. Organisations plan their governance, organisational setting and archetype requirements. After they create, adapt and adopt archetypes to satisfy their needs for communication and check if these archetypes satisfy the Archetype Quality Criteria (AQC). The Act stage provides improvements based on continuous research in ADP methodologies.

Public repositories from England, Sweden, Brazil, Spain and Australia are examined. Among these initiatives, special attention has been paid to the openEHR approach because it is more mature, has a higher number of archetypes and provides detailed information about its organisational settings in the ADP.

The analysis performed within the openEHR Clinical Knowledge Manager shows that archetype editors are responsible for a large number of archetypes, the number of published archetypes is low and the number of archetypes assigned to the orphan team is around 95%. This situation suggests that there is a need to increase the size of the development community. It is important to note that archetypes in team review and draft stage are perfectly useful to facilitate communication between different EHR systems. They can successfully satisfy local needs in systems already implemented.

The archetype quality evaluation shows that OpenEHR CKM, results in very high quality published archetypes. These archetypes satisfy most of the requirements defined by EuroRec to evaluate the quality in the ADP. Although experts acting as archetype editors are responsible for a large number of archetypes, they have successfully preserved their quality.

The integration of educational resources, AQC and supporting material within development tools and archetype repositories is proposed to facilitate the learning process and ensure best practice. Additionally, there is a need for strategies to cover other parts of the clinical knowledge such as processes and decision support rules within the Clinical Knowledge Manager. In future, if DCM obtains the acceptance between the different organisations it could be possible to create a domain where experts can online define semantic requirements in a format that can be translated to openEHR, ISO/EN13606, LRA and HL7 CDA.

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ABBREVIATIONS

ADL	Archetype Development Language
ADP	Archetype Development Process
AIM	Advanced Informatics in Medicine
AM	Archetype Model
AQC	Archetype Quality Criteria
AQL	Archetype Query Language
ARR	Archetype Repository Requirements
ASTM	American Society for Testing and Materials
CC-BY-SA	Creative Commons Attribution- Share Alike
CCD	Continous Care Document
CCR	Continuity of Care Record
CDA	Clinical Document Architecture
CDS	Clinical Decision Support
CEN	European Committee for Normalisation
CKM	Clinical Knowledge Manager
CMET	Common Message Element Types
COPD	Chronic Obstructive Pulmonary Disease
CR	Business Requirements
CR	Clinical Requirements
DCM	Detailed Clinical Models
DICOM	Digital Imaging and Communications in Medicine
EHR	Electronic Health Records
EHRA	Electronic Health Record Architecture
GUI	Graphical User Interface
HIS	Health Information Systems
HL7	Health Level 7
HSE	Health Service Executive
ICD	International Classification of Diseases
ICT	Information Communication Technologies
IGR	Information Governance Requirements
IHE	Integrating Healthcare Enterprise
IHTSDO	International Health Terminology Standards Development Organisation
IXS	Identity Cross-Reference Service
KPI	Key Performance Indicators
LOINC	Logical Observation Identifiers Names and Codes
LRA	Logical Record Architecture

NEMA	National Electrical Manufacturers Association
NHS	National Health Service (United Kingdom)
ODMA	OpenEHR Data Modelling Approach
OMG	Object Management Group
OO	Object Oriented
PCC	Patient Care Coordination
PDCA cycle	PDCA cycle also known as Continuous Improvement Cycle is a four stage methodology that includes Plan, Do, Check & Act stages
PIX	Patient Identifier Cross Reference
RIM	Reference Information Model
RM	Reference Model
R-MIM	Refined Message Information Model
SDO	Standard development Organisation
SNOMED CT	Systematized Nomenclature of Medicine – Clinical Terms
SynOD	Synapses Object Dictionary
TC	Technical Committee
TR	Technical Requirements
TS	Technical Specification
UMLS	Unified Medical Language System
VistA	Veterans Health Information Systems and Technology Architecture
vMR	HL7 Virtual Medical Record
VTIM	Verksamhetsorienterad Tillämpad Informations Modell
WADO	Web Access to DICOM Persistent Objects
XCPD	Cross Community Patient Discovery
XDS	Cross Enterprise Document Sharing

CHAPTER 1: INTRODUCTION

1.1. INTRODUCTION

Since Electronic Health Records (EHR) systems have been introduced in hospitals and other healthcare providers to manage patient data, there is a need to organise the information that they contain. After more than 15 years of working in this field and different attempts of standardise this process, there are two approaches ISO/EN 13606 (ISO13606, 2008-2010) and OpenEHR (OpenEHR) that propose the archetype (Two Level Model) paradigm as new technique to transfer patient data between EHR systems.

In contrast to the old message paradigm, the archetype paradigm is more flexible and easily scalable because it provides the means to handle the knowledge evolution. This technology avoids reimplementation of systems, migrating databases and allows the creation of future-proof systems (van der Linden et al., 2009b) Advocates also mention its ability to record the patient information from the cradle to the grave (Freriks, 2007b).

Different national or regional Health Services have chosen to implement systems based on archetypes at a national or regional level. This is the case of Sweden where the Swedish authorities are building their Information Communication Technologies (ICT) national infrastructure based on the ISO/EN13606 standard (Swedish Association of Local Authorities and Regions, 2008). In the region of Minas Gerais (Brazil) the ISO/EN13606 standards has also be chosen to be implemented at regional level(Portal Público do Registro Eletrônico em Saúde, 2010). Moreover the National Health Service in United Kingdom has selected a profiled version of ISO/EN1606 called Logical Record Architecture (LRA, 2010) to be deployed at national level. The results from these and other projects created in Spain (Robles, 2009) and Australia (Gök, 2008) provide experiences of real systems already implemented based on the archetype paradigm that could even be applied in the deployment of ICT infrastructures at European level (Freriks, 2007a). It is aligned to the high interest of the European Commission in the creation of an interoperable EHR across member countries (E-Health Europe 2008).

Given an increasing acceptance of this new technology, this research is focused on providing a better understanding of the Archetype Development Process (ADP) by analysing it from different points of view and the outcome of this dissertation is intended to be useful for the scientific community for future archetype development.

The ADP is a technique where clinicians participate in order to define the relationships between concepts that are used in an EHR system. This is a long process that involves many actors with different backgrounds who collaborate to achieve a consensus in the definition of these clinical concepts.

The ADP can be affected by technical factors such as repositories and development tools. Moreover organisational settings and policies influence the ADP. This dissertation aims to determine of how these and other factors impact on the ADP in order to identify best practice and to establish a methodology that minimises the subjectivity of the process and maximises the quality of the archetypes developed.

1.2. MOTIVATION

Although archetype models were relatively recently (Beale, 2000) proposed as a tool for constraining the Reference Models for electronic health records , there are many initiatives and projects that have been implemented based on both OpenEHR and ISO/EN 13606 creating a considerable number of publications in the literature. The lessons learned from their experiences provide enough information to recognise how to increase archetype quality in the ADP.

Experienced practitioners in the art of archetype development (L. Sato, 2006, Kalra, 2008a) have identified the need to identify good practice in the Archetype Development Process (ADP). Quality measurements and guidelines are required to develop and implement archetypes and templates at a national scale.

Archetype modelling requires a methodology to minimise subjective influences such as personal context and background of the actors who are involved in the development process, as well as the organisational influences. A standard methodology in the ADP would facilitate agreement between multiple archetype editors and reviewers who define the "shape" of clinical knowledge in the EHR. For instance, there are areas such as the relationship between archetypes and terminologies or the selection between different Reference Model classes where concepts are closely related and archetype definition are likely to be confusing in the absence of standardised methodology.

Another benefit of implementing a methodology for archetype development is that novel archetype editors can easily learn the process. This is an important consideration because the community of developers is growing very fast. Moreover the resulting archetypes developed by the same methodology will be semantically consistent if the methodology is based on Archetype Quality Criteria (AQC).

1.3. RESEARCH QUESTION

This thesis aims to execute an evaluation of the Archetype Development Process

Best practice in the context of this work, involves the definition of quality for archetypes and the ADP:

- What are the requirements that must be satisfied by an archetype to affirm that it is a "good" archetype?
- How can be applied the AQC to the ADP?

In addition it is necessary to understand how different organisations develop archetypes:

- What is the current state of the ADP? This research aims to provide information about the pace of development and the maturity level of the current archetypes.
- What are the factors that impact on the ADP? This question includes organisational settings, policies, governances, community support, repositories and development tools.
- Why are there so few published archetypes?

1.4. GOALS AND OBJECTIVES

The dissertation has the following goals and objectives which are required to answer the questions stated above:

A. Examine current initiatives based on archetypes, especially those which have public access to their repositories.

B. Perform exhaustive analysis based on a selection criteria that identifies how the most representative archetypes have been developed including information about how the actors involved in the ADP are organised in different roles and their contribution.

C. Determine existing Archetype Quality Criteria (AQC) that could be applied as best practice in the ADP.

D. Identify how the organisation impact on the archetype status.

E. Study how archetypes that satisfy selection criteria evolve over time to determine how the time of development impact on their status.

F. Examine the quality level of archetypes that satisfy the selection criteria based on their performance against an Archetype Quality Criteria.

G. Study possible linear dependences between the average time of development and other factors involved in the ADP

H. Study the different archetype and template development tools.

I. Identify the published supporting material that can be applied to the ADP.

J. Understand the different approaches for EHR communication.

K. Propose actions that could be applied to improve the ADP based on the information obtained from previous objectives.

1.5. ORGANISATION OF THE RESEARCH

This document is organised in the following sections:

- Chapter 2 – Literature Review: presents a literature review that is divided in three sections one for each of three of the central concepts underpinning the work: *Electronic Health Record*, *Two Level Model* and *Archetype Development Process* (ADP). The chapter begins by describing the main characteristics of Electronic Health Records such as EHR architecture requirements, data types, terminologies and ontologies, interoperability levels and identity. Furthermore, it explains the Two Level Model and the differences between the ISO/EN 13606 and OpenEHR approaches. It summarises how these standards satisfy EHR architecture requirements and presents other standards that are related to EHR communication. Finally, the chapter presents what organisation, governance, methodologies, supporting material, repositories, development tools and other issues are applied in the ADP.

- Chapter 3 – Methodology: explains how multiple selection criteria are applied to study the organisational settings in the ADP, how archetypes evolve over time and archetype quality. Also this chapter describes relational databases created by the author in this research.

- Chapter 4 - Results: presents the results of the analysis performed on the archetypes in the OpenEHR Clinical Knowledge Manager (CKM, 2010). These results show how different actors interact in the ADP, it analyses the differences between *published*, *team review* and *draft* archetypes and evaluates the conformance of published archetypes to the requirements established by EuroRec (EuroRec, 2010).

- Chapter 5 – Evaluation: This chapter includes a summary of the findings, this information is applied to perform multiple evaluation of the ADP. In addition this chapter proposes a set of actions to improve the ADP.
- Chapter 6 Conclusions: The last chapter presents the conclusions of this work and limitations and future work.

CHAPTER 2: LITERATURE REVIEW

2.1.- THE ELECTRONIC HEALTH RECORD

2.1.1. WHAT IS AN ELECTRONIC HEALTH RECORD SYSTEM?

Electronic Health Record (EHR) Systems allow the integration of data from multiple sources. The information flows among the different hospital devices and departments. The patients receive better care because Electronic Health Record (EHR) systems integrate the patient data of many types including demographics, medical history, medication and allergies, immunization status, laboratory test results, radiology images and billing information (T. Handler, 2003). Moreover, EHR systems allow patient digital information to be accessed, while ensuring confidentiality and continuity of care. Furthermore other users who are interested in areas such as the educational, research or decision support services have access to the information to patient records with different levels of anonymity(Iakovidis, 1998).

2.1.2. EHR HISTORY: HOW HAS THE EHR EVOLVED?

In the late eighties, different initiatives around the world identified that the need to share patient information could be addressed electronically. At that time, we started a journey were technology has experienced a huge evolution, based on Moore's law, computers now are more than 100,000 times faster (Moore, 1965), our capability to store information has almost no limits when we implement a cluster where information is stored in more than one machine, as Google does with their search engine. This technology evolution has also modified EHR systems requirements and performance.

In 1988, the Advanced Informatics in Medicine (AIM) initiative was created by the European Comission to study EHR architecture. The Good Electronic Health Record project investigated the object modelling approaches to the EHR and implementation(GEHR, 1992). The Synapses project led by Trinity College Dublin(Synapses Project, 1998), proposed a new object model, the Synapses Object Model (SynOM) a standardised set of definitions of healthcare objects(Grimson et al., 1998). These objects were in a Data Dictionary/Directory called Synapses Object Dictionary (SynOD) and they are the Archetypes precursors (ibid). The results of these projects were applied by Beale in *Archetypes Constraint-based Domain Models for Futureproof Information Systems* (Beale, 2000). He proposed a new system architecture with the Reference Model where clinical knowledge is represented as Archetypes and is independent of the rest of the system. To support this new approach, the OpenEHR foundation was established. The OpenEHR foundation is a non-profit organization working to improve the Electronic Health Records internationally. (OpenEHR, 2009)

Within the European Committee for Normalisation (CEN), the Technical Committee (TC) 215 created the Electronic Health Record Standard ISO 13606 based on many R&D work from 1999, including the OpenEHR reference model (OpenEHR). Although the ISO13606 standard has a smaller scope than OpenEHR, both are based on the Two Level Model, archetypes and EHR_EXTRACTS. The differences beween the standards are explained in detail in chapter 3.2

On the other hand the Health Level 7 (HL7) has been working in since 1987 on the definition of standardised communication between health systems in the seventh layer (Application level) of the Open System Interconnection model (ISO/IEC 10731, 1994) . HL7 was established in 1987 as a non-profit foundation and in the same year its working group created the first draft standard to cover structure of

the interfaces, ADT (Admission, Discharge and Transfer) order entry and display oriented queries. In 1996 HL7 v1 was accepted as an ANSI standard and different revisions have been made from the first version with versions 2 and 3. Whilst the subvariants of HL7 v2 have been highly successful and still dominate the market, the flexibility of this specification makes difficult to achieve interoperability level for a large number of systems without further specification. HL7 has defined the Clinical Document Architecture (CDA, 2006) in which allows to achieve the semantic intercommunication level. More detailed information about the CDA specification is presented in the following chapter.

Although it is possible to map between HL7 CDA and the archetypes from OpenEHR or ISO 13606, this is not a trivial process. There are overlaps between the different approaches which complicate the decision of different national or regional Health Services who wish to implement an EHR system which is interoperable with other countries and regions.

Another actor in this field is Integrating the Healthcare Enterprise (IHE). IHE is a non-profit organization where vendors and healthcare professionals are associated for the development of technical specifications based on existing standards (IHE, 1997). The organisation aims to promote the existing standards and provide solutions for interoperability problems. IHE has defined multiple profiles in the following areas: IT Infrastructure, Patient Care Devices, Patient Care Coordination, Laboratories, Eye Care, Cardiology and Radiology. Each profile describes all the actors involved and the possible transactions between them. The transactions are described based on DICOM, WADO, HL7 v2 or HL7 CDA. IHE doesn't specify any profile based on either ISO/EN 13606 or the OpenEHR approach.

2.1.3. WHAT IS THE CURRENT SITUATION?

The European Union is highly interested in the creation of an interoperable EHR across member countries (E-Health Europe, 2008). The European Commission is aware of the current barriers that prevent EHR interoperability, and it is working on different initiatives to solve the identified problems. In 2007 the European Commission approved Mandate 403 that encourages European Standard Development Organisations (CEN, CENELEC and ETSI) to work together to ensure that the communication structures based on CEN 13606 and HL7 RIM provide a safe semantic interoperability(European Union, 2007). The European Commission partially funds the epSOS project, a three year pilot project, which aims to demonstrate cross–border interoperability between 12 member states. The epSOS project will transfer Patient Summaries and ePrescriptions between the EHR systems of the beneficiaries. The results and developed infrastructure to guide the near future in the Health Informatics in our continent (epSOS, 2010).

Other developed countries such as the United States agree on the high importance of the EHR (CMAJ, 2010). US congress has recently approved an investment of nearly $50 billion in health information technology. One of the main strategies of this investment is to "encourage the adoption and use of the EHR technology"(iHealthBeat, 2009).

2.1.4. INTEROPERABILITY

Within the literature we can find numerous different interoperability definitions and classifications. After a large literature review the Information Standard Board describes one possible agreed

classification(Information Standard Board, 2008). The following classification describes three interoperability levels:

- Technical interoperability: two systems are able to transfer data between each other in an accurate, affective and consistent way.
- Semantic interoperability: two systems are able to transfer data between each other with technical interoperability and in addition are able to represent the information without meaning or context modification in different settings, networks, software applications or systems. The systems will be able to integrate decision support applications to implement simple and complex alerts.
- Process interoperability*:* two systems are able to transfer data between each other with semantic interoperability, moreover the systems are able to filter and summarise the information to integrate it by using different triggers within the clinician workflows.

The application of semantics to facilitate communication is especially helpful in the health environment where different Health Information Systems (HIS) have been created by different vendors. In order to achieve interoperability within a large number of systems, for instance within US or Europe, we need systems able to transform the information stored in their local databases to an agreed, compatible and well defined structure that is understandable by other systems.

Whilst it would enable share information within different systems, in the case of Europe, semantic interoperability across different countries requires additional transformation to translate the information to different languages. For example, our system could traduce from English to Spanish a discharge summary.

2.1.5. EHR ARCHITECTURE REQUIREMENTS

In 2004, the ISO technical specification (TS) 18308 was published by ISO Technical Committee 215. This document specifies the requirements for an Electronic Health Record Architecture (EHRA). This document identifies the main purpose of the EHR and secondary uses. The standard states that the main purpose “is to provide a documented record of care which supports present and future care by the same or other clinicians”. The secondary purposes include different areas as medico-legal, quality-management, education, research, public and population health, health service management, billing, finance and reimbursement (ISO18308, 2004).

The 18308 standard defines the requirements in different groups:

- Structure: The EHR must organise the information with different sections to help with user navigation. The EHRA must allow merging the information with other information from a different EHR independently of hardware and software. The information format must satisfy the SDOs specification about data types.

- Process: The EHR shall support the integration of the clinician processes in the Health Information System. Within their daily work, clinicians need to retrieve, process and create information within the system to perform actions such as ordering and care planning. The EHR should manage and store any clinical event to provide the right information in the right place and time to support the clinical decisions and lever clinician workflow efficiency through guidelines. The EHR must ensure the quality assurance for an integrated care where multidisciplinary teams work together.

- Communication: In order to achieve the communication between different EHR systems is based in two different methods: messaging is used to transfer information between two systems which don't have the same EHR architecture standard. On the other hand the record exchange transfers the information between two systems with the same EHR architecture.

- Privacy and Security: The EHR must preserve the personal information and provide the mechanisms to ensure the privacy and security, with regard to the surrounded cultural and legal requirements such as the management of the informed consent and provide different access levels to different people depending of their roles.

- Ethical: This point relates to the high importance of the right to informed consent and the right to confidentiality.

- Medico-legal: The medico-legal requirements mandate that every input or modification to the EHR must be permanently stored with the information about authorship of the original text and the EHR must preserve it as long as the local legal jurisdiction dictates.

- Consumer/Cultural: EHR provide information not only to the clinicians, it also can go farther in the patient care and it could allow patients to access information related with their disease, improve the communication between consumer and clinicians and allow patients to incorporate important information to monitor their daily lifestyle.

In 2008 HL7 defined the Electronic health record system functional model which complements the requirements for the EHR. In fact, this document has started the process to become an ISO standard but it is still in the draft form (ISO10781, 2009) but is very close to publication at the time of writing. This document presents the functions of the EHR in three different groups. These groups are:

- Information infrastructure for security, terminology services, workflow management.
- Supportive tasks such as clinical support, research, report or measurement.
- Direct care for care management, clinica decision support and operations management and communication.

2.1.6. DATA TYPES

In order to communicate different systems, one ISO18308 standard requirement is to establish a common definition of the data format, which enables both sides, to identify what kind of information is being transmitted. In written form, this information is expressed with symbols or characters that enable a person or machine understand it, but it is essential to identify what language or format has been used to record the information, to avoid misinterpretation of the symbols.

In the IT environment the need to standardise how the information is stored, leads to the definition of data types that enable computers to work in logic, maths, text and create groups of data. In 1994 the ISO approved the ISO 11404 standard which defined language independent datatypes to harmonise data in for the different software interfaces and programming languages(ISO/IEC 11404, 1996).

The CEN Technical Specification 14796, standardises the possible values and properties of data in five different groups(CEN/TS 14796, 2003):

- Primitives: This group includes the usual data types used in any IT environment; they are imported from the ISO11404 standard instead of being redefined. Boolean, string, character, list, set, array, bag, byte, integer, real, double (ibid).

- Basic: the basic group includes data types that identify resources events and object as well as how to combine different data able to fit in the clinician workflow. Boolean Data Value (BL) identifies the logical value, Encapsulated Data (ED) defines a group for written text combined with multimedia data for human interpretation, Universal Resource Identifier (URI) identifies the protocol and the address of a resource as the Internet Standard RFC 1748 specifies (IEEE, 1994), Interval (IVL) allows to group consecutive values, Interface Identifier (II) used to identify an instance, thing or object, it is based in the OID the global unique identifier defined by ISO.

- Textual and Coded data types. a few data types are defined in order to record different texts, codes and descriptors: Simple Text (ST) free text without code, Coded Text (CT) free text with a code attached, Concept Descriptor(CD) attributes that represent a concept in a defined concept system, CD can be specialised in simpler versions such as Coded Value (CV) only the coded data without any other information, Coded with Equivalent (CE) useful to identify the same concept in different coding systems, Concept Role (CR) useful for qualifiers codes within terminology systems such as SNOMED CT that indicate the concept role, Coded Simple Value (CS) is the abstract superclass for all simple codes.

- Quantity, These are the computable data types to indicate order sequences and to express quantity for measurements units and time: Ordinal (ORD) expresses a position within series by numbers or free text, Physical Quantity (PQ) useful to record by using units of measurement such as grams or litres, Duration records the length of a period of time and to indicate if the period is backward or forward, Quantity Ratio (RTO) is useful to specify administration dosages such as 5 mg/100 ml.

- Time, the data types to record the concrete time when an action is happening are: Date is a string that represent a particular day based on the standard ISO 8601 (ISO 8601, 2004) with the option to use reduced precision if we don't have enough information about the exactly day of an incident, Time Point (TS) specifies one instant recording the difference with referenced time expressed with the Coordinated Universal Time (UTC), Interval of Time(IVL <t>) defines a start and end time, Periodic Interval of Time (PIVL) specifies an periodical intervals of time with their phase and onset period, Event Periodic Interval of Time (EIVL) allows to record a periodic interval with relation to daily activities.

Given that in the health environment the HL7 had created their own data types not wholly compatible with the CEN/TS 14796 Health Informatics: Data Types, CEN TC 215 and HL7 work together in an effort to harmonise the different data types in the health industry. As a result from their collaboration the standard ISO 21090- Health Informatics – Harmonized Data Types for Information exchange is being developed. Currently ISO/TS 21090 is in the enquiry stage.

2.1.7. TERMINOLOGIES AND ONTOLOGIES

The idea of a standardised vocabulary started in London in the 17th century when the local authorities created a list with around two hundred possible causes of death. That was the precursor of the International Classification of Diseases (Gersenovic, 1995).Nowadays many different initiatives work to create different healthcare terminologies and ontologies that establish a formal definition of the knowledge within different medical areas.

Schulz et al. (2008) explained the differences between terminologies and ontologies. They defined terminology as a set of terms that represent the system of concepts in a particular area. Within a terminology the terms are classified in relation to their meaning based in the linguistic relationship, in medical informatics the example is the UMLS.

On the other hand Schulz states that ontology is a formal representation of reality, it represents the knowledge of one area by defining the concepts within this domain and the concept relationships, these relationships are based on logical formulations between the entities and their properties without the restriction of the human language (Schulz et al., 2009). Computers use ontologies as computable representations of the concept of meaning (Roma-Ferri, 2008).

There are ontologies focused on different areas of the medical field. For instance Gene Ontology is specialised on Genomics (Gene Ontology, 1998) Protein Ontology (PRO) on proteins or Influenza Ontology on the flu. All of these examples are included within the Open Biological and Biomedical Ontologies (OBO, 2006), framework which is coordinated by the US National Centre for Biomedical Ontologies. The OBO community works towards the interoperability between different ontologies and ensures the quality in the development.

Likewise there are many terminologies that cover different areas of the medical field. There are examples with a concrete scope, such as LOINC, which has focused on laboratory medicine and others such as SNOMED CT which includes clinical terms from most of the clinical areas such as procedures, diseases, allergies and adverse events, pharmacy, findings, encounters etc.

Because their standardised concepts can be processed by computers, the biomedical ontologies and terminologies have increased their importance in the last decade.

Using an encoded terminology or ontology within EHRs will help the development of different software applications for purposes as decision support, record communication or sharing and data mining. When we use the ontology based data our information can be shared easily between other systems. It also allows the combination of multiple data sources that help to create better analysis of the data and therefore facilitate a better understanding of the information stored.

The ontologies are in constant development and review to follow the changes within the healthcare. Different ontologies have their own policies to allow evolution, for example ICD has different versions, or within SNOMED CT individual terms can be moved, redefined, retired or outdated.

In order to satisfy the need to store patient information consistently, the terminologies allow us to record this information by using concepts with international recognition. Although the number of biomedical ontologies is quite large, the most relevant ontologies for the EHR creation are:

- SNOMED CT (Systematized Nomenclature of Medicine – Clinical Terms) is a medical terminology developed by the International Health Terminology Standards Development Organisation (IHTSDO). SNOMED CT establishes different possible relationships between the different concepts, for example the “IS A” relationship enables the developers to create a hierarchical classification between the words, from the root concept *fruit* you could create subtype group of words for *orange* and *strawberry,* which are included in the first one (SNOMED, 2009). These logical relationships can implemented within the HIS for ontological purposes. SNOMED CT has a huge size with more than 310,000 concepts (Bodenreider, 2008).

- LOINC (Logical Observation Identifiers Names and Codes) is an initiative that standardises the names to identify laboratory test and other clinical observations assigning them an

international code(LOINC, 2010). This project that has been developed by the non-profit organisation Regenstrief Institute Inc. includes more than 45,000 concepts (Bodenreider, 2008)

- ICD (International Classification of Diseases) is a periodically revised classification of diseases, symptoms, findings and other medical terms. Every concept is assigned to a code which is up to six characters long (WHO, 2007).

- UMLS (Unified Medical Language System), this system aims to provide the possibility of using medical terminologies together (UMLS, 2010). It is based in a Metathesaurus with more than 1,5 million concepts and a semantic network or ontology that enables to establish different relationships between the different definitions of the same concept in different terminologies.(Chen et al., 2009) UMLS contains the terminologies cited above LOINC, SNOMED CT, ICD 10 as source of the UMLS Metathesaurus. Although the ontologies are becoming more and more important due to the growth of poularity of HIS systems, in the last ten years the number of published articles per year about UMLS remains constant. In contrast other terminology and ontology systems have increased their impact in this time (Bodenreider, 2008)

2.1.8. IDENTITY

Health organisations need to unambigously identify patients, organisations, clinicians and equipment. Patient identification has been one challenge in some countries where the citizens don't have a national identification. In the case of Ireland, the Health Service Executive (HSE) is working to assign a unique patient identificater and is also working towards unique identification of health professionals. Faldum and Pommerening (2005) analyse the optimal format for patient identifiers. They define a set of four characteristics of a good identifier that include the following features: case insensitivity, error checking, not longer than eight characters and avoidance of any possible inference from the identity data, e.g. time, order (Faldum and Pommerening, 2005).

The ISO/DTS 22220 standard regulates the traits that can be used in the identification of subjects of care, it includes the data elements and structure to collect the patient information with a secure patient identification.

The development of a system to identify all citizens as possible patients is a very difficult and expensive task. In contrast to it there are a couple of solutions that provide the means for create a federated system of information where is possible to have different patients identifiers combined with a secure information transference. The Health Services Standardization Project (HSSP, 2005) is the result from the collaboration between the Object Management Group (OMG) and HL7. The project has defined the Identity Cross-Reference Service (IXS, 2009)which allows identification of entities among different systems (e.g,. patients)

On the Integrating Healthcare Enterprise (IHE, 1997) has defined different profiles such as the Patient Identifier Cross Reference for Master Patient Index (PIX) and the Cross Community Patient Discovery (XCPD, 2009) that together define mechanisms to identify patients and handle different patient Identifiers throughout the Affinity Domains.

2.1.9. CHAPTER 2.1 SUMMARY

This chapter started with the presentation of the Electronic Health Record. It has shown how crucial it is to preserve the patient information. The chapter continues with a description of the evolution of certain relevant EHR projects and the current situation where the US government and the European Commission work towards the implementation interoperability between the EHR within their territory. The last section explains the most important EHR components based on the different standards defined by ISO or HL7. These standards define the EHR requirements and data types that combined with the terminology and the semantic interoperability are the most important characteristics of the EHR.

2.2. THE REFERENCE MODEL

2.2.1. INTRODUCTION

For the past 15 years, standards have continued to evolve to support EHR communication. Experiences accumulated from research projects and systems implemented have impacted in the standardisation process. As mentioned in the previous chapter, the European standardisation organisation CEN TC 251 has recently completed a third iteration of an Electronic Health Record (EHR) standard. The first two standardisation attempts didn't support the evolution of the clinical knowledge. Perhaps this contributed to the fact that they didn't get approved as full standards.

The proposed solution to that problem creates a separation of information into two different levels: *clinical knowledge* and the *system information*. This structure is called the dual model approach and has been defined in the ISO 13606 standard and the specifications of the influential openEHR project.

There are also another initiatives created by different SDOs that define how the EHR systems can interchange patient information. In the current health informatics environment many standards claim to solve the intercommunication between EHR systems but the main problem is that they don't provide the interoperability from one standard to another. At time of writing, the efforts in the translation between the different approaches haven't had successful results.

2.2.2. ONE LEVEL MODEL

The idea of separating clinical knowledge from system information is a response to the limitations that experts identify in the ISO 18308 standard- Requirements for an Electronic Health Record Reference Architecture (ISO18308, 2004). They recommend that the EHRA must permit evolution because systems need to ensure the creation and maintenance of a life-time EHR. They also claimed that EHRA should provide semantic interoperability of the clinical concepts between EHR systems. These requirements couldn't be satisfied easily. Two European EHR standards ENV 13606 and ENV 12265 were created before the Two Level Model provided a solution to this challenging need of EHR systems.

The majority of EHR systems, such as OpemEMR and the Veterans Health Information Systems and Technology Architecture (VistA) are based on a one level reference model with a large number of users. OpenEMR is an open source application that supports many tasks such as writing prescriptions, medical practice management and recording the patient billing information within the EHR (OpenEMR, 2010). This application is implemented using the PHP language in combination with MySQL databases providing persistence. VistA is a health information system that provides care to over 4 million veterans around 160 hospitals in USA that are based on an EHR. The system has been built on the client server architecture (Vista, 2010).

I. ENV 12265 ELECTRONIC HEALTH RECORD ARCHITECTURE STANDARD

In 1995 CEN TC251 created prENV 12265 Electronic Health Record Architecture standard whose scope was to define the architectural principles for content and structure of EHR but only focused on the

information domain (European Committee for Standardizacion, 1995). European EHR developers and researchers used it as reference architecture for the storage, processing, and display of health information. The European Prestandard scope didn't include structures for the clinical knowledge or any interchange format. The document defined two basic information components: the record item and record item complex. The record item is an architecture component that represents basic information in the EHR. In contrast, the record item complex is an architecture component that details the structure and the content within the structure EHR.

The European Prestandard didn't include any interchange format. Also at this early stage in the evolution of a European EHR, CEN TC 251 work didn't include the domain knowledge in their standardization efforts.

II. COMMITTEE ON IMPROVING THE PATIENT RECORD

In 1997 the Committee on Improving the Patient Record of the Institute of Medicine (IOM, 2010) in US analysed the situation of what at that time was an emerging technology (Committee on improving the patient record et al., 1991). Their work had a huge impact with more than 700 citations identified in Google Scholar (Google Scholar, 2010). Even, some of the identified recommendations were included in the ISO 18308 standard of Requirements of EHR.

The experts involved in the Committee on Improving the Patient Record provided a set of recommendations about issues related to the EHR. These recommendations suggest joining forces between private and public sectors to facilitate the adoption of EHR. They encouraged incremental research in this field and promulgate standards for data and security, review the laws and regulations to overcome legal and costs distribution barriers and the need for educational programs for students and practitioners (Committee on improving the patient record et al., 1991).

III. ENV 13606

The outcome from the continuous work within CEN TC 251 was the development of the ENV 13606 in 1999, which replaced prENV 12265 and is the predecessor of the current standard for EHR communication (European Committee for Standardizacion, 1999). This standard is divided into four parts:

- Part 1-The extended architecture: is based on the architecture described on ENV 12265 including additional components that describe the record structures and semantics. The EHR systems could construct, use, share and maintain the content of the healthcare records. In order to organise the information, the reference model defined the structures such as Folder, Composition, Link, Item, Cluster that were incorporated to the current EHR communication standard.

- Part 2-The domain termlist: provides a set of terminological measures in order to support different degrees of interoperability.

- Part 3-The distribution rules: use different data objects to establish the access privileges that are essential to implement the security policies.

- Part 4-Messages for the exchange of information: this part defined various messages that allow to request or update a mirror repository of a patient's EHR.

While the ENV13606 standard extended the reference model with a bigger number of components and had included messages for the EHR communication, it was still based on One Level Model. The Two Level Model was proposed one year later by Beale (Beale, 2000).

2.2.3. CEN/ISO EN13606 – ELECTRONIC HEALTH RECORD COMMUNICATION

The CEN/ISO EN13606 standard for the Electronic Health Record Communication in Health Informatics has been developed by TC215. It is divided into five parts that include the Reference Model, the archetype specification, reference archetypes, security and interface specification. This standard defines the communication between different EHRs based on the Information viewpoint defined in ISO Reference Model for Open Distributed Processing (ISO10746, 1998), therefore it is independent of the system architecture or databases. The communication between systems is based on the exchange of EHR Extracts that preserve the clinical meaning from the original source and ensure the confidentiality of the data. EHR Extracts allow systems to add, transfer, access or modify the information stored in the EHR.

In contrast to the previous standardisation attempts, CEN/ISO 13606 is based on the Two Level Model and facilitates the development of archetypes that create structures to define constraints to express the domain knowledge. Moreover, the standard is compatible with other approaches such as OpenEHR EHR Extracts and archetypes. In relation to HL7, it has been demonstrated that ISO 13606 can be mapped to HL7 version 3 messages and the HL7 Clinical Document Architecture. Although the HL7 CDA specification could be described as a subset of ISO 13606/OpenEHR (Schloeffel, 2006), the automatic transformation between these models has not been achieved at time of writing.

Acceptance for the Two Level Model is growing, the European Commission published in 2004 the European eHealth Action Plan which recommends the implementation of systems based on the archetype paradigm rather than message paradigm (Communities, 2004). In 2008 the Swedish Association of Local Authorities and Regions announced that their national EHR system was going to be based on the ISO/CEN 13606 standard (Swedish Association of Local Authorities and Regions, 2008).

I. THE TWO LEVEL PARADIGM

The Two Level Model is the solution to support knowledge evolution creating future-proof systems that are able to preserve the patient record from the cradle to the grave. The ISO13606 standard creates two separates layers. As it has been mentioned before there is one static layer (called system information in the previous chapter) that defines the most generic information and another second layer that is able to define the semantic relationships of the clinical concepts (it was referred as clinical knowledge in the previous chapter) . Both layers are described in detail in the next section:

II. THE REFERENCE MODEL

The first part of the standard defines **the Reference Model (RM)**, a stable structure that includes the more generic information. The reference model doesn't include any clinical information, therefore it is independent from the evolution of clinical knowledge. The reference model defines a hierarchical structure to organise the information that could be sent in an EHR Extract. The reference model defines the following constructs:

- Folder: provides the ability to group different compositions based on a common characteristic such as the clinical team, time relationship or a condition relationship (e.g. GP folder or Episodes 2000-2001).

- Composition: is a set of information from a single clinical encounter or a record documentation session (e.g. Radiology Report or Discharge Summary). The composition allows the composer to record the date, legal jurisdiction and time or interval of the clinical encounter. The composer is the professional, device or software that creates, synthesises or organises the information of the composition. In some cases the composer is not specified because in one action such as multi-professional tele-consultation there are multiple actors implied, in these cases the clinical role of every agent is declared.

- Section: is a part of a composition that is defined by a clinical heading (e.g. Family History or Allergy information). The clinical headings identify the different workflow stages and provide easier navigation through the composition. The section might include additional sections and/or entries.

- Entry: allows identification of any single clinical action, observation interpretation or intention by recording it independently. It is also called clinical statement (e.g. a diagnosis or blood pressure measurement).

- Element: is a single data value (e.g. drug name or symptom)

- Cluster: is a combination of elements organised as a nested data structure within the same entry (e.g. audiogram results or imaging details).

In addition to the classes that dictates how the information is going to be organised, the RM includes other classes that are able to record additional information to satisfy the requirements for the communication between EHR:

- Audit information: records when and by whom the information was introduced into the EHR system in order to satisfy the medico-legal requirements defined in the ISO 18308 standard. Any composition includes the audit data set that identifies the originating EHR system.

- Functional Role: the information about the agent that participates in the patient care. The functional role identifies the agent, the functions performed and how these functions are performed (in person, by phone), the healthcare facility and the place or location.

- Attestation information: certifies the information authenticity because it stores the attester's confirmation that a document is correct. This mechanism ensures that the content is not modified or misinterpreted. It ensures that the EHR system satisfies the legal responsibility requirement.

- Related Party: the mechanism that allows recording information about subjects related to the patient ensuring that this information is unambiguously distinguished to the patient information.

- Link: allows crating semantics links between parts of the EHR, for instance the historic cause of a problem or cause effect relationships that help the understanding of the patient information.

- Demographic: This is an optional package that includes descriptors for any person, organisation, device or software component that are included in the EHR system. One of the benefits of this package is that the descriptive details are not repeated because any entity that is referenced in the EHR Extract is always done via an identifier. In cases where the information included in the EHR Extract needs to be anonymous, the local identifiers ensure that the EHR Extract is fully understood without compromising the patient personal details.

The first layer is the Reference Model (RM) that includes the more generic information about the system, based on this RM, there is a second layer of archetypes that define constraints to the main classes of the RM to satisfy the clinical needs for recording information. The RM includes only generic information to ensure that this level is persistent over time.

III. THE ARCHETYPE MODEL

The archetype is a set of constraints on the reference model that provides semantic relationships between the elements based on clinical knowledge. These relationships create structures that represent how the clinical knowledge is organized. In order to ensure semantic interoperability, clinical communities could use archetypes as a tool to define the Record_Component hierarchies within the EHR Extract. Archetypes are formally expressed by the Archetype Development Language (ADL), this language is able to define the individual archetype constrains and satisfy the archetype model.

The Archetype Model (AM) is usually presented as a constrained form of UML diagrams. The model includes the archetype definition and the information required to create an archetype. Whilst the archetype model is static, the archetypes based on this model are able to evolve over time therefore they are able be adapted to the clinical practice changes. The AM is composed of four packages:

- The archetype class details the identifying information of the archetype, also includes the specialization parent of the archetype if required. The archetype identification is achieved by a repository identifier or an OID identifier. The archetypes model specifies that the nodes are:
  - C_complex_object These are the object defined in the underlying Reference Model defined in ISO 13606:1 (e.g. Entry, Section). The root refers to the Reference Model structure where the archetype defines the constraints.
  - C_primitive_object: This object is used to set constraints on primitive data such as integers, dates, strings, etc.
  - Archetype_slot: A node that defines the archetypes that may appear at that point in the current archetype. Any archetype is a constraint of this node because the archetype is a constrain of the Reference Model objects e.g. Entry,Section.
- The Archetype Description records the metadata associated to the archetype and records the author, contributors, date of creation, and other details. If the archetype is translated to different language the specific details of each archetype translation is recorded by the Archetype_Description_Item. When the archetypes are stored in a repository the Audit_Details attribute indicates the revision history.
- The constraint model expresses in terms the constraints between the archetype nodes. The constraints are defined by the combination of twelve classes. For instance some of them are C_attribute, Archetype_internal_ref and Constrain_ref, archetype_slot, cardinality, etc.

- The Archetype Ontology allows the archetype to be neutral to terminology. The constraint and terms included in the archetype are bound to a terminology. The Archetype_Ontology records which terminology the terms come from, their name and codes.

In the same way that the clinical knowledge is independent of the RM, the archetype model doesn't have to be linked to the ISO 13606 RM. The archetypes are a powerful tool able to define the knowledge constraints. They are currently applied in the medical field but it wouldn't be a surprise if the archetypes are incorporated in information systems for different fields, for instance financial, economics or sociology.

2.2.4. THE OPENEHR APPROACH

In contrast to the ISO 13606 standard which is focused only on the communication between different EHR systems the OpenEHR approach includes the full implementation of an EHR. OpenEHR has defined mechanisms to create, store, maintain and query EHR information and the templates for representing the information.

Although both ISO 13606 and OpenEHR share most of the hierarchical classes of their reference model such as Composition, Folder, Cluster, Element, there are some differences in the following classes:

- ISO 13606 has only a generic Entry that could record all of the possible entries. In contrast, the OpenEHR RM defines four different classes of entries for Admin_Entry, Observation_Entry, Action_Entry, Instruction_Entry. The OpenEHR RM includes less generic information. It impacts on the development process because these different entries could create confusion between the archetype developers (L. Sato, 2006).

- The OpenEHR RM includes Data Structures that specifies tables (Item_Table), trees (Item_Tree), list (Item_list), single element (Single_Item) and the History_of_Events.

In spite of these differences, there are mechanisms for transforming OpenEHR archetypes into ISO 13606 and viceversa.(Martinez-Costa et al., 2009)

I. ARCHETYPE QUERY LANGUAGE

Within the OpenEHR approach the queries are expressed in the Archetype Query Language (AQL) which is a generic structured language based on SQL. In contrast to the existing databases, the AQL queries don't depend on the local database schema, they are expressed at the archetype level. Given that an AQL query works in the same way in any OpenEHR system and is neutral to system implementation, they can be shared between different systems. AQL syntax allow to define parameters for the query criteria, which is substituted with real criteria value at run time.

The ability to share queries between decision support tools increases the possibility of creating scalable solutions. For instance clinical experts could achieve consensus on the clinical factors that are related to one disease and one DSS can import the recommended query based on evidence to detect the patient risk of stroke, based on information stored in an EHR such as patient lifestyle, family history, laboratory test, etc. The CEN TC 251 didn't standardise the AQL because it was out of scope.

II. TEMPLATE OBJECT MODEL

The templates are defined by the OpenEHR foundation as the local adaptation of archetypes that often corresponds to a screen form, document, report or message. The template might incorporate additional constraints to the archetype definition based on local needs (Beale, 2007b). Although they are also expected to be expressed in ADL, templates are new third layer above the archetypes and the reference model that enables to create future-proof systems where the Graphical User Interface (GUI) is flexible enough to present on the screen the information that the templates require(van der Linden et al., 2009a).

The template could create a large structure where various archetypes are aggregated. It also could simplify the archetype structure by removing elements or nodes that are unnecessary and setting default values or further constraints specifically adapted to a local implementation.

Templates are bound to terminology subsets in order to provide a unambiguous definition of the concepts when they are presented on the screen, included in a document or in a message. Although templates are supposed to be defined locally they can be shared between different systems, for instance the OpenEHR foundation and clinicaltemplates.org have their own public template repository. (Beale, 2007a)

The templates are closely related to archetypes because they are able to set constraints, establish terminology bindings and fulfil slots. Because of these similarities the templates model has not been included within the EN 13606 standard. OpenEHR templates are defined in the template package as Operational Templates which are defined in the same language as archetypes. They differ from archetypes in that their root object is an Archetype_Root and the Operational Template can add the ontology structures from the constituent archetypes (Beale, 2007a). Apart from the fact that EN 13606 doesn't include the template model within the specification, EHR systems based on this standard could create Organisational Archetypes, which are archetypes locally adapted for administrative purposes. In contrast to the Clinical Archetypes which are the representation of the agreed domain knowledge the Organisational Archetypes don't have to be applicable in different systems. This solution provides the template benefits to the implementation of EN 13606 systems.

III. CONFORMANCE OF REFERENCE MODEL TO ISO 18308

The full implementation defined by OpenEHR specifications is mapped to the ISO 18308 (ISO18308, 2004) standard of requirements for EHRA by Beale (Beale, 2006). The document details the OpenEHR architecture conformance to the requirements described within standard. The OpenEHR architecture satisfies most of the EHR requirements described in the document for structure, processes, communication, medico-legal, ethical, consumer/cultural, evolution, privacy and security.

From the 126 requirements identified in ISO 18308 only eleven of them were identified by Beale as requirements without full conformance in openEHR. These eleven exceptions identified where the OpenEHR architecture doesn't fulfil the individual requirements include three cases where the OpenEHR approach has partial conformance of the requirements. Two more requirements are intended to be satisfy in the future and only six cases remain as "to be done" tasks. These requirements are related to tasks such as provide the means for different levels of emphasis, recording ethical approval for secondary uses. In relation to the support of data importation from different message protocols such as HL7, UN/EDIFACT (United Nations, 2003) and DICOM, the OpenEHR approach is able to map data from other sources to be incorporated into the record. Beale affirms that the transformations from ISO 13606 are easy, the importation of HL7v2 messages has been achieved and HL7v3 is also possible. If one format cannot be converted the information can be encapsulated in the EHR Extract (ibid).

In contrast, ISO 13606 has not yet been mapped to the EHRA requirements in the 18308 standard. The similarities between the RM of the OpenEHR approach and ISO 13606 standard suggest that most of the conformance statement related to the EHR communication will be equally conformed. For instance the structure requirements for organising the information, the structure and non-structured data and archiving support are satisfied by the hierarchical structures such as Folder, Composition, Section, etc., the data types and audit details. The experiences gained by the community after six years since the ISO 18308:2004 standard of Requirements for the EHRA were approved are currently being applied in the standard revision. The standard has started the revision process and it is in the enquiry stage at time of writing. The new version of the standard is likely to include new requirements identified from the EHR systems already implemented.

2.2.5. OTHER STANDARDS FOR EHR COMMUNICATION

I. HL7 APPROACHES

The HL7 is a non-profit organisation that works towards the standardisation for interoperability of health information technology.

However the v2 messages are widely implemented (Corepoint Health, 2009), in 2005 HL7 published the specification for v3 messages to solve problems from the v2 messages. The v3 messages are based on the Reference Information Model, they are human readable and reduce the number of options of previous the version. As consequence both standard are not fully compatible.

The Reference Information Model (RIM) defines around 70 different classes to represent the business logic in any health environment (e.g. Act, Role, ActRelationships). The RIM expresses the data content needed in the administrative or clinical domain in a comprehensive and generic way (RIM, 2010). The CDA or v3 messages define semantic and lexical connections in their content based on the relationships between RIM classes.

The Clinical Document Architecture (CDA, 2006) is a specification based on XML that provides the means to define the structure and semantic of clinical documents. CDA is a part of the HL7 v3 standard based on the HL7 RIM. This specification communicates different Health Information systems by exchanging documents. CDA specifies that the document content will have a mandatory part that includes human readable text and an optional part that includes structured information that is machine computable. CDA based messages can be exchanged between systems directly. Because the specification doesn't define how documents are transported, the CDA documents could be transmitted by different means such as HL7v3 messages, HL7v2 messages or even EHR Extracts.

As Blobel (2006) affirmed, there is an analogy between the dual model approach and CDA approach. He explained that CDA documents are created based on the generic RIM and its refinements as *Refined Message Information Model* (R-MIM) and *Common Message Element Types* (CMET) for EHR-related scenarios"(Blobel, 2005).

In comparison to 13606 and OpenEHR model where clinical knowledge is defined by archetypes in a flexible way able to be adapted to the local needs, CDA is based on the RIM that provides a static view of the health information. The HL7 methodology provides more control about the information that is implemented restricting the freedom of the systems; in contrast the HL7 RIM is static information model that have limitations to support the knowledge evolution.

II. LOGICAL RECORD ARCHITECTURE (LRA)

After the investigation of the possible implementations of OpenEHR, CEN/ISO 13606 and HL7 CDA approaches the National Health Service of UK concluded that the transformability between EN 13606 and HL7 CDA lead to loss of information because an underlying semantic framework is needed. The NHS created its own model called the Logical Health Record Architecture (LRA, 2010), which is derived from the reference model defined in EN 13606:1:2007 but also incorporates some extensions (Sato, 2008). The LHRA model modifies the reference model defined by EN 13606 to support that the static information structures are full integrated with SNOMED CT. Different experts have identified that both the OpenEHR and EN 13606 approaches have problems for terminology binding and that post-coordination could be challenging (Garde et al., 2007, Qamar et al., 2007, Schloeffel, 2006, Markwell et al., 2008). LHRA tries to solve the problem with a structure that avoid any duplicated or conflict when the terminology is bound to the Care Component ELEMENT Classes providing post coordination support.

The LRA defines the top level structure of the documents aligned to the HL7 CDA R2 and the conformance to the ISO 13606:1 is almost full. There are two exceptions in the conformance because LRA proposed an extension for the standard with the class CR_Participation represents the involvement (e.g. author, subject, performer) of a role (e.g. patient, healthcare professional)the LRA pre-adopts the use of ISO 21090:2008 Harmonised data types for the information interchange that is still under development.

III. DETAILED CLINICAL MODELS (DCM)

This is an interesting project undertaken mainly by the HL7 community to create the means to express the clinical knowledge with independence of the underlying RM. DCM aims to ensure the clinical knowledge is shared between the different RM in a consistent way. At this moment there are many standards in the health informatics such as ISO 13606, NHS LRA, HL7, CDISC that need to coexist together (DCM, 2010). DCM project aims to enable the communication between systems based on different standards. Within the joint initiative on SDO Global Health Informatics Standardization, ISO and HL7 collaborate to develop the DCM specification.

IV. CONTINUITY OF CARE RECORD (CCR)

The **American Society for Testing and Materials** (ASTM, 2010) developed the E2369 - 05e1 Standard Specification for Continuity of Care Record (CCR) that identified the information recommended for the patient summary (CCR, 2005). The specification details the most relevant patient data to support the continuity of care between different encounters. The CCR scope includes administrative, demographic, and clinical data and allows the healthcare providers to aggregate the most crucial patient data.

Aligned to the ASTM specification, in 2007 HL7 published the Continuity of Care Document (CCD). This specification maps the CCR concepts to CDA creating the specification for their standardized version of the patient summary.

Major private companies such as Google and Microsoft have adopted CCR as the standard to communicate their PHR systems. Google Health allows its users to exchange information with many different organizations through an API based on CCR. In contrast, Microsoft Health Vault supports both CCR and CCD.

2.2.6. MEDICAL IMAGE STANDARDS

I. DICOM

Digital **I**maging and **Co**mmunications in **M**edicine (DICOM, 2010) is a standard created by the National Electrical Manufacturers Association (NEMA, 2010) for the exchanging and management of medical images between medical imaging equipments or/and other Health Information Systems. This standard has been widely adopted by vendors and healthcare providers ISO has adopted DICOM and the ISO 12052 standard Health informatics -- Digital imaging and communication in medicine (DICOM) including workflow and data management has been published in 2006.

II. WEB ACCESS TO DICOM PERSISTENT OBJECTS (WADO)

WADO defines the web access to DICOM object with options for retrieving objects in JPEG format, MIME type or HTML website. It is included in the part 18 of the DICOM standard.

2.2.7. CHAPTER 2.2 SUMMARY

This chapter presented the previous work and standards before the advent of the Two Level Model. It continued by explaining the reference model and archetype model defined in the ISO 13606 standard and compared this model with other approaches. The comparison with openEHR shows that both models are closely related communication with the difference that OpenEHR has a wider scope and provides the means to support the full implementation of an EHR system. In contrast, the HL7 v3 and CDA standards are based on the Reference Information Model and the NHS LRA approach has derived the ISO13606 RM. These differences make automatic conversion of information between the different specifications very difficult, and there is a joint initiative called DCM where different SDOs work together in order to provide the means to define the clinical knowledge constraints with independence of the RM.

2.3. THE ARCHETYPE DEVELOPMENT PROCESS (ADP)

2.3.1. INTRODUCTION TO THE CONTINUOUS IMPROVEMENT CYCLE

Deming addressed the importance of organisational settings for quality and productivity, he also highlighted the importance of quality management in the design phase (Deming 1986). In combination with Shewhart's work on the quality of products (Shewhart 1931), Deming worked on the development of a methodological approach to increase the productivity after the II World War in Japanese industry. The resulting methodology is called the PDCA cycle or Continuous Improvement Cycle, also there are references to this cycle as Deming cycle or Shewhart cycle.

PDCA cycle is a four stage methodology (Plan, Do, Check, Act) for achieving continuous improvement and development in a process. This methodology has been successfully applied in different fields such as Business Processes Modelling, Quality Management, Quality of learning (A Kanji 1996) or performance management. Also it is applied in the ISO 14001 standard of Environmental Management Systems.

In order to propose the application of PDCA cycle to the ADP this chapter includes a literature review of the ADP organised in the four stages described by the PDCA cycle.

I. INTEGRATION OF THE PDCA CYCLE TO THE ADP

— Plan: Within this stage the organisation sets the archetype governance and determines the tools that are going to be applied in the ADP. At this point the organisation can adapt publicly available governance such as archetype principles, editorial checklist or EuroRec requirements to its local needs and establishes requirements for the ADP. Additional requirements might be needed in order to satisfy local legislations or different translations could be needed depending on the number of languages of the region where the archetypes are applied. The selected requirements will be included in the Archetype Quality Criteria.

— Do: This stage can include creating, adapting and adopting the archetypes that are going to be applied in the systems. The ODMA methodology described by Buck et al. (Buck, Garde et al. 2009) could be applied in the first interaction of the PDCA cycle. Also supporting material is applied in the ADP to provide support in the selection of RM classes.

— Check: This stage involves monitoring and measuring how applied the defined policies, objectives and requirements established in the Plan stage to the ADP have been applied. In order to achieve the best practice, the archetype development process (ADP) needs to be supported by a set of quality criteria to evaluate the archetypes. It ensures the robustness and safety of the systems based on archetypes, while increasing their level of interoperability. The AQC needs to verify that the archetypes satisfy your requirements

— Act: This stage involves actions to continually improve performance and quality of the ADP. These actions include the development of supporting material for the ADP and research on the refinement of requirements and governance. This information can be applied for educational purposes in order to increase the community.

2.3.2. CONTINUOUS IMPROVEMENT CYCLE: PLAN

The plan stage involves the definition of requirements and establishment of mechanism that are going to be applied in the ADP. This section explains the community organisation, governance, archetype lifecycle and other issues such as Intellectual Property.

I. GOVERNANCE AND ROLES

OpenEHR applies the governance and policies that have been approved by the Revision Board and organise the people involved in the ADP by different roles. In 2006 Garde et al. identified the requirements to create a repository with mechanisms to support Domain Knowledge Governance (Garde et al., 2006). Their proposed repository would author, update, manage and disseminate knowledge in archetypes. The users are assigned to a role that determines their access level and interaction duties. Their repository users are the system administrator, archetype administrator, lead developer, unprivileged user and reviewer. The unprivileged user is only able to search archetypes. The only task of the system administrator is to be responsible for user administration within the repository. In contrast, the lead developer, the reviewer and the archetype administrator are in charge of searching, designing and displaying archetypes. The archetype design process is performed by the collaboration between these actors. The main tasks identified in the design process are:

- Compare archetype versions
- Define new archetypes or new versions of an existing one
- Edit, assign ontology attributes and translate existing archetypes
- Review, discuss, vote for an archetype
- Approve and publish archetypes
- Assign roles to users working in the Archetype Development Process

II. ROLES IN OPENEHR

People assigned to administrator and archetype editor roles of the openEHR Clinical Knowledge Manager (CKM) shared archetype resource tool, are responsible for management of the tool. These are the only roles with ability to upload new and modified archetypes and templates. The archetype editor role is similar to the lead developer described above by Garde et al. (2006).

III. ARCHETYPE EDITOR

The openEHR organisation has assigned the role of archetype editor to three persons who are in charge of leading the development, verifying the metadata and references of archetypes, collating the reviewer comments. Based on the reviewer comments the archetype editor is responsible for modifying the archetype. Also where one archetype needs to be changed back, the archetype editor communicates the reasons for this change to the reviewers. (McNicoll, 2010)

IV. REVIEW TEAMS

Within the OpenEHR Archetype Development Process domain experts from different areas are organised in teams in order to collaborate together to provide the most generic definition of the archetype. Different experts work voluntarily in the archetype definition and provide valuable inputs based on their expertise. These experts are invited by the archetype editor. If they agree to participate in the review process they will provide their opinion, propose modifications and participate in ballots to approve the developed archetype. Archetypes will be defined as the maximal data set related to one concept. As a result of their work, archetypes restricted to a specific medical field can be applied in

multiple clinical environments where the modelled clinical concept is needed. We have described some of the key roles involved in archetype development, the next section describes how the archetype is modified in the ADP to achieve published status.

V. ARCHETYPE LIFECYCLE

The OpenEHR foundation also define the archetype review authoring and publication process using the CKM. Figure 1 shows this process in a diagram including the main actions that will be necessary to develop an archetype within the OpenEHR CKM. The process starts with the detection of the need for recording one concept. If the current archetypes in the repository don't satisfy this need, it is necessary to create an archetype. The first steps involve creating a draft of the archetype and establishing a balanced team. In the team review stage, the domain experts discuss the archetype definition as many times as required until a consensus is achieved. Once the reviewers agree on the archetype definition, the archetype status is set as published and additional translations and terminology bindings.

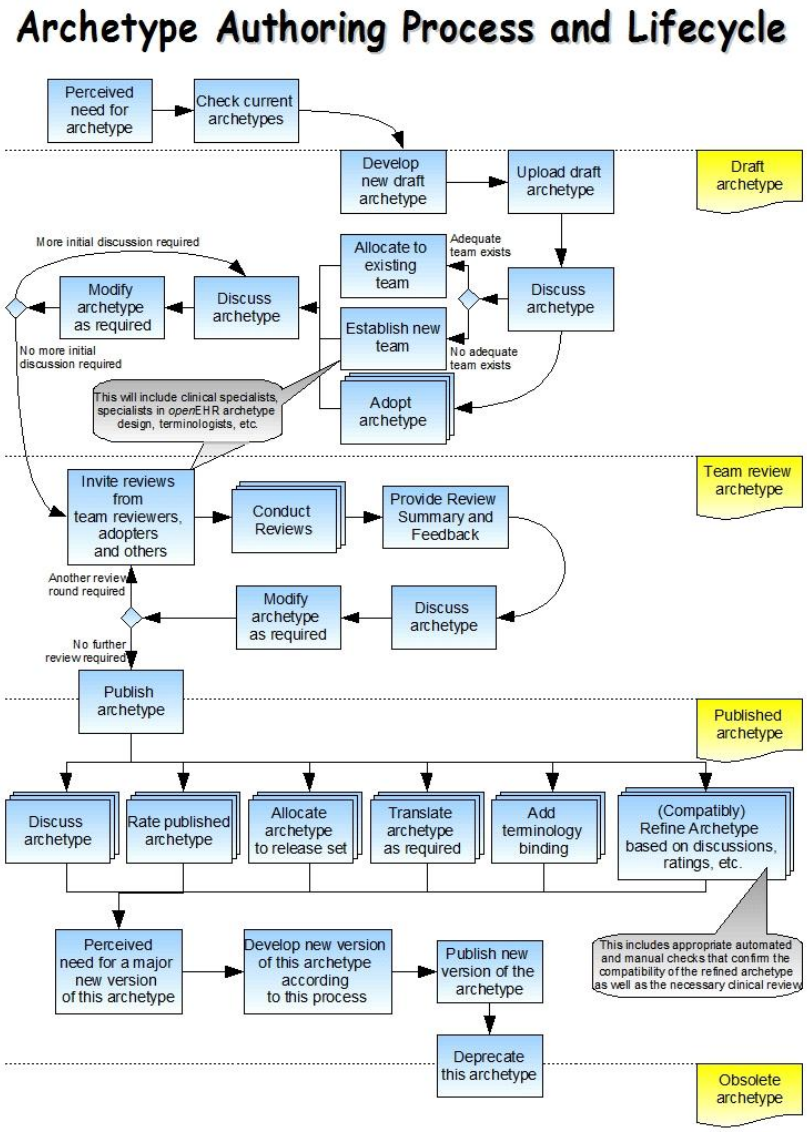

Figure 1. Archetype authoring, review and publication process (Leslie, 2008a)

VI. INTELLECTUAL PROPERTY ISSUES

When the ADP has set the archetypes the published status, the Intellectual Property issues arise because the archetype license could influence the archetype adoption by other institutions. The set of archetypes published in a repository could be under different types of licenses. Healthcare institutions might be reluctant to purchase a system based on archetypes if a company own the rights of them.

The policies of the OpenEHR foundation work towards facilitating the continuous development and make available their specifications without charge; therefore they publish the archetypes in the Clinical Knowledge Manager under a Creative Commons license. At the beginning, they are using the Creative Commons Attribution- Share Alike (CC-BY-SA) license, which allows any person to share or remix the information on the condition that, he or she must attribute the work executed by the OpenEHR Foundation, and that any result from the alteration or modification of the OpenEHR work only can be distributed under the CC-BY-SA license. The foundation has started a revision of the IP licenses in order to modernise and address the limitations identified by commercial users. At time of writing in summer 2010, the internal discussion within the OpenEHR Board and senior members was expected to achieve the final decision before the end of 2010.

VII. ARCHETYPE DEVELOPMENT COMMUNITY ORGANISATION

We have dealt with the current roles and organisation in the OpenEHR archetype development process but there is a proposed new organisation that allows multiple committees to be organised depending on their expertise. Kohl et al. described an organisational structure to support the archetype development and maintenance process. The proposed structure is a hierarchical organisation where various committees are responsible for different areas or tasks. (Kohl, 2008)

- The users: they are people with different backgrounds who participate in the archetype designing and modification process (ibid).

- The professional committees: are responsible for one specific domain knowledge. Kohl describes a structure were committees are organised depending on their expertise (Figure 2). The hierarchical structure defines that the professional committees responsible for the more general information (e.g. nursing committee) will share the responsibility for smaller areas with the highly specialised professional committees (e.g. emergency nursing group). The committee is composed of users, whose membership is dependent on their professional background and interest, and the chair of this committee, who is an expert in the specific medical area (ibid).

- The Design committee: could include representatives of companies that provide the technical background through material about relevant standards and programming recommendations.

- The Orphan committee: is responsible of the archetypes which don't fit in the any professional committee.

- The Clinical Review Board: is composed of a group of experts that represent different subgroups of the users (e.g. chair of the design committee), also government representatives could be included in this group.

The design process of a new archetype under this ideal organisation requires that one of the committees established accepts the responsibility for an archetype before it is created. If additional committees are interested in participating in archetype development, they could indicate the level of involvement they wish to have in the review process. The archetype is supervised by a member of the professional committee and another of the design committee when they approve the archetype the archetype status is set to committee draft and all committee members discuss the problems and alternatives of the archetype definition. If consensus is achieved within the responsible and the linked committees, the archetype will be revised once more by the next superior committee in the hierarchical structure. This happens as many times as required until the archetype is published in the root committee or clinical revision board.

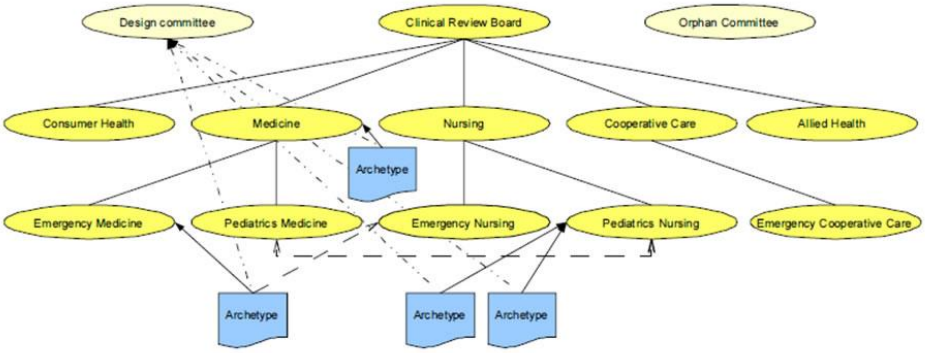

Figure 2. Proposed committee distribution (Kohl, 2008)

The authors identified two main advantages from this model. The first one is that committees could be applied to other knowledge resources, for example HL7 CDA. If this model is implemented in an international level, the second benefit is that the increased coordination will avoid designing incompatible archetypes.

2.3.3. Continuous Improvement Cycle: Do

I. Implementation

In this stage the strategies adopted in the plan stage are put into practice, the archetypes are elaborated by the collaboration between reviewers, teams and archetype editors. In the literature, there are a few publications that present the methodologies and recommendations to put in practice the lessons learned from previous experiences in archetype design.

OpenEHR Data Modelling Approach (ODMA)

In 2009, Buck et al. presented the OpenEHR Data Modelling Approach that they applied to development of a prototype neonatology EHR. Data modelling starts with analysis of the existing electronic or paper based documentation system. Their five step development model has these stages:

1- Determine all items from the previous documentation system.

2- All the items from the previous step are transformed into concepts. The goal of this activity is the creation of a hierarchical structure that classifies all the previous items depending on their clinical meaning. From this hierarchical structure the concepts will be examined to identify repeated items and structures.

3- Map the derived concepts to existing archetypes within the system and public repositories.

   - If all items of concept are included in an existing archetype it can be **reused**.
   - If only some of the items included in the concept are defined in an archetype this archetype can be **specialised** and extended to incorporate the missing items.
   - If there isn't any archetype that models the concept a **new** archetype could be created.

4- Archetype development can be done by using both a specific archetype editor and a text editor.

5- Design templates to adapt archetypes to local circumstances or combine items from different archetypes. In cases where the archetype includes more items than the set of items that are needed in a particular context a template will exclude the unnecessary items

This methodology has been successfully tested with the elaboration of the neonatology EHR. In their project, Buck et al. started by identifying 1800 items that through the development process led to the creation of 132 archetypes and 16 templates. They identified that one of the benefits of this methology is identification of overlapping items in the second step to avoid the repeated modelling of items in several archetypes. The implemented system had a 50% archetype reusability ratio, as half of the defined archetypes were applied in more than one scenario. One of the benefits of having a high reusability ratio is that the time and effort in the development process is minimised (Buck et al., 2009).

Another experience that explains the archetype development process was presented by Leslie (2007). She identified the brainstorming as the first step where the archetype designer searches for any source to obtain new concepts or additional information of this field such as textbooks, publications, minimum data sets, guidelines, paper or electronic forms. Afterwards, the archetype designer starts the modelling by determining what Entry class corresponds to the concept. This step also involves identifying data elements, protocol, state or context for interpretation, allowable events, pathway steps and concepts that need terminology/coding. In the final step, the concept is mapped to the repository for reuse, specialisation or creation of a new archetype (Leslie, 2007).

From the experience gained by the archetype editors in the archetype development process, Leslie detailed the main characteristics of an archetype:

- Wholeness: The archetype shall include the maximal data set. This ensures that it is interpreted in isolation.
- Discrete: The archetype shall represent a single concept. This will help to reduce the scope and archetypes and avoid overlapping definitions of archetypes.
- Specialisation: This process used to solve the overlapping concepts by aggregation, reduction or constraint on the existing archetypes.
- The approach is based on three principles: the information must be *simple*, *generic* and *re-usable*.

Thomas Beale, who is arguably the originator of the archetype paradigm, has identified a set of archetype design principles (Beale, 2007b). Some of these principles are similar to the information above stated by Leslie (2007). Beale also adds the following:

- The archetype defines constraints on the structure, types and values of instances of the Reference Model (RM). It enables archetypes to have different granularity levels according to the different classes defined in the RM.

- Every archetype node must be uniquely named, human readable and the archetype content must be supported by references.

- Archetypes are translatable to different languages without language primacy. They are also neutral to terminologies because the archetype development process is independent of the terminology which is bound to the archetype.

- Archetypes may define compositional relationships to other archetypes by using Slots. A Slot sets constraints in the archetype nodes to define which archetypes can be allowed or excluded. Slots increase the reusability of archetypes because they allow the definition of hierarchical structures between archetypes

- Archetype support knowledge evolution without invalidating the data based on the previous definition because any archetype modification creates is stored as a new version of the archetype.

II. DESIGN WITHIN OPENEHR AND EN 13606

Now focusing in an important aspect of the ADP, this section presents how the different RM classes are selected. Both OpenEHR and EN 13606 use the same Archetype language specification (ADL 1.4) with small but significant differences in the underlying RM. The following diagrams show how these differences impact the design process:

SUPPORTING MATERIAL DECISION ALGORITHMS

Given that archetypes define constraints over the reference model classes, the archetype designer is free to choose what reference model classes match with the concept that he/she wants to model. The decision algorithm to select the appropriate class in the ISO 13606 RM is described in the following diagram (Moner, 2010b). These questions help to identify the RM class that corresponds to the concept that the designer wants to model. Depending on the kind of concept required and the answers to different questions (from 1 to 5) the archetype designer identifies whether the concept is part of a document, functionality, stand alone concept, multiple or single element. The figure shows that the answers to the questions will lead the archetype designer to select the appropriate RM class (Composition, Section, Entry, Cluster and Element). In the author's experience, this approach is almost always directly and easily understandable, with only one exception. In the case that the archetype designer wants to model a stand alone concept that is recorded in more than one encounter, he or she may need advice from an expert.

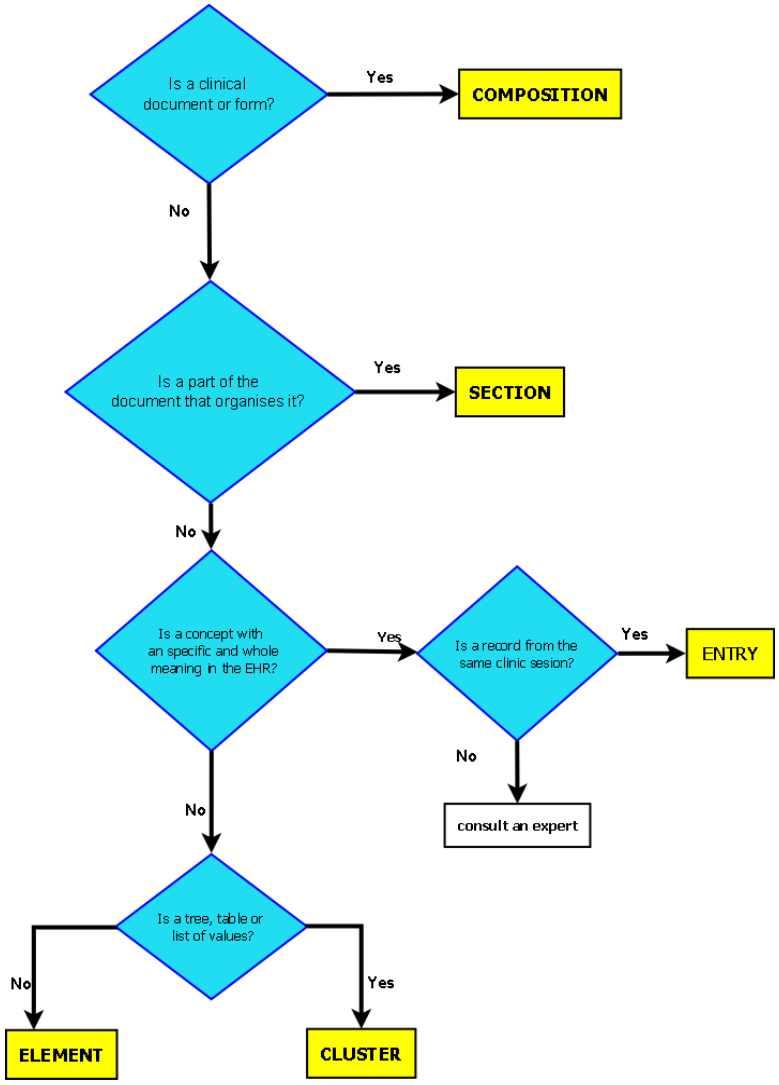

Figure 3. Translation from the Diagram presented in the UNE 13606 Workshop (Moner, 2010b)

In addition, if the archetype designer wishes to define the archetype for the OpenEHR reference model, the diagram is closely related to the previous one because of the similarities between the models. The OpenEHR RM differentiates between different entry classes and adds the Structure class. The OpenEHR diagram is more complex with twelve different questions.

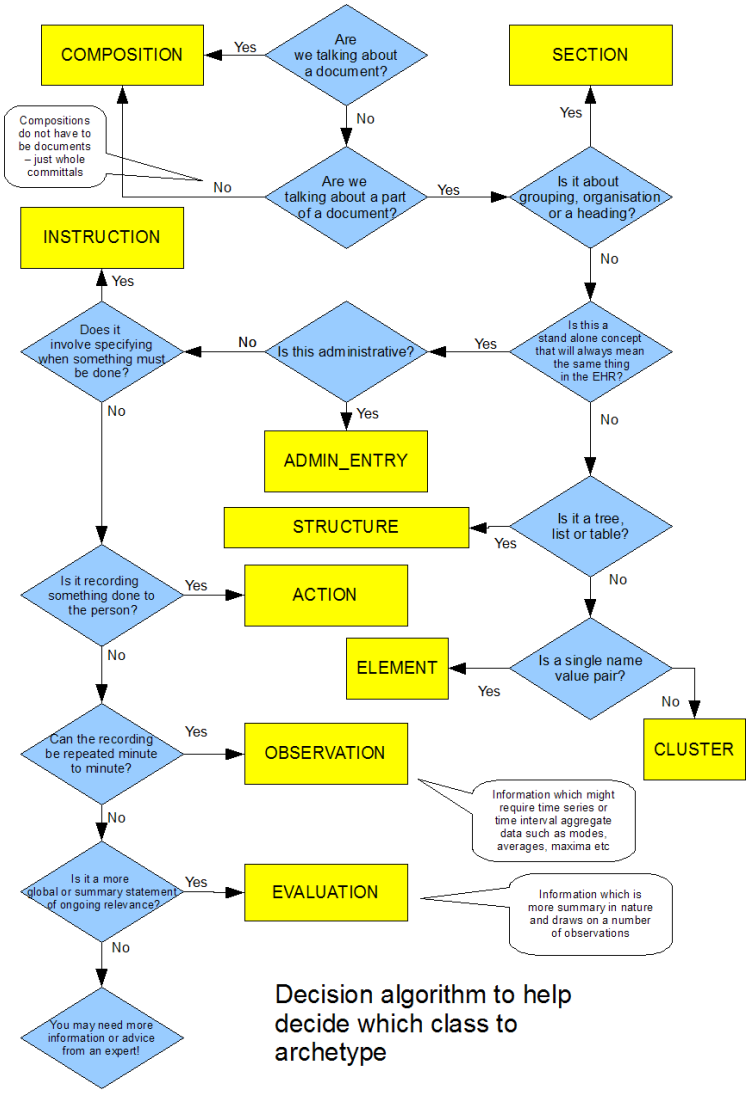

Figure 4. OpenEHR decision algorithm (OpenEHR Decision Algorithm, 2010)

- The observation entry records the information that is has been obtained by the clinician or medical device measurements, the clinician or patient observation, or any test related to the patient. The information recorded objective and verifiable by other clinician or device if the conditions don't change.

- The Evaluation entry records the information resulting from the clinician evaluation activity. In this activity the clinician combines the information of different observations to provide an opinion, assessment or conclusion. This is the result from a subjective process. Some examples are diagnosis, assessment, goals and speculative plan.

- The instruction entry records processes that other clinician or device performs in order to modify the patient state or obtain one intervention.

- The action entry records the results from the processes performed, they could have been described by the instructions.

OpenEHR provides some examples about how to choose between the different entries in order to help the new archetypes designers in this confusing task. The examples show how the problem/diagnosis

archetype is applied in combination with different observation archetypes to record the evaluation of an auscultation, patient speech and one health professional assessment.

The selection between the different types of Entrys defined in the OpenEHR RM requires strong understanding on the part of the archetype designer. OpenEHR affirms that the differentiation between the different types of Entry is based on experiences resulting from years of work.

Figure 5. OpenEHR Entry in context (OpenEHR Entry in context, 2008)

Additional information about how to differentiate between the entries has been provided by Freriks (2009). In an unpublished paper he provides a detailed explanation and a few examples about the differences between the entries (Freriks, 2009).

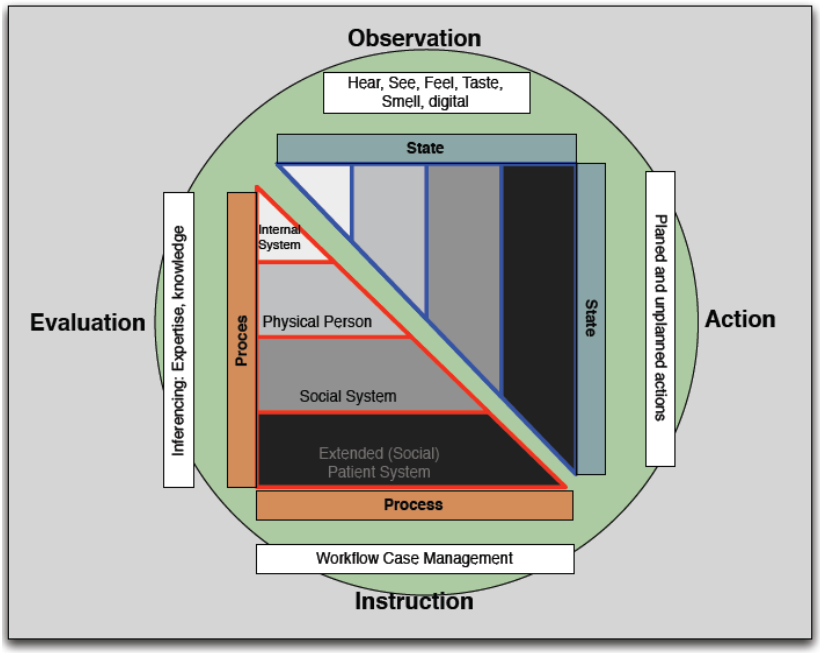

Figure 6. Relationships between Entries (Freriks, 2009)

III. TOOLS FOR DEVELOPMENT

ARCHETYPE EDITOR TOOLS

LinkEHR-Ed is a tool implemented in Java under the Eclipse platform that is able to edit archetypes based on different reference models(LinkEHR-Ed, 2009). The editor part of LinkEHR-Ed has been released freely as an open source program. Another important feature is that this tool also performs

mappings between the archetypes and un-normalised information stored in the databases or XML documents of the implemented systems. LinkEHR-Ed generates the XQuery script to translate the un-normalised information into normalised XML documents that satisfy both the archetypes and the reference model. (Maldonado et al., 2009) One of the limitations of this tool is that it is not able to search directly terminologies such as SNOMED CT, therefore the designer needs a terminology browser.

Other archetype editor tools, such as the LiU Archetype Editor (LiU Archetype Editor, 2007) created in Java language and the Ocean Archetype Editor (OpenEHR Archetype Editor, 2009) created in VB.Net, C#.Net languages, are also provided as open source tools. Also they provide very similar user interfaces presenting the archetype items as a tree on the left hand side and support drag and drop functionalities. Different archetype fields such as purpose, keywords, author and other contributors are recorded as free text. The tools allow selecting between archetype items in order to define constraints on the underlying RM and bind the terms to terminologies.

TEMPLATE EDITOR TOOLS

There is only one tool able to create and manage templates. It has been created by Ocean Informatics and it is called Ocean Template Designer (Ocean Template Designer, 2010). This is another tool developed in VB.Net and C#.Net languages and it is able to combine different archetype together and set their local constraints. This tool is provided under commercial license and it is able to be evaluated under request.

In the same way that templates are closely related to archetype this tool has similarities with the OpenEHR Archetype Editor. The list of items of an archetype is displayed on the left hand side and users are able to set additional constraints on the displayed properties. Also the Ocean Template Editor can generate and edit forms to be displayed on a screen. It includes some Graphical User Interface features such as modification of colours, size of fields, or item location on the screen. Also it is easily integrated with local repositories of archetypes and allows definition of the set of terms that are to be displayed in the drop dawn menus and link it to SNOMED CT.

MEDICAL OBJECT TOOLS

The Medical Objects is a software Australian company which is working in a project that integrates the clinical guidelines defined by GLIF with forms based on either CEN/ISO 13606 or OpenEHR archetypes (Medical Objects, 2010). The communication is based HL7v2 messages to satisfy their local needs. Medical Objects software suite effectively integrates the archetypes and templates with the decision support knowledge using GELLO and clinical guidelines defined by GLIF. The company provides freely the GLIF Editor and Archetype Editor.

IV. ARCHETYPE AND TEMPLATE REPOSITORIES

Archetypes are stored in common agreed repositories that allow both sides, source and receptor, to identify the semantic links and relationships between the concepts included within an EHR Extract. The chapter 2.4 presents some EuroRec requirements that also include recommendations for repositories. These are the public archetypes repositories across the world:

- The OpenEHR Clinical Knowledge Manager is a public repository which contains more than two hundred archetypes based on the Open EHR reference model. The CKM has recently included a template repository. In contrast to other repositories that are just a place where the archetypes are published, the CKM provides the means to encourage domain experts to collaborate in the definition of archetypes. The CKM is a tool that allows the domain experts to

discuss, review and organise themselves in teams in order to facilitate the consensus on the archetype definitions (CKM, 2010).

- The NHS repository: The UK's National Health Service has published around 200 archetypes that were created in the Lorenzo project (NHS repository, 2007). In 2006 the NHS investigated the feasibility of adopting CEN 13606. Among the conclusions of the investigation was the observation that archetypes were easier to use than the HL7 V3 semantic equivalent and the recommendation for further testing of the archetype-based approach. One year later the Lorenzo project started as a pilot project for the archetype approach. In this project 650 archetypes and 60 templates were created (Leslie, 2008b), most of them have been published and after a quality review, some have been incorporated to the Open EHR repository.

- Minas Gerais Repository: This repository also known as Portal Público do Registro Electrônico em Saúde has been recently created (June 2010) and includes 10 archetypes(Portal Público do Registro Eletrônico em Saúde, 2010). These archetypes model different clinical concepts such as allergies, nutrition, daily activities, etc in order to facilitate the communication between the different EHR systems implemented in the region of Minas Gerais (Brazil). (ibid)

- Swedish CKM: Although the Swedish national project is based on the ISO/EN 13606 standard, currently there are no tools based on 13606 to create an archetype repository (Swedish repository, 2010). To solve this problem the Swedish National Board of Health and Welfare selected Ocean Informatics tools to create the Swedish repository. The Swedish repository has been created with OpenEHR tools and includes 59 archetypes. The repository is publicly available with 17 demographic archetypes that conform to the Swedish Information Model called Verksamhetsorienterad Tillämpad Informations Modell (VTIM, 2010). Moreover 20 clinical reference archetypes are included. The community is composed by 18 registered users including one translator and 2 reviewers (Swedish repository, 2010).

Swedish Repository	
Status	**Number of archetypes**
Draft	49
Team review	1
Published	0
Rejected	9
Obsolete	0

- The Poseacle Repository: contains the OpenEHR, NHS archetypes and others from Spain. The repository stores the archetypes transformed between the OpenEHR and ISO13606 reference model expressed in both OWL and ADL format (Poseacle, 2009). The project started in 2004 from the cooperation between the Murcia University and the Technical University of Valencia. Martinez-Costa et al. identified the benefits of representing and managing clinical archetypes in OWL rather than ADL. They affirm that the OWL representation is more efficient at performing semantic activities such as comparison, classification, selection and consistency checking (Martínez-Costa et al., 2009). They designed a solution based on the combination of Semantic Web and Model Driven Engineering technologies to transform ADL into OWL for the ISO13606 EHR architecture (Poseacle, 2009)

V. DSS, GUIDELINES AND WORKFLOW

There are examples such as the NHS project called Map of Medicine where clinical guidelines are shared in a computable format with benefits to the clinical practice (Map of Medicine, 2010). The Map of Medicine project has defined 390 pathways which represent the patient care journey through 28 specialities based on the evidence. The project started in the Royal Free Hampstead NHS Trust in London where in order to reduce the waiting times a tool was created. This tool provided a visual representation of clinical pathways. The benefit was an increased communication between the primary and secondary care and the development of clinical pathways evidence-based in order to improve the quality and safety of patient care. Some time after the managers realised the international potential of the Maps of medicine, these pathways became publicly available in their website (Map of Medicine, 2010) .

Also there are sources that host clinical guidelines that have been approved through peer review that could be shared as clinical knowledge in an implementable format. Some examples of these sources are the National Guideline Clearinghouse (National Guideline Clearinghouse, 2010) or Guia Salud from the Spanish Ministry of Health (Guia Salud, 2010) where the guidelines are evaluated before they get published in order to maximise the quality of the clinical practice.

The large number of models for representing guidelines includes PROforma (COSSAC, 2010), GLIF (Peleg, 2001), Arden Syntax (Arden Syntax, 2010), etc. Likewise there is a large number of programs some of them privative such as Arden Syntax or Arezzo (Arezzo, 2010) and other open source as Tallis that provide the means for defining clinical guidelines (Tallis, 2010). There is a need to integrate the guidelines with the EHR that haven't been standardised yet. Although there are examples as Arezzo that has integrated the guidelines with the EHR information for GPs in New Zealand and Chronic Obstructive Pulmonary Disease (COPD) patients in UK, the company offer the communication only as an ad hoc implementation rather than a communication based on the standards(InferMed, 2010).

Chen (2009) affirms that there is a bidirectional barrier in the interoperability between the EHR and the clinical guidelines. On the one hand the differences between the models for representing guidelines complicate the integration of the recommendation within the EHR. On the other hand, the differences between the multiple EHR set limitations in the definition of fine grain queries and triggers (Chen, 2009).

In order to solve the second problem described by Chen, the HL7 Virtual Medical Record (vMR) project is working to provide a solution (virtual Medical Record, 2010). The vMR model aims to provide a common language for representing the Clinical Decision Support (CDS) inputs and outputs. vMR data model is derived from the HL7 RIM and can be shared between multiple CDS engines and systems in order to support scalability and interoperability between CDS and reduce the dependency to proprietary systems. The vMR data model is combined with the GELLO language which is an object oriented (OO) language for defining the queries and expressions for CDS(GELLO, 2009). In this area the above described Medical Object tools integrates archetypes with clinical guidelines developed defined with the GLIF editor.

These examples show that there have been some advances and work done but the lack of a standardised communication between guidelines and EHR systems is an impediment that needs to be solved.

2.3.4. CONTINUOUS IMPROVEMENT CYCLE: CHECK

I. OPENEHR EDITORIAL CHECKLIST

OpenEHR has published an editorial checklist as supporting material that leads the archetype editor work. This checklist details all the tasks that the archetype editor perform in order to satisfy the quality criteria required by the organisation (Leslie, 2009)

1- Verify that the archetype scope is a single clinical concept without overlaps to other archetypes and it is appropriately authored and referenced. This archetype starts its lifecyle in the draft state.

2- Form a balanced team including experts from different professional backgrounds and cultures. The experts are invited to the review including a briefly information about the archetype and the proposed timeframe. Additional reviewers could be added at any time.

3- Initiate the review process and set the archetype in the Team Review status, collate the reviewer comments and revise the archetype.

4- The review process could be repeated as many times as required until the reviewers achieve consensus and the archetype status changes to published.

5- After the archetype is published, translations and terminology coding start.

II. ISO/EN 13606: PART 2

Given that at the time of publishing the standard there were little information about the best practices in the archetype development the second part of the standard details recommendations for archetype definition, description and publication. Likewise this section provides information about the archetype node constraints. Some of these requirements have been also adopted by EuroRec.

III. ARCHETYPE REQUIREMENTS DEFINED BY EUROREC

The European Institute for Health Records or EuroRec Institute (EuroRec, 2010) is a non-profit organisation that promotes the quality of EHR systems (EHRs). EuroRec is a European certification body that defines functional criteria and provide the EHRs quality labelling.

The EuroRec Institute has published a document that details the management and maintenance policies for EHR interoperability resources (Kalra, 2008b). The document details the requirements to ensure the quality of clinical archetypes and repositories based on both ISO 13606 and OpenEHR. The document presents the questions that the clinical teams, regional care managers and vendors need to address in order to adopt an archetype. Due to the fact that archetype development process is relatively new, there is not yet a strong enough evidence base for a proven development process. However, there is a consensus on the good practices that are detailed as a set of requirements:

BUSINESS REQUIREMENTS

Kalra et al. explain that the archetype created shall define formal representations for the different stakeholders of EHR. The documentation information of the archetype shall indicate any certification, approvals or uses and allow potential users to determine its quality, bases and currency. The purpose shall also be recorded with enough detail to identify the scenarios where it can be applied (ibid).

CLINICAL REQUIREMENTS

Clinical Usage: EuroRec also recommends that archetypes must specify the nature of the clinical entities and could include restrictions related to specific scenarios or populations. These restrictions must be documented to ensure that the archetype is successfully applied. The archetype could be specific for a subset of scenarios, workflows or applied to different target population of citizens, particular specialities, disciplines or professional groups (ibid).

Clinical domain coverage: The archetype scope shall be indicated with sufficient detail and include or reference one or more concepts from an internationally recognised terminology system. Although the possibility of overlap between archetypes shall be minimised any possible overlap shall be documented. The archetype shall specify the nature of the clinical entities involved, the scenarios or workflows supported, the target population of citizens. If two archetypes are closely related, the differences in their scope must be recorded (ibid).

Evidential basis: In addition, Kalra et al. state that an archetype author should start by ensuring that there is no potential for duplication or overlap with existing archetypes and collect relevant evidence. Evidence shall be referenced with examples from the published knowledge as the source of information for the overall design and the individual nodes. The archetype could also include notes from the author to document the conformance to references, when the knowledge or the archetype is due to be reviewed and the peer review process (ibid).

Communities of use: In order to be applied in different communities and jurisdictions the archetype shall record the purpose, usage, stakeholders, evidential basis and support multiple translations (ibid).

IV. TECHNICAL REQUIREMENTS

Conformance to standards: Archetypes shall conform to the ISO 13606 standard part 2 (for EHRcom archetypes) or the latest version the archetype model defined by OpenEHR (for OpenEHR archetypes).

Modelling requirements: EuroRec claim that archetypes shall record which information model is supported, identify uniquely an archetype globally, and specify classes involved as root or other nodes. In order to allow the consistent mapping to the EHR data, any archetype node shall be labelled to one or more international terminologies and indicate any constraints for multiplicity and data value.

The EuroRec document recognises that the process for identifying the recommended binding methodology of archetypes nodes to SNOMED-CT is in progress and the outcome from this research will be included in future versions of this document.

V. INFORMATION GOVERNANCE REQUIREMENTS

Authorship: The archetype shall record information about the person and/or organisation responsible for the creation, governances and maintenance. Additional information about the jurisdiction and dates of creation, revision or deprecation should be included. (ibid)

Version management: Any modification is recorded as a new version and it shall specify the reason for change, the date, the person and organisation responsible. The archetype version management shall differentiate three cases that depend on the archetype modification. The archetype modification from the previous version could only affect to the use, only to the constraints or both.

If any item of the archetype in the previous version is not conformant to the new archetype definition, the new definition shall become a totally new archetype and the previous archetype version shall be deprecated.

Access and licensing: The archetype shall indicate the publication status, license and use restrictions. If there is any restriction, the archetype shall include them and also how the permissions may be obtained.

Endorsement of quality labelling, certification

The archetype shall detail any approval, endorsement, certification, quality label or future deprecation from the different communities and legislations by expressing the onset and expiration date.

VI. ARCHETYPE REPOSITORY REQUIREMENTS

A repository needs a quality management plan to establish the requirements that the archetypes must conform to. A Scientific Review Board supervises the adoption of new archetypes based on the conformance of archetypes to quality criteria. Archetypes certified by a recognised body can also be adopted by the Scientific Review Board.

A repository shall help users and software to locate, query or retrieve the indexed archetypes and present them to conform to international standards. The search results depend on archetype properties such as the archetype structure, certification jurisdiction, etc. If the search results include obsolete archetypes, the search engine shall notify this information.

A repository shall include any update or modification of all the archetypes, as well as recording the history and audit information. The clients could request services for example be informed of any important update and modification or even they could have a local copy of the requested archetypes synchronised with the repository.

2.3.5. CONTINUOUS IMPROVEMENT CYCLE: ACT

This section involves the actions taken to improve quality in the ADP. Given that archetype development is a concept that has been created not long time ago there are many areas such as educational resources, development methodologies and community involvement that can be improved in the future.

The archetype itself could be considered as a technique that provides the means for continuous quality improvement defined in the Act stage of the Continuous Improvement Cycle. Within the Archetype Definitions and Principles an archetypes is described as a concept that is able to be interpreted in isolation and it includes the maximal data set related to this concept (Beale, 2007b). It requires that archetypes need to be able to deal with the evolution of knowledge. Any new concept identified by the community of clinical experts can renew the discussion and modify the current definition of archetypes (even if they are in the published stage).

I. ISO/EN 13606 WORKSHOP

In July of 2010 a group of international experts in the archetype development and EHR systems based in both ISO/EN 13606 and openEHR specifications met in a 2- day workshop in order to share experiences and align strategies for the future. Their experience can lead for further scientist research in the

archetype development process and identify Key Performance Indicators of this process. This information needs to be shared between the community of EN13606 users.

This group of experts agreed to take actions to improve the acceptance of ISO 13606 and provide additional resources to widespread adoption of the best practice in the ADP. The Swedish Centre for eHealth recognised that data types have been one of the major problems in Swedish systems implementation. Also some of the delegates pointed out the need for research about how to improve identification of entities based on the integration of OID and HL7 IXS that might impact on the demographic model. In order to solve this problem, the attendants agreed to develop

- A profile of the ISO 21090- Health Informatics – Harmonized Data Types for Information exchange as a simplified version of this standard because this specification includes a large number of data types.
- Educational resources to identify best practice in ADP including terminology bindings.
- Technical resources such as XML Schemas and implementation guides

They identified the needs for establishing a community of EN1360 users and future collaborations with other organisations such as HL7, IHTSDO, openEHR and EuroRec. As Kohl et al. explained knowledge resources could be shared between different organisations. (Kohl, 2008)

II. EDUCATION

Currently the number of training courses about archetypes is small. Currently there are only two organisations that offer educational courses about archetypes, these are Ocean Informatics and the Universidad Politécnica de Valencia (Universidad Politécnica de Valencia, 2010).

Ocean Informatics offer different training courses about the OpenEHR approach and archetype development. The courses are between one and two days long with the following modules and can be oriented to technical or clinical people. The course is organised in different modules that allows a personalised educations. Clinician modules include the openEHR clinical modelling, standards, terminologies. Clinicians learn how to use the Ocean software such as Archetype Editor, Template Designer and Terminology Service and how to use them in real examples such as Emergency Department or Labs results. Developer modules include the OpenEHR Reference Model, Archetype Model, Archetype Query Language and Archetype Definition Language. These modules are presented

The Universidad Politécnica de Valencia courses about the ISO/EN 13606 standard are oriented towards technical people. They are planning to include a new edition that is oriented towards clinicians. The course is currently in Spanish and includes an introduction to EHR standards with a highly detailed explanation of the ISO/EN 13606, archetype design and how can be applied ISO/EN 13606 to legacy data. The course includes practical exercises with LinkEHR-Ed applied to real scenarios.

III. COLLABORATIVE DEVELOPMENT IN GOOGLE WAVE: THE WOUND CARE ARCHETYPES EXPERIMENT

Another action has been identified as an attempt to increase the quality in the ADP. In 2009, OpenEHR started the definition of Wound Care Archetypes within the Google Wave collaborative tool (Google Wave, 2009).This is an online application created by Google in 2009 designed to allow real-time communication and collaboration. The wave allows different users to edit together a document keeping the track of all the modifications and the order in which they have been made. The users can move the

timeline back if they want to see the previous document state or even reverse the latest inputs. The purpose of this trial was to evaluate if this tool was able to provide benefits in the early stages of the ADP.

Initial upload

The Wound Care Archetypes Wave was created and leaded by Ian McNicoll, who is one of the editors of the OpenEHR CKM. The development process started on 4th of December 2009 and the last input was on 11th of February 2010. The archetype editor started the Wave including the archetypes title, scope, a mindmap of the archetypes and some references mostly from internet resources rather than the literature. The set of archetypes included two observation entries, one action, one evaluation one instruction and one assessment tool.

Role interaction

When the Wave was made publicly available and an invitation was sent to the OpenEHR mail list. Twenty experts accept to participate in this initiative. One of the invited experts was working in a thesis about chronic wound documentation with openEHR. This expert actively participated in the Wave and provided the following information: one template and four archetypes previously developed by himself and nine references to the literature. After 94 different inputs, these archetypes were enriched by the information and comments from invited experts working in this area.

OpenEHR evaluation

In a personal communication with one Ocean Informatics member, he claimed that the Wave paradigm might be useful but Ocean Informatics considers that the Google wave tool is currently too chaotic for archetype/template development (McNicoll, 2010).

CHAPTER 3: METHODOLOGY

3.1. INTRODUCTION

This analysis aims to provide valuable information about the current state of the ADP and the factors that impact in this process. Chapter 1.4 detailed the Goals and Objectives that this document plans to address and have guided the methodology design. Based on the information presented in the literature review the following strategies have been chosen:

- The current initiatives based on archetypes, detailed in chapter 2.3.3, are examined in chapter 3.5.1. This information has been used to determine the repository selection criteria to determine the analysis scope.

- Archetype selection criteria have been created to identify the most representative archetypes. These selection criteria are presented in chapter 3.5.2. They are essential to perform the exhaustive analysis proposed in the first chapter

- Another objective of this research is the selection between the different AQC. This is described in chapter 3.5.3 where the different AQC identified in chapter 2.3 are evaluated.

Once the selection criterion have been established, the methodology adopted in this chapter has been organised according to the Continuous Improvement Cycle (Plan-Do-Check-Act) described at the start of chapter 2.3. The Continuous Improvement Cycle has been useful within the methodology design stage to address different objectives of this research.

- **Plan:** In order to identify how community organisation impacts on the ADP, the analysis determines the participation of the actors involved in this process. Community organisation includes how archetype editors, contributors and teams interact in the ADP. Also the study identifies how archetypes are distributed between the teams.

- **Do:** this stage presents the archetypes that satisfy the defined archetype selection criteria. The analysis shows how the number of modifications impact on archetype evolution and their status. In addition, the study includes one analysis about possible dependences between different factors and their influence to the development time

- **Check:** This stage evaluates the performance of the OpenEHR ADP against an Archetype Quality Criteria that have been selected in Chapter 3.5.3.

- **Act:** The results from the analysis are the basis for the proposed actions detailed in chapter 5.2.

3.2. CONTINUOUS IMPROVEMENT CYCLE: PLAN

3.2.1. TEAMS

The development process has been described as a collaborative process where developers are organised in teams. The teams are composed by a balanced group of members from different backgrounds and cultures. The analysis aims to identify the current team organisation within the OpenEHR CKM and determine how the archetypes are distributed among the different teams.

This study reviews all of the teams working in the CKM from information that has been obtained directly from the CKM. The OpenEHR CKM indicates the reviewer teams that are working in the archetype development process and the archetypes that each team are developing. The teams working in the OpenEHR CKM are: Weight Team, AEG, Pathology Synoptic Report, Demographic Team, Adverse Reaction Team, Danish Review Team and Orphan Team. The number of archetypes developed by each team has been recorded manually from the CKM information.

3.2.2. ROLE INTERACTION

This study will also identify how experts are assigned to different roles. This information is presented by the OpenEHR CKM that displays the person responsible and the purpose of every archetype modification. Every proposed archetype modification needs to be approved by reviewers before the new version is created. The proposed modifications are stored as branches of the current version of the archetype. The archetype editor and the archetype reviewers argue and discuss possible changes. When a consensus is achieved and the proposed changes are approved by the reviewers, the proposed branch is set as the new version of the archetype.

I. ARCHETYPE EDITORS

The archetype editor is the person responsible for archetype quality by ensuring that the archetype metadata, including any evidential references are properly authored. This person has been assigned to the team by the OpenEHR Foundation. Archetype editor duties include collating the outcomes from discussions between the clinicians and communicating the information for change back to reviewers.

II. CONTRIBUTORS

Every archetype indicates the contributors to its development process. They are the not exactly the same as the team members because not all members of a team are involved in all the archetypes that the team is responsible for.

3.3. CONTINUOUS IMPROVEMENT CYCLE: DO

The archetypes that satisfy archetype selection criteria are examined in detail. This study is focused on the distribution of archetype modifications between published, team review and draft archetypes. This study details the number of archetype modifications and the amount of work required to achieve their current status.

The point of change between the different editing states has been analysed for published archetype in order to identify any differences between their development process and the equivalent process in team review and draft archetypes.

Multiple issues have been addressed in this chapter to identify the Key Performance Indicators (KPI) in the ADP. The published archetypes have been analysed in order to find relationship between the time of development and number of nodes, number of modifications or contributors (contributors are the people who participate in the development). Because the ADP is still in an early stage there is only a very limited number of published archetypes. As a consequence there is not enough data to determine any useful correlation between these concepts.

Table 1 presents a summary of the different analyses performed to the published archetypes (Appendix 8.5) and shows that the correlation coefficients are not close to the minimum required to establish any lineal inference ($R^2 > 0.9$)(Steel, 1960).

ID	Correlation between	Correlation Coefficient (R^2)	Evaluation
AN1	Number of days of development and number of nodes in an archetype	0.115	There is not dependences between the analysed data
AN2	Number of days of development and number of contributors	0.1349	There is not dependences between the analysed data
AN3	Number of days of development and number of modifications	0.0642	There is not dependences between the analysed data
AN4	Number of contributors and average of days between steps	0.0028	There is not dependences between the analysed data
AN5	Number of archetype modifications and average of days between steps	0.69	The relationship is not high between the analysed data

Table 1. Correlation analysis results

3.4. Continuous Improvement Cycle: Check

In this section the EuroRec requirements (Kalra, 2008b) have been established as an Archetype Quality Criteria (AQC) in order to determine the level of quality in ADP of the OpenEHR approach.

The performance of the OpenEHR archetypes or repository to the requested requirement is indicated by the following levels:

- No conformance: The requirement is not satisfied
- Partial conformance: The requirement is not fully satisfied
- Full conformance: The requirement is fully satisfied
- No applicable yet: There is a reason why it is not possible to measure this requirement at the moment.

3.5. Selection Criterion

The analysed archetypes and repositories have been chosen based in the following selection criterion:

3.5.1. Repository selection criteria

The choice of analysing the OpenEHR repository rather than the NHS, Swedish or Poseacle repository is based on the following reasons:

- The OpenEHR repository has adopted some of the NHS archetype released.
- The OpenEHR development community involves the highest number of reviewers and users from different background and countries.

- The OpenEHR Clinical Knowledge Manager (CKM) provides the means to enable the collaboration in the development process from community members.
- The OpenEHR CKM provides a well documented archetype history with transparent policies and tools that facilitate the access to the information.
- The archetype quality in the OpenEHR CKM is supported by the archetype editors who ensure that all the uploaded archetypes satisfy the quality governance.
- At the time of this study (July 2010) the Swedish archetype repository is in a very early stage without any published archetype, 98% of the archetypes are in draft version and 46% of them were created last month.
- Minas Gerais repository contains a small number of archetypes. Also, this repository doesn't provide information about how people involved in the development are organised and the archetype history.

3.5.2. ARCHETYPE SELECTION CRITERIA

Because of the large number of archetypes included within the OpenEHR CKM, the study has defined multiple selection criteria that delimit the number of archetypes analysed. These selection criterions have been applied in two different stages:

FIRST SELECTION CRITERION BASED ON THE ARCHETYPE STATUS

The team reviewed and published archetypes were identified as the most representative archetypes because they have been discussed inside the development team and a certain level of consensus has been achieved between them. This characteristic guarantees that these archetypes have sufficient maturity to provide valuable information about the archetype development process. After the complete analysis of this set of archetypes, the conclusions couldn't be validated with the Draft archetypes. Therefore a second selection criterion including a set of draft archetypes was established.

SECOND SELECTION CRITERION FOR KEY ARCHETYPES

In order to validate the study, a second analysis has been performed with archetypes in draft status. These archetypes have been selected from the *Poll - Top 10 archetypes for use in an Emergency* with more than 5% of votes where analysed. In total 9 draft archetypes were included in the study (H. Leslie, 2009).

3.5.3. SELECTION CRITERIA FOR CHECK STAGE

Based on the repository selection criteria the OpenEHR approach has been chosen because the level of maturity is higher than other approaches. From all the possible requirements identified in the literature review the reasons why the EuroRec requirements have been selected rather than the OpenEHR Editorial Checklist, Archetype Principles or ISO/EN 13606-2 recommendations are:

- EuroRec requirements include most of the recommendations included in ISO/EN 13606-2
- The OpenEHR Editorial Checklist and the Archetype principles have been created by the same organisation that is going to be analysed.
- EuroRec is the only organisation specialised in certification of quality.

The archetype selection has been based on their maturity level. This selection has been restricted to the archetypes that have been published before 2010. As a consequence the archetypes included in the study are: Apgar score, Body weight, Body mass index, Body temperature, Height/Length, Blood pressure and Respirations. These archetypes have been analysed individually against Business, Clinical, Technical and Information governance requirements defined by EuroRec. In addition the EuroRec Archetype repository requirements have been check in the OpenEHR CKM.

3.6. SOURCE OF INFORMATION: OPENEHR CKM

Based on the above explained selection criteria the analysis of the OpenEHR CKM has been performed on archetype development activity up to January of 2010 when the OpenEHR repository was composed of 234 archetypes and the supporting community had 404 registered users. The following table details the states of the archetypes.

Status	Number of archetypes
Draft	206
Team review	15
Published	7
Rejected	6
Obsolete	0

Table 2. Relationship between the number archetypes and their status in the CKM

The information analysed has been obtained from the archetype history displayed in the CKM where any archetype modification is presented as a branch. Every branch has a person responsible. The CKM details for any modification are:

- Branch creation time: The upload time of the archetype in the repository.
- Log message: information about the differences from the current version of the archetype at that time.
- Person responsible for the modification: The person responsible of the branch is in most of the cases an archetype editor

3.7. DATABASES

A set of relational databases have been created with the software Microsoft Access to store the information about every branch that is committed in the archetype development process. According to the relational databases theory every table field as primary key that uniquely identifies each record of the table. The information is stored in three different tables: Archetypes, Modifications and Authors.

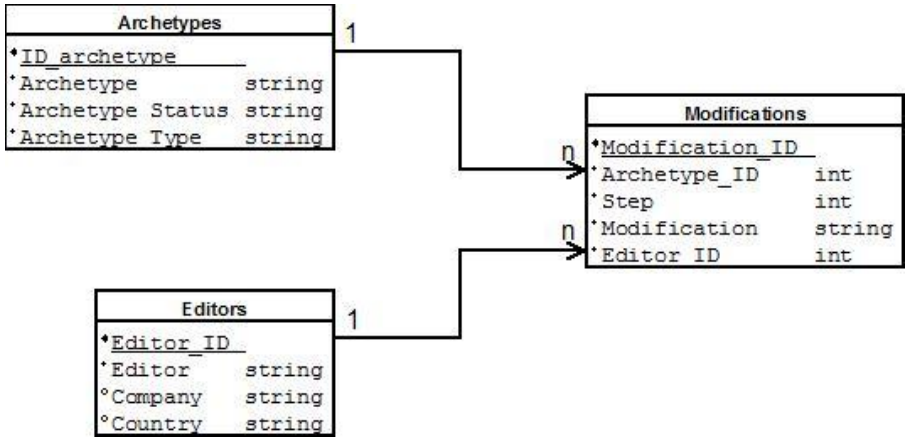

Figure 7. Relational Shema for Archetype Development Process Database

Archetypes Table: has 28 records with information about the archetype analysed. This table contains the following attributes

- **ID_Archetype:** This is the primary key of the table.
- **Archetype:** The name of the archetype is stored as a string.
- **Archetype Status:** Although the archetype status can be "Published", "Team Review", "Draft" and "Rejected", the scope of this study only involves "Published" and "Team review" archetypes. This field is stored as a string.
- **Archetype Type:** The OpenEHR reference model differentiates between the archetypes according to their functionality. It is stored as a string with the following values: Cluster, evaluation, observation, demographics, action, admin and element.

The Editor Table: Has 9 records with the information about the person in charge of the modification. Although in most of the cases the responsible person will be an archetype editor, the results show that there are some exceptions such as translation and testing where different people might create additional inputs.

- Editor_ID: The primary key of the table
- Editor: Name and surname of the author of modification
- Company: It indicates the organisation where the author belongs
- Country: Indicates the country of the organisation

Modifications Table: It has 161 different records with the following information.

- Modification_ID: Primary key of the table
- Archetype_ID: It is the relationship to the Archetype table
- Step: The number of modifications that has been performed
- Modification: The description recorded in the Log message
- Editor ID: It is the relationship to the Author table

4. RESULTS

4.1. CONTINUOUS IMPROVEMENT CYCLE: PLAN

4.1.1. ROLE INTERACTION

I. ARCHETYPE EDITORS

The contribution of content in the archetypes only can be done by the people designated by OpenEHR to be archetype editors. As result of this policy, the archetype editors Heather Leslie and Ian McNicoll are responsible of the edition of 80 percent of the modifications. The repository includes also archetypes created by Sam Heard and Heather Leslie within the NHS project in 2007.

There are some exceptions where the modifications weren't created by archetype editors. In these cases, the modifications didn't involve the clinical content and the purpose was either the archetype translation or the CKM testing. The translation based modifications were created by Sebastian Garde and Sergio Freire, on the other hand Shala Foozonkhan was responsible of the testing modifications.

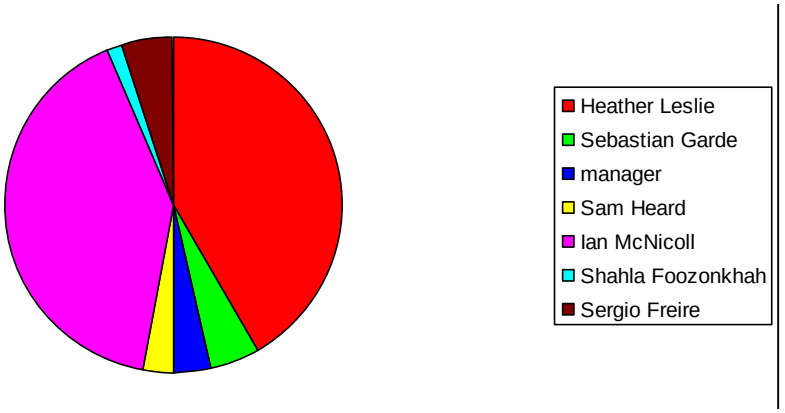

Figure 8. Distribution of archetype modifications between the people involved in the ADP

II. CONTRIBUTORS

The variations in the number of contributors impact on the archetype status, they are people who collaborate with archetype editors in the archetype modelling process. The following table show how the published archetypes have in average 15.0 contributors around three times more than team review archetypes. Also the number of contributors for draft archetypes is scarce with only one person in average.

Archetype contributors			
	Draft Archetypes	Team Review Archetypes	Published Archetypes
Average of contributors	1.0	5.6	15.0
Max	4	18	30
Min	0	0	7
Standard Deviation	1.6	4.2	7.5
Median	0	6	14

Table 3. Relationship between the number of contributors and archetype status

III. TEAM RESULTS

The following table shows the number of archetypes created by the different teams. Most of the teams are working on a small number of archetypes. Although after the team creation, it is likely that this group of experts uses their knowledge to model different archetypes, in the case of the Weight team this group of people was created specifically to create an archetype. The Orphan team is responsible of most of the archetypes (230 archetypes) in the CKM repository and their scope includes different domains such as demographic, admin, device details, imaging data or clinical review. Most of the archetypes of the orphan team remain as draft versions except for 3 published archetypes and 4 team review archetypes. Teams working on a small group of archetypes are more likely to achieve published status for the archetypes that they are responsible for.

Team	Published	Team Review	Draft
AEG	5	0	0
Weight Team	1	0	0
Demographic Team	1	0	7
Adverse Reaction Team	0	1	0
Pathology synoptic Report	0	8	6
Orphan Team	3	4	223

Table 4. Distribution of archetypes between development teams

4.2. CONTINUOUS IMPROVEMENT CYCLE: DO

The distribution of the archetypes analysed among the different hierarchical structures defined in the OpenEHR RM shows that all the published archetypes are Observation Entry. In contrast, the team review archetypes are mostly Clusters and the draft archetypes are highly distributed between the RM classes. There are few if any similarities between the distribution of the team review and the published archetypes.

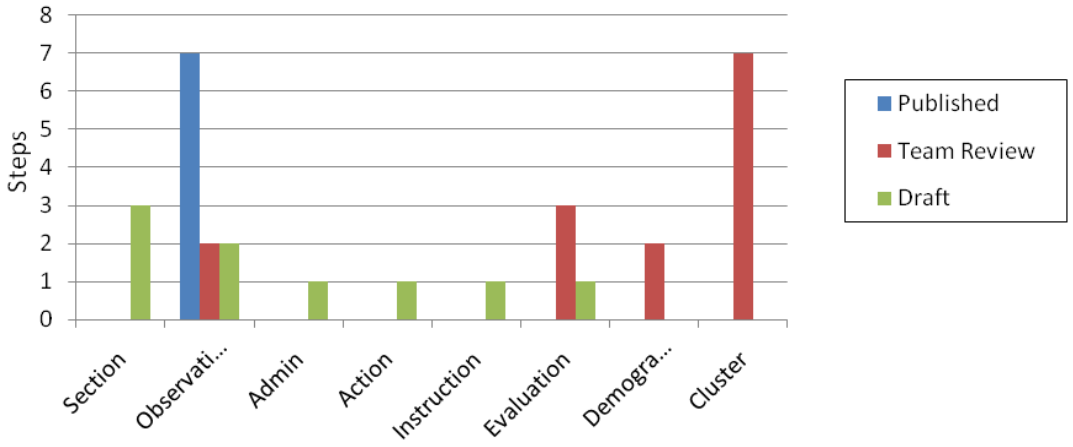

Figure 9. Distribution of studied archetypes by openEHR RM classes

The distribution of the number of modifications among the analysed archetypes shows that the Observation archetypes are the class with a highest number of modifications. The distribution of the number of modifications is clearly influenced by the published archetypes because all of them increase the average number of modifications only in the observation entries. The average number of modifications in the clusters and demographic archetypes exactly matches the team review average of modifications. The other hierarchical structures have fewer modifications, because they are either highly influenced or only determined by the draft archetypes

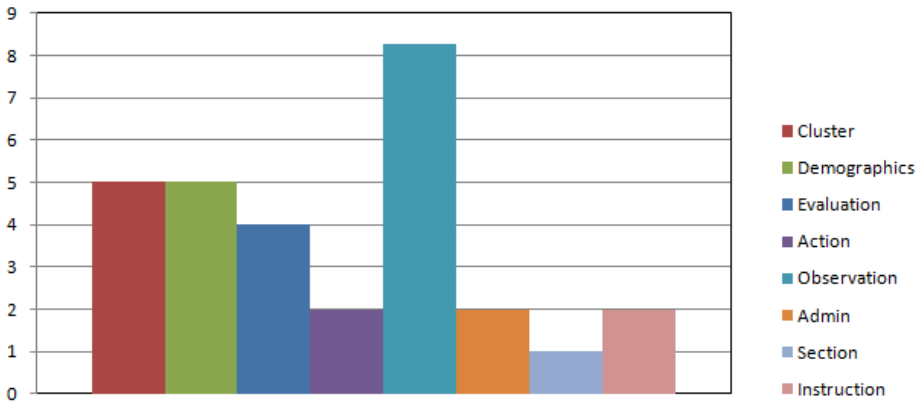

Figure 10. Distribution of the average of steps between RM classes

4.2.1. ARCHETYPES EVOLUTION

The following figures show the evolution of the studied archetypes over time. The information provided is a detailed evolution of the individual archetypes. The number of modifications in the archetype is displayed in the Y-axis and the X-axis provides dates for the modifications.

Most of the published archetypes were created in July 2008 except for the body temperature that was created in May 2008. The number of modifications that the published archetypes required to achieve their current consensus varies between 6 (Body mass index archetype) and 18 (Respirations archetype). The body temperature archetype was the first archetype to becomes stable in January 2009

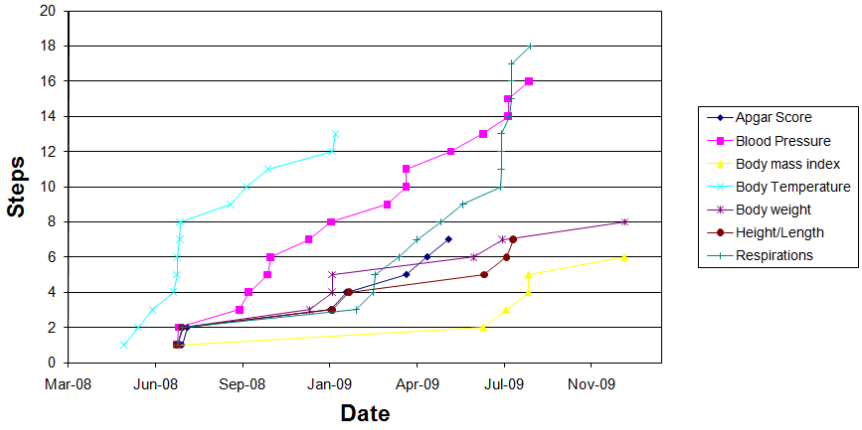

Figure 11. Evolution of published archetypes

In contrast to the Published archetypes, most of the Team Review archetypes have been created in 2009 except for the Problem and Heart rate and rhythm archetypes. They have a smaller number of modifications that vary between three for the Heart rate and rhythm archetype and seven for the Pulse Oximetry, Melanoma of Skin and Clinical Synopsis archetypes. Although some of these archetypes present a large number of modifications from the clinical discussion, they couldn't achieve published status.

It is interesting that there are Team review archetypes with higher number of modifications than the body mass index, which is a published archetype with only six modifications.

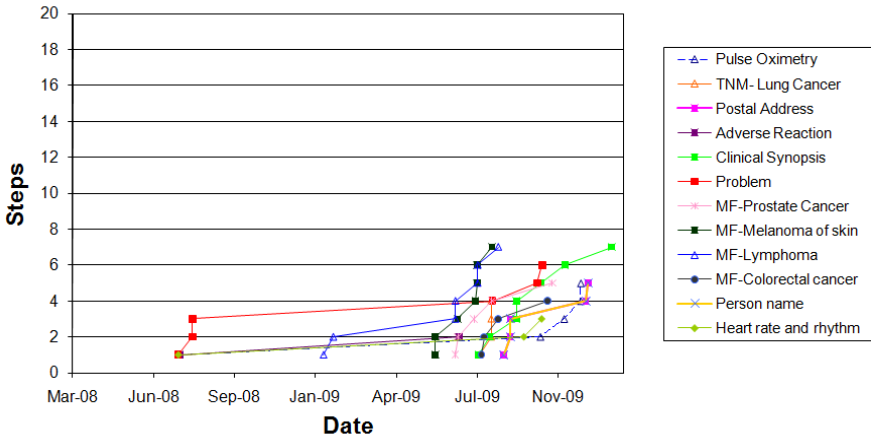

Figure 12. Evolution of team review archetypes

The selected Draft Archetypes have been created mostly in 2008 except for the laboratory test. Although they have been created before most of the team review archetypes, they haven't had enough inputs to achieve the minimal consensus needed for the Team review status. For instance the diagnostic report archetype has been created in March 2008 but there isn't any other modification or input after this point. The number of modifications varies from one modification of the diagnostic report to four modifications of the diagnosis archetype. In contrast to the Team Review and Published archetypes, the most of draft archetypes analysed present a long time without modifications. Between March of 2009 and January of 2010 only one archetype has been modified.

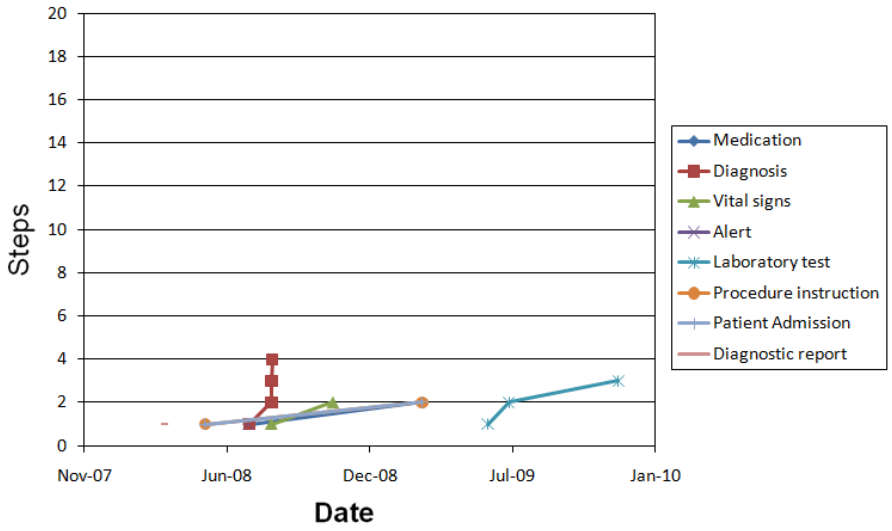

Figure 13. Evolution of draft archetypes

The average number of development days is the average number of days between the initial upload and the latest modification. There are two draft archetypes that haven't been modified after the initial upload, in these cases they have zero development days. Table 5 shows how the development process has been longer for the published archetypes. A detailed table that summarises the information about each archetype is presented in the appendix 8.1.

Days of development			
	Draft Archetypes	Team Review Archetypes	Published Archetypes
Average of Days of development	144.0	195.4	395.9
Max	304	495	514
Min	0	15	243
Standard Deviation	130.9	167.1	99.8
Median	134.5	112.0	404.0

Table 5. Relationship between the archetype status and the average days of development

The average of number of days between steps has been calculated from the division of summation of all days of development among the number of modifications that the archetype had. In this case, the two draft archetypes that haven't been modified after the initial upload were not included. The results are presented in the table 6 where the published archetypes have the smallest interval between modifications. Likewise the team review archetypes have only a lightly longer interval between modifications. In contrast, the elapsed time between modifications of the analysed draft archetypes is more than 3 times greater than published and team review archetypes. The table that contains the detailed information about each archetype is presented in the appendix 8.2.

Days between steps			
	Draft Archetypes	Team Review Archetypes	Published Archetypes
Average	172.0	72.4	51.7
Max	304.00	345.00	103.00
Min	7.75	5.00	20.00
Standard Deviation	126.3	98.4	30.6
Median	167.3	27.0	51.0

Table 6. Relationship between the archetype status and the average days between steps

Given that the published archetypes have on average more development days and fewer days between modifications, they will have the highest number of modifications. Table 7 shows the differences in the number of modifications among the multiple archetype status. The average of modifications is almost twice as high in the published archetypes when compared to the set of team review archetypes. While there is a clear relationship between the number of modifications of an archetype and its status, there are examples of team review archetypes with a higher number of modifications than the published archetypes.

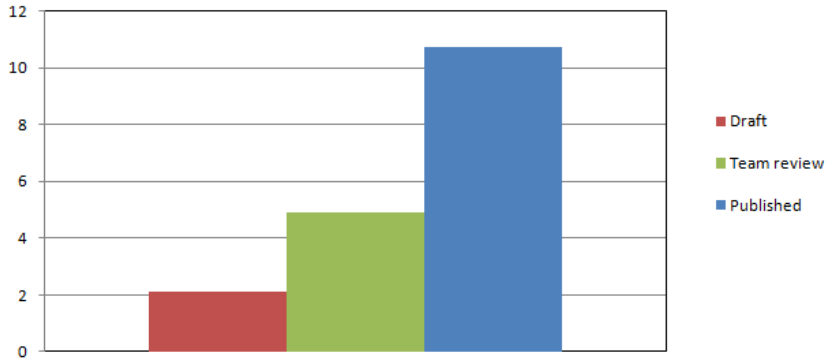

Figure 14. Relationship between the archetype status and the average of modifications

Number of modifications			
	Draft Archetypes	Team Review Archetypes	Published Archetypes
Average of modifications	2.4	4.9	10.7
Max	4	7	18
Min	0	2	6
Standard Deviation	1.0	1.5	4.9
Median	2.0	5.0	8.0

Table 7. Relationship between the archetype status and the average of modifications

Published archetypes (Appendix 8.1) are analysed in more detail in order to identify the level of similarities between their draft and team review stage (Table 8 and 9), and the results obtained for draft and team review archetypes (Figures 5 and 7). The obtained results show that the current draft archetypes need slightly more modifications and time (2.4 modifications and 144.0 days of development) than the current published archetypes (2.1 modifications and 92.7 days of development) to achieve the team review stage. On the other hand, most of team review archetypes are not very close to the number of modifications and time that the current published archetypes needed to achieve this status.

Days of Development in published archetypes		
	Until they achieve the team review stage	Until they are published
Average of days of development	92.7	332.5
Maximum	352	614
Min	0	162
Standard Deviation	136.1	148.6
Median	7.7	332.0

Table 8. Statistics relating to days of development until archetypes achieve team review status and published stages

Number of modifications in published archetypes		
	Until they achieve the team review stage	Until they are published
Average of modifications	2.1	10.4
Max	3	18
Min	1	6
Standard Deviation	0.7	5.4

Median	2.0	7.0

Table 9. Statistics relating to number of modifications until archetypes achieve team review status and published stage

4.2.2. ARCHETYPE TRANSLATIONS

After an archetype is published the archetype translators incorporate support for different languages. Within the analysed archetypes, fifteen branches were created for translation purposes. The translation languages are Portuguese, German, Dutch and Spanish.

4.2.3. REJECTED BRANCHES

The OpenEHR governance for publishing archetypes establishes that the archetype editors must ensure that the archetype published in the archetype repository satisfies the quality criteria. Any modification has to be approved by the archetype editor before it is uploaded. This mechanism has successfully maintained the number of rejected branches as a very small percentage of only 3.1 %. There are only 5 cases from 161 modifications where a branch was rejected based on the content.

4.3. CONTINUOUS IMPROVEMENT CYCLE: CHECK

4.3.1. QUALITY ASSESSMENT BASED ON EUROREC REQUIREMENTS

In order to measure the quality of the OpenEHR published archetypes and the OpenEHR CKM, they have been checked against an Archetype Quality Criteria based on the EuroRec requirements (Kalra, 2008b). The following tables detail the performance of the OpenEHR archetypes and repository for the individual EuroRec requirements.

Note: The following requirements have been obtained from the document titled "Q-Rec Management and maintenance policies for EHR interoperability resources" (Kalra, 2008b). The detailed requirements haven't been rephrased in order to preserve accuracy of the analysis.

Business requirements						
BR.1-An archetype shall define a formal representation for one or more discrete kinds of clinical (health or health care) entity within an electronic health record.						
Apgar score	Body weight	Body mass index	Body temperature	Height/Length	Blood pressure	Respirations
Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.
Comments: The openEHR archetypes are able to be applied by different healthcare entities						
BR.2-An archetype shall define the structural organisation and kinds of permitted data content for representing one or more clinical entities as a use pattern (i.e. a constraint pattern) for a specified electronic health record information model.						
Apgar score	Body weight	Body mass index	Body temperature	Height/Length	Blood pressure	Respirations
Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.
Comments: The OpenEHR archetypes define the structural organisation and permitted data for all the items modelled.						
BR.3-An archetype shall specify the use pattern in sufficient detail and with						

sufficient precision that different conforming clinical data instances drawn from different EHR systems and communities of practice can be represented consistently when using the same (specified) electronic health record information model.						
Apgar score	Body weight	Body mass index	Body temperature	Height/Length	Blood pressure	Respirations
Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.
Comments: The OpenEHR archetypes are able to represent consistently the instances of the EHR Reference model. The data from different systems can be transmitted consistently if they use the same archetype and RM.						
BR.4- An archetype shall include or reference information about its intended usage sufficiently that potential or current technical or clinical adopters can unambiguously determine the clinical scenarios and kinds of EHR data to which it applies.						
Apgar score	Body weight	Body mass index	Body temperature	Height/Length	Blood pressure	Respirations
Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.
Comments: The archetype usage is clearly stated in every archetype						
BR.5- An archetype shall include or reference information that enables a potential or current user to determine its evidence basis, quality and currency.						
Apgar score	Body weight	Body mass index	Body temperature	Height/Length	Blood pressure	Respirations
Full Conf.	No Conf.	Full Conf.	No Conf.	Full Conf.	Full Conf.	Full Conf.
Comments: There are two archetypes without references. Within the summary of findings in chapter 5 is presented an explanation about how the references are needed and the consequences in Body Weight and Body Temperature archetype						
BR.6- An archetype shall include or reference information that informs a current or potential user about the certifications, approvals and uses of it, globally.						
Apgar score	Body weight	Body mass index	Body temperature	Height/Length	Blood pressure	Respirations
No applicable yet	No applicable yet	No applicable yet	No applicable yet	No applicable yet	No applicable yet	No applicable yet
Comments: EuroRec, which is the only organisation which intends to certify and quality label archetypes, has not started the certification process yet.						

Table 10. Performance of OpenEHR published archetype against EuroRec Business requirements

Clinical requirements						
Clinical usage requirements						
CR.1- An archetype shall specify the precise nature of the clinical entity (or set of entities) for which it defines a use pattern.						
Apgar score	Body weight	Body mass index	Body temperature	Height/Length	Blood pressure	Respirations
Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.
Comments: The openEHR archetypes specify the entities when they are required.						
CR.2- An archetype shall specify any particular clinical scenarios or workflows for which it is particularly intended.						
Apgar score	Body weight	Body mass index	Body temperature	Height/Length	Blood pressure	Respirations
Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.
Comments: The openEHR archetypes specify the particular scenarios and workflows when they are required						
CR.3- An archetype shall specify any particular sub-populations of citizens for whose health or health care it particularly applies.						

Apgar score	Body weight	Body mass index	Body temperature	Height/Length	Blood pressure	Respirations
Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.
Comments: The openEHR archetypes define the population where it is applied within either scope, use or misuse fields. Also, it would be recommended create additional requirements that verify that the misuse field is not empty. In case that one archetype is for general use, it should be indicated.						
CR.4- An archetype shall specify any particular speciality, discipline or professional groups for whose use it is primarily intended.						
Apgar score	Body weight	Body mass index	Body temperature	Height/Length	Blood pressure	Respirations
Partial Conf.	Full Conf.	Partial Conf.	Full Conf.	Full Conf.	Partial Conf.	Partial Conf.
Comments: Although the archetypes don't specify the discipline or professional groups they have full conformance to the requirement if they are for general use or partial conformance if the professional group or speciality can be inferred with the scope. The OpenEHR CKM classifies the archetypes between the professional groups but this information is not included within the archetype.						
CR.5- It shall be possible for an archetype to include specific usage guidance, such as a restriction to certain sub-populations or scenarios, that apply to individual EHR nodes and/or constraints within it (i.e. that apply to individual parts of the archetype rather than its whole).						
Apgar score	Body weight	Body mass index	Body temperature	Height/Length	Blood pressure	Respirations
Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.
Comments: The information about any particular node is recorded within the Scope Field of the Archetype if it is necessary						
Clinical domain coverage						
CR.6- An archetype shall include or reference one or more concepts from an internationally registered terminology system to which it corresponds most closely, in order to permit its clinical scope to be widely understood, and compared with other archetypes.						
Apgar score	Body weight	Body mass index	Body temperature	Height/Length	Blood pressure	Respirations
No Conf.	Full Conf.	No Conf.	No Conf.	No Conf.	Full Conf.	No Conf.
Comments: Most of the archetypes are not bounded to any terminology. The Blood pressure archetype has bound 3 of 15 nodes to terminologies and the Body Temperature archetype only one concept						
CR.7- The clinical scope of an archetype shall be sufficiently precise that EHR instances conforming to the archetype may meaningfully be interpreted and analysed collectively (i.e. that their data values are comparable - e.g. it would be meaningful to list the values in a table or plot them on a graph).						
Apgar score	Body weight	Body mass index	Body temperature	Height/Length	Blood pressure	Respirations
Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.
Comments: The OpenEHR archetypes satisfy this requirement						
CR.8- An archetype shall include or reference sufficient information to permit areas of clinical scope overlap between archetypes to be identified, for example by mapping individual nodes within it to internationally registered terminology concepts.						
Apgar score	Body weight	Body mass index	Body temperature	Height/Length	Blood pressure	Respirations
No Conf.	Full Conf.	No Conf.	No Conf.	No Conf.	Full Conf.	No Conf.

Comments: Although the archetype scope defines the possible overlaps, most of the individual nodes are not mapped to international recognised terminologies.

CR.9- An archetype shall be able to include part or all of another pre-existing archetype if part of the entity it represents has already been defined in a way that meets the requirements of its use cases and users; such re-used archetype fragments shall be identifiable as being identical across the various archetypes that use them.

Apgar score	Body weight	Body mass index	Body temperature	Height/Length	Blood pressure	Respirations
Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.

Comments: The OpenEHR approach uses the Slots structures for definition of hierarchical structures between archetypes. They enable the reusability of archetypes

CR.10- An archetype shall be able to be a constrained (specialised) version of a pre-existing archetype, for example to narrow its applicability to a sub-set of the use cases of the original archetype; a specialised archetype shall be uniquely identified independently of the archetype it specialises, but shall identify the archetype it specialises.

Apgar score	Body weight	Body mass index	Body temperature	Height/Length	Blood pressure	Respirations
Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.

Comments: Although these archetypes are not specialisations of any other archetype, they are able to be specialised.

CR.11- It should be possible to identify parts of two or more archetypes that have the same scope (i.e. if they define constraints to represent the same portions of a clinical entity), so that differences or similarities between them can be recognised.

Apgar score	Body weight	Body mass index	Body temperature	Height/Length	Blood pressure	Respirations
Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.

Comments: The OpenEHR archetypes identify the relationship with archetypes that have similarities in their scope. For instance Body mass index archetype clearly states that it is related with height and body weight archetypes

CR.12- An archetype's use pattern should be inclusive of all of the minor variations in clinical entity representation across its use cases, users and scenarios; i.e. it should be a superset of the sub-components of the various required representations of the clinical entity.

Apgar score	Body weight	Body mass index	Body temperature	Height/Length	Blood pressure	Respirations
Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.

Comments: The OpenEHR archetypes satisfy this requirement

CR.13-The representation of sub-components (data items) of an entity within an archetype should be optional unless those data items are accepted to be mandatory across all of its intended use cases, users and scenarios.

Apgar score	Body weight	Body mass index	Body temperature	Height/Length	Blood pressure	Respirations
Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.

Comments: The OpenEHR archetypes satisfy this requirement. The data items are defined as mandatory when they can be applied across all the use cases where the archetype is applied.

CR.14- Notwithstanding the above, an archetype's design should avoid meeting an over-inclusive set of use cases and including so many optional properties that it results in very diverse kinds of conforming EHR instances.

Apgar score	Body weight	Body mass index	Body temperature	Height/Length	Blood pressure	Respirations
Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.

Comments: The OpenEHR archetypes satisfy this requirement. The archetype editors avoid the

definition of an over-inclusive set of use cases.

CR.15- An archetype's scope should be focussed enough that the likelihood of overlap with other archetypes in the same domain is minimised.

Apgar score	Body weight	Body mass index	Body temperature	Height/Length	Blood pressure	Respirations
Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.

Comments: The OpenEHR archetypes satisfy this requirement. Whilst the archetype scope is defined in enough detail to minimise possible overlaps the scope definition could be improved if it is recorded or organised in a computable way.

CR.16- An archetype should reflect the extent of consensus and degree of alignment of requirements across the relevant user communities; multiple archetypes should be considered in areas where consensus is limited or sound reasons exist for fostering diversity of representations (such as an area of active research or innovation, or to comply with differing jurisdictional policies).

Apgar score	Body weight	Body mass index	Body temperature	Height/Length	Blood pressure	Respirations
Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.

Comments: The analysed OpenEHR archetypes are not affected by jurisdictional policies. Multiple stakeholders participated in their development to achieve the international acceptance.

CR.17- It should be possible for a community of practice to identify the set of archetypes that is relevant to its domain, and to identify the extent of domain coverage (including gaps and overlaps of coverage).

Apgar score	Body weight	Body mass index	Body temperature	Height/Length	Blood pressure	Respirations
Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.

Comments: The OpenEHR CKM is able to classify the archetypes by different clinical domains directly.

Evidential Basis

CR.18- An archetype shall be able to include references to one or more kinds of published knowledge that have informed its overall design, and/or to which it conforms; (examples of relevant knowledge include clinical guidelines, care pathways, standard data sets, professional policies, reporting templates).

Apgar score	Body weight	Body mass index	Body temperature	Height/Length	Blood pressure	Respirations
Full Conf.	No Conf.	Full Conf.	No Conf.	Full Conf.	Full Conf.	Full Conf.

Comments: The body weight and the body temperature archetype don't include any reference material. Within the summary of findings there is detailed explanation about the archetypes that don't satisfy this requirement.

CR.19- An archetype shall be able to include references to one or more kinds of published knowledge or policy to which any individual node or nodes within it conform.

Apgar score	Body weight	Body mass index	Body temperature	Height/Length	Blood pressure	Respirations
No Conf.	No Conf.	No Conf.	No Conf.	No Conf.	No Conf.	No Conf.

Comments: The references are not linked to individual nodes, and this process is not described within ADL 2.0 specification (Beale T & Heard, 2007)

CR.20- An archetype shall enable any reference to published knowledge or policy to include a textual reference to it, a description of it, an executable link such as a URL, and any notes provided by the author to specify the extent of conformance, or reasons why conformance has not been considered appropriate or feasible.

Apgar score	Body weight	Body mass index	Body temperature	Height/Length	Blood pressure	Respirations
Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.

Comments: When references are included the author can include links, notes and descriptions.

CR.21- An archetype shall enable any reference to published knowledge or policy to include a date when that knowledge is due to be reviewed (and therefore when the

archetype itself might also need to be reviewed).						
Apgar score	Body weight	Body mass index	Body temperature	Height/Length	Blood pressure	Respirations
No Conf	No Conf	No Conf	No Conf	No Conf	No Conf	No Conf
Comments: Although the OpenEHR archetypes don't indicate information about programmed future revisions of the references, every time that they are implemented or used new issues can emerge and create new adjustments in the reference information.						
CR.22- An archetype shall be able to include information about *de facto* specifications (such as existing clinical information systems) that have been its primary design basis.						
Apgar score	Body weight	Body mass index	Body temperature	Height/Length	Blood pressure	Respirations
No Conf	No Conf	No Conf	No Conf	No Conf	No Conf	No Conf
Comments: The reviewed OpenEHR archetypes don't provide any information about the information systems that impact on the design or where archetype have been implemented						
CR.23- An archetype shall be able to include information about the set of clinical and non-clinical stakeholder communities that have provided requirements that it meets.						
Apgar score	Body weight	Body mass index	Body temperature	Height/Length	Blood pressure	Respirations
Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.
Comments: The OpenEHR archetypes provide information about any person who contributes in the archetype development process.						
CR.23- An archetype shall be able to include information about the set of clinical and non-clinical stakeholder communities that have verified its correctness via peer review.						
Apgar score	Body weight	Body mass index	Body temperature	Height/Length	Blood pressure	Respirations
Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.
Comments: The OpenEHR archetypes need to achieve a consensus within the group of reviewers in order to be published						
CR.24- The author of an archetype should first ensure that appropriate effort has been made to identify relevant evidence, consult relevant stakeholders and examine existing systems in use.						
Apgar score	Body weight	Body mass index	Body temperature	Height/Length	Blood pressure	Respirations
Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.
Comments: The OpenEHR editorial checklist verifies that the archetype author has created a balanced team.(Leslie, 2009)						
CR.25- The author of an archetype should first ensure that any existing published archetypes are examined for potential duplication or overlap, and should aim to re-use relevant existing specifications.						
Apgar score	Body weight	Body mass index	Body temperature	Height/Length	Blood pressure	Respirations
Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.
Comments: The OpenEHR editorial checklist verifies that archetype authors don't create any overlapping archetype (Leslie, 2009)						
CR.26- An archetype should specify if its draft versions have been through an open consultation or social computing form of peer review (e.g. published on a wiki site for public comment).						
Apgar score	Body weight	Body mass index	Body temperature	Height/Length	Blood pressure	Respirations
No Conf.	No Conf.	No Conf.	No Conf.	No Conf.	No Conf.	No Conf.

Comments: The OpenEHR archetypes don't indicate how their draft version has been created but OpenEHR has published in their website how is this process for most of their archetypes (Leslie, 2008a)						
Communities of use						
CR.27- An archetype shall be able to include or reference multiple instances of information relating to its scope, purpose, usage, stakeholders and evidential basis so that different communities of use can include such information as is relevant to their own jurisdictions.						
Apgar score	Body weight	Body mass index	Body temperature	Height/Length	Blood pressure	Respirations
Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.
Comments: While it is not stated, the OpenEHR archetypes don't have any limitation about jurisdictions because they are intended to be applied internationally.						
CR.28- An archetype shall be able to include multiple natural language translations of any or all of its textual content, and be able to distinguish pure translations from alternative wording for a different community of practice or jurisdiction.						
Apgar score	Body weight	Body mass index	Body temperature	Height/Length	Blood pressure	Respirations
Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.
Comments: The OpenEHR archetypes are able to satisfy local needs for alternative wording or different community of practice and jurisdiction						

Table 11. Performance of OpenEHR published archetype against EuroRec Clinical requirements

Technical requirements						
Conformance to standards						
TR.1- An archetype shall conform to the requirements specified in Section 6 of ISO/EN 13606 Part 2.						
Apgar score	Body weight	Body mass index	Body temperature	Height/Length	Blood pressure	Respirations
Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.
Comments: The OpenEHR archetypes satisfy the requirements specified in Section 6 of ISO/EN 13606 Part 2.						
TR.2- The information in an archetype shall be capable of being represented using the information model specified in Section 7 of ISO/EN 13606 Part 2 or to any more recent model version published by the openEHR Foundation (on www.openEHR.org).						
Apgar score	Body weight	Body mass index	Body temperature	Height/Length	Blood pressure	Respirations
Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.
Comments: The OpenEHR archetypes satisfy the archetype model published by the organisation						
Modelling requirements						
TR.3- An archetype shall specify the EHR information model for which it is a use pattern.						
Apgar score	Body weight	Body mass index	Body temperature	Height/Length	Blood pressure	Respirations
Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.
Comments: Every archetype details the information model within the file name. For instance openEHR-EHR-SECTION.respirations.v1.adl						
TR.4- An archetype shall specify the class within the EHR information model that is the root for EHR instances that conform to the archetype s constraints.						
Apgar score	Body weight	Body mass index	Body temperature	Height/Length	Blood pressure	Respirations

Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.
Comments: Within the OpenEHR archetypes the root node is assigned to the 'at0000' label. For instance the Blood pressure archetype assigns: OBSERVATION[at0000]						
TR.5- Every node in the archetype shall specify the class within the EHR information model that is the corresponding node for EHR instances that conform to the archetype s constraints.						
Apgar score	Body weight	Body mass index	Body temperature	Height/Length	Blood pressure	Respirations
Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.
Comments: Within the OpenEHR archetypes every node is assigned to the 'atXXXX' label different than the root node.						
TR.6- The identifier of an archetype, and of each of its nodes, shall be globally unique and replicated consistently whenever it is communicated.						
Apgar score	Body weight	Body mass index	Body temperature	Height/Length	Blood pressure	Respirations
Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.
Comments: The OpenEHR archetypes are unique identified because the organisation has a governance to avoid it but this mechanism could be improved by using OID for the archetype identification						
TR.7- The clinical label for each node (its name) shall be drawn from a published controlled vocabulary, and preferably from a published international terminology.						
Apgar score	Body weight	Body mass index	Body temperature	Height/Length	Blood pressure	Respirations
No Conf.	No Conf.	No Conf.	No Conf.	No Conf.	No Conf.	No Conf.
Comments: The OpenEHR clinical labels of archetypes nodes are individually bounded to international terminologies. The Blood pressure archetype has only 3 of 17 nodes bounded to SNOMED CT.						
TR.8- The definition of each node shall permit the unambiguous and consistent mapping of appropriate original EHR data and EHR system data items to it.						
Apgar score	Body weight	Body mass index	Body temperature	Height/Length	Blood pressure	Respirations
Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.
Comments: The OpenEHR archetypes define unambiguously the kind of data that is assigned to every node based on CEN 14796 (CEN/TS 14796, 2003)						
TR.9- Any node in the archetype shall be capable of being mapped to additional terms that offer an equivalent meaning to its name, and to natural language translations of the name.						
Apgar score	Body weight	Body mass index	Body temperature	Height/Length	Blood pressure	Respirations
Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.
Comments: The OpenEHR archetypes are able to be translated to different languages						
TR.10- The existence and multiplicity (cardinality) of each node will reflect the most inclusive requirements from across its use cases and users (i.e. it will specify optional in preference to mandatory constraints unless there is a consensus otherwise).						
Apgar score	Body weight	Body mass index	Body temperature	Height/Length	Blood pressure	Respirations
Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.
Comments: The OpenEHR archetypes satisfy this requirement avoiding cardinality limitations if one attribute can be repeated. For instance the number of occurrences for Confounding factors within the Respirations archetype is set to 0.. (optional, repeating)*						
TR.11- An archetype hierarchy shall avoid redundant, duplicate or near-duplicate nodes unless there are clear requirements for these and their definitions make clear how each is to be used.						

Apgar score	Body weight	Body mass index	Body temperature	Height/Length	Blood pressure	Respirations
Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.
Comments: The OpenEHR archetypes satisfy this requirement as it is stated by the archetype principles (Beale, 2007b)						
TR.12- Data value constraints (such as value ranges and term value lists) shall cater adequately for the diversity of anticipated values from its defined patient populations.						
Apgar score	Body weight	Body mass index	Body temperature	Height/Length	Blood pressure	Respirations
Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.
Comments: The OpenEHR archetypes satisfy this requirement as it is stated by the archetype principles (Beale, 2007b)						
TR.13- If an archetype constraint permits a null data value, it shall have been verified that corresponding EHR instances are consistent with the requirements of the user communities and do not introduce the risk of ambiguous or unsafe meaning to the clinical entity being represented.						
Apgar score	Body weight	Body mass index	Body temperature	Height/Length	Blood pressure	Respirations
Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.
Comments: The OpenEHR archetypes satisfy this requirement because the null data value is allowed but there isn't any archetype node that assigns this data value.						
TR.14- The term value list associated with an archetype node that has a coded or enumeration data value shall be demonstrably consistent semantically with the name of that node.						
Apgar score	Body weight	Body mass index	Body temperature	Height/Length	Blood pressure	Respirations
Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.
Comments: The OpenEHR archetypes satisfy this requirement because all the archetype nodes are consistent with their name. The archetype editors ensure the archetype consistency						
TR.15- Language translations for values within a term value list shall always be complete and correspond to the original terms on a specified one-to-one basis..						
Apgar score	Body weight	Body mass index	Body temperature	Height/Length	Blood pressure	Respirations
Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.
Comments: The OpenEHR archetypes satisfy this requirement because every archetype node is translated individually						
TR.16- An archetype node shall constrain the values of any relevant properties of the corresponding class of the EHR information model to exclude values that might otherwise contradict or conflict with the consistent representation of the clinical entity corresponding to the archetype as a whole.						
Apgar score	Body weight	Body mass index	Body temperature	Height/Length	Blood pressure	Respirations
Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.
Comments: The OpenEHR archetypes don't include any value contradicting the consistent representation of the archetype as a whole.						
TR.17- References to term value lists by means of a pattern or query specification for a given terminology shall specify the terminology system and version for which it has been validated.						
Apgar score	Body weight	Body mass index	Body temperature	Height/Length	Blood pressure	Respirations
No Conf.	No Conf.	No Conf.	No Conf.	No Conf.	No Conf.	No Conf.
Comments: Although Ocean Informatics has a tool to create term value list from terminologies the OpenEHR archetypes don't include them						
TR.18- References to other archetypes and/or archetype fragments to be included						

within an archetype shall be specific to the version of each archetype.						
Apgar score	Body weight	Body mass index	Body temperature	Height/Length	Blood pressure	Respirations
No necessary	Partial Conf.	Partial Conf.	Not necessary	Partial Conf.	Partial Conf.	No necessary
Comments: When archetypes are referenced within the archetype scope field the archetype version is not included. In contrast, when archetypes are included as a Slot the archetype version is specified.						

Table 12. Performance of OpenEHR published archetype against EuroRec Business requirements

Information governance requirements						
Authorship						
IGR.1- An archetype shall always include information about the person and/or organisation that has taken primary responsibility for its creation.						
Apgar score	Body weight	Body mass index	Body temperature	Height/Length	Blood pressure	Respirations
Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.
Comments: OpenEHR archetypes always define the archetype author and the organisation where he or she belongs						
IGR.2- An archetype shall always include information about the person and/or organisation that has taken primary responsibility for its design basis.						
Apgar score	Body weight	Body mass index	Body temperature	Height/Length	Blood pressure	Respirations
Partial Conf.	Partial Conf.	Partial Conf.	Partial Conf.	Partial Conf.	Partial Conf.	Partial Conf.
Comments: OpenEHR archetypes don't specify who is the person leading the archetype development (archetype editor), this is a problem because his person doesn't have to match with the archetype author. The OpenEHR CKM does specify within the archetype history field who is the person responsible of every modification.						
IGR.3- The person and/or organisation details may include professional or academic qualifications, organisational accreditation or other credentials.						
Apgar score	Body weight	Body mass index	Body temperature	Height/Length	Blood pressure	Respirations
Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.
Comments: OpenEHR archetypes don't include this information but it is possible to be included						
IGR.4- An archetype shall include the date and time and location (jurisdiction) of its creation.						
Apgar score	Body weight	Body mass index	Body temperature	Height/Length	Blood pressure	Respirations
Partial Conf.	Partial Conf.	Partial Conf.	Partial Conf.	Partial Conf.	Partial Conf.	Partial Conf.
Comments: OpenEHR includes information about when have been created but none of the created archetypes indicate any information about jurisdiction of creation.						
IGR.5- An archetype shall include the data and time when it must either be reviewed (to verify its clinical validity and evidence basis) or deprecated.						
Apgar score	Body weight	Body mass index	Body temperature	Height/Length	Blood pressure	Respirations
No included	No included	No included	No included	No included	No included	No included
Comments: OpenEHR archetypes don't specify any planned revision.						
IGR.6- An archetype shall specify the party or organisation that is primarily responsible for its quality maintenance.						
Apgar score	Body weight	Body mass index	Body temperature	Height/Length	Blood pressure	Respirations
No	No	No	No included	No included	No	No included

included	included	included			included	
Comments: OpenEHR archetypes doesn't specify the organisation responsible for their quality maintenance						
Version management						
IGR.7-Any modification to an archetype shall result in a revised version that references the former version.						
Apgar score	Body weight	Body mass index	Body temperature	Height/Length	Blood pressure	Respirations
Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.
Comments: The OpenEHR archetypes always define the person and organisation						
IGR.8- Archetype version management shall distinguish modifications: (a) that extend its descriptive or quality management data but do not alter its current use or the constraints that determines conformant EHR instances; (b) that enlarge or reduce or alter the ways in which it might be used but do not alter the constraints that determines conformant EHR instances; (c) that alter the constraints and extend the domain of conformant EHR instances (i.e. the change is backward compatible).						
Apgar score	Body weight	Body mass index	Body temperature	Height/Length	Blood pressure	Respirations
Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.
Comments:						
IGR.9- No revision to an archetype may render non-conformant any instance of EHRdata that conformed to a previous version: in such circumstances a totally new archetype shall be created and the existing archetype shall, if appropriate, be deprecated from further use.						
Apgar score	Body weight	Body mass index	Body temperature	Height/Length	Blood pressure	Respirations
Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.
Comments: The OpenEHR archetypes always define the person and organisation						
IGR.10- All modifications shall specify the person and organisation responsible for the change, the date and time of the change, a description of what has been changed and the reasons for making the change.						
Apgar score	Body weight	Body mass index	Body temperature	Height/Length	Blood pressure	Respirations
Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.
Comments: The OpenEHR archetypes always define the person and organisation						
Access and licensing						
IGR.11-An archetype shall include a clear statement of any copyright or usage restrictions that apply to it.						
Apgar score	Body weight	Body mass index	Body temperature	Height/Length	Blood pressure	Respirations
Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.
Comments: The OpenEHR archetypes always define the person and organisation						
IGR.12- An archetype that has restrictions on its use shall include license information and details of how any relevant permissions may be obtained.						
Apgar score	Body weight	Body mass index	Body temperature	Height/Length	Blood pressure	Respirations
Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.
Comments: The OpenEHR archetypes always define the person and organisation						
IGR.13- An archetype shall include a clear indication if it is a draft version (and liable to change), or if it is deemed complete but has not yet been endorsed by its authoring organisation.						
Apgar score	Body weight	Body mass index	Body temperature	Height/Length	Blood pressure	Respirations

Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.	Full Conf.
Comments: The OpenEHR archetypes always define the person and organisation						
Endorsement, quality labelling, certification						
Comments: Given that OpenEHR has not started any certification process yet the Endorsement, quality labelling and certification requirements can not be evaluated.						

Table 13. Performance of OpenEHR published archetype against EuroRec Information Governance requirements

Archetype repository requirements
ARR.1- The controller of an archetype repository shall publish and implement a quality management plan that includes a quality assessment of any candidate archetype offered for storage; this might for example be undertaken by a scientific review board.
Conformance level: Full conformance
Comments: OpenEHR has published an editorial checklist and the archetype principles. Instead of a scientific review board, archetype editors are responsible of the archetype quality.
ARR.2- This quality assessment shall include either the undertaking of a validation against the quality criteria listed here or any future more formal criteria, or by requiring evidence of this assessment having been undertaken by the archetype authors, or by ensuring that the archetype carries a quality label or certificate from a recognised issuing body.
Conformance level: Full conformance
Comments: The information about the archetype quality criteria is presented in the Repository help (Archetype checklist link)
ARR.3- The controller of the repository shall ensure conformance to any relevant licences or restrictions for use of an archetype, and provide appropriate means for potential users of it to be informed of these.
Conformance level: Full conformance
Comments: OpenEHR CKM indicates archetypes copyright
ARR.4- The repository shall index each contained archetype using terms and other mechanisms that enable users and software components to locate the set of archetypes that are relevant to a query or retrieval request.
Conformance level: Full conformance
Comments: OpenEHR CKM includes a search engine that satisfy this requirement
ARR.5- The repository shall enable archetypes to be identified by searching on any of its structured information properties.
Conformance level: Full conformance
Comments: OpenEHR CKM includes a search engine that satisfy this requirement
ARR.6- The repository shall support the provision only of archetypes that have been certified or quality labelled, or approved for use within a given jurisdiction, if this is a condition specified in the request.
Conformance level: Partial conformance
Comments: OpenEHR CKM includes a search engine might satisfy this requirement but there isn't any archetype certified to test it.
ARR.7- The repository shall be able to provide any if its archetypes in at least one format that conforms to a published international standard or specification.
Conformance level: Full conformance
Comments: OpenEHR Archetypes are presented in ADL format that conforms ISO 13606 part 2
ARR.8- Where more than one format is supported, a user or requesting service shall be able, per request, to nominate one of these as the preferred retrieval format.
Conformance level: Full conformance
Comments: OpenEHR CKM allows the selection between different formats.
ARR.9- The repository shall ensure that it can be notified of any modifications or updates to an archetype that it holds by its original authors, or other recognised authoring bodies, in a timely fashion.
Conformance level: Full conformance

Comments: OpenEHR CKM satisfy this requirement because it allows archetype adoption
ARR.10- The repository and its services shall maintain a complete and audited version history for all of its archetypes.
Conformance level: Full conformance
Comments: OpenEHR CKM satisfy this requirement because it provides an individual audited history for every archetype
ARR.11- Requesters of obsolete versions of an archetype shall be provided with a notification that an update (or updates) exist and be able to nominate the version(s) to be returned.
Conformance level: No applicable yet
Comments: OpenEHR CKM might satisfy this requirement but there are not currently obsolete archetypes
ARR.12- An archetype repository shall support a standardised set of interfaces and services once these are defined.
Conformance level: Full conformance
Comments: The OpenEHR support different services such as: download, vision management, search, etc. The EuroRec requirement doesn't identify exactly the services that are required because the research in this field is still ongoing.
ARR.13- A repository service should provide a notification service to its registered clients of relevant archetype updates and additions.
Conformance level: Full conformance
Comments: The OpenEHR CKM has implemented this service
ARR.14- A repository service should provide a service whereby registered clients may maintain and keep synchronised a local copy of the set of archetypes for a given domain.
Conformance level: No conformance
Comments: This service is not available within the OpenEHR CKM

Table 14. Performance of OpenEHR CKM against EuroRec archetype repository requirements

4.4. CHAPTER 4 SUMMARY

The chapter has presented how archetype editors, team review and contributors participate in the ADP. In addition a selected set of archetypes were analysed in detail, recording the number of modifications depending on their status. Lastly, the quality of the OpenEHR published archetypes has been measured based on their performance against the EuroRec Requirements. Next chapter summarises the results obtained in this section, evaluates them and proposes actions based on them.

5. EVALUATION

5.1. FINDINGS FROM THE STUDY

This section summarises the results obtained in the analysis performed by the author to provide information about what is the current state of the ADP:

5.1.1. PLAN

- There are a very small number of persons acting as archetype editors in charge of a relatively large number of archetypes.
- The number of review teams is also limited with a large number of orphan archetypes.
- The average number of contributors is probably insufficient for draft and team review archetypes.

5.1.2. DO

- Unsurprisingly, the published archetypes have the highest number of modifications than team review and draft archetypes. Also the average number of days between modifications is smaller than the others.
- In contrast to the team review and published archetypes, most of the draft archetypes analysed have existed for a long time without modifications. Between March of 2009 and January of 2010 only one archetype has been modified.
- The small number of archetype editors helps to satisfy the OpenEHR governance. Likewise it also results in a small number of rejected archetypes.

5.1.3. CHECK

The small number of OpenEHR-published archetypes and the OpenEHR CKM have been evaluated in this study against 79 requirements defined by EuroRec. The overall results of the OpenEHR-published archetypes show that they employ a high quality development process where the responsible archetype editors ensure that the OpenEHR governance and requirements are satisfied (58 requirements are fully satisfied). It was found that 7 requirements were partially satisfied and 13 not satisfied. Moreover the requirements related to endorsement, quality labelling and certification couldn't be evaluated because OpenEHR has not started their certification process yet. This is not unreasonable, given the small number of archetypes that have been brought all of the way through the process. The list of requirements that are not fully satisfied by OpenEHR are described below:

- **Business Requirements (BR):** The business requirements are completely satisfied with the sole exception of the evidence base BR5. Two archetypes (Body weight and Body Temperature) didn't include references to any source of information. As it was mentioned in the last chapter. Although these concepts could be considered to be fundamental, these references are important to understand that temperature can be expressed in Celsius and Fahrenheit degrees. Additional discussion could take in place within the body weight archetype because this

archetype is used to record information as Pounds or Kilograms but these physical magnitudes are units of mass according to different Metric Systems. Physics define the weight unit of force and is recorded as newton (symbol N) within the International System of Units (The International System of Units, 2010) and Pound-force (lbf) within the Imperial System (British Weights and Measures Association, 2010). Therefore the archetype name should be changed to Body Mass or the units of measurements should be changed. This result highlights the importance of implementing the Archetype Quality Criteria within the ADP.

- **Clinical Requirements (CR):** Clinical usage is well documented in the analysed archetypes but there is partial conformance of CR4 because the information about the discipline or professional groups for whose use the archetypes are primary intended, needs be inferred from the scope as it is not specified.

  The definition of clinical domain in the analysed archetypes doesn't satisfy the CR6 and CR8 because most of the archetypes are not bound to any terminology. Only the Blood Pressure (3 bound of 15 possible nodes) and Body Temperature (1 node) archetype have some nodes bound to international recognised terminologies. The reason why archetypes are still not bound to international terminologies could be due to the principles of the OpenEHR lifecycle, which states that terminology binding starts after the archetype achieves published status.

  The evidence-based requirements show that archetypes could be improved by linking their references to individual nodes (CR19). The problem is that the current version of ADL doesn't describe how this task could be performed. A process similar to the terminology binding could be implemented to assign references to individual nodes. Archetypes could detail information about programmed revisions (CR21) and information systems where archetypes have been implemented (CR22). In addition, archetypes don't indicate how their draft version has been created, but OpenEHR has published their archetypes either by open consultation or peer review based on social computing (CR26).

- **Technical Requirements (TR):** Although archetypes are uniquely identified with the name assigned by the developing organisation this mechanism could be improved by using an OID for archetype identification (TR6). Also the archetypes nodes and term value list are not generally bound to internationally recognised terminology systems (TR7 and TR17). The archetypes referenced in the scope should include the version of the referenced archetypes (TR18)

- **Information Governance Requirements (IGR):** OpenEHR archetypes don't record the person leading the Archetype Development Process. This person could be different to the archetype author (IGR2). Likewise archetype quality could be improved with information about planned future revisions (IGR5) or jurisdiction of its creation (IGR4).

- **Archetype Repository Requirements (ARR):** The OpenEHR CKM could offer a service that allows users to keep a local synchronised copy of the archetypes contained in the repository (ARR14)

5.2. DISCUSSION

5.2.1. ORGANISATIONAL SETTING EVALUATION

The leading role of archetype editors in the OpenEHR ADP has successfully achieved a high level of quality in the developed archetypes even when every archetype editor is responsible for a remarkably large number of archetypes. Furthermore, these archetypes have a small number of rejections and they are consistently reused.

The problem is that the number of published archetypes remains very low. Given that archetype editors coordinate the review process, it can be argued that the small number of archetype editors is a possible point of congestion in the ADP. On the other hand, the high impact on the archetype quality of people who are assigned to this role recommends keeping this role for people with a strong background in the ADP and highly committed with the organisation. One possible solution could be the creation of another role in the organisation to help archetype editors in more administrative tasks by providing support in the communication to reviewers.

The current situation suggests that the community is not large enough. The community of reviewers provide the inputs that induce modifications in archetypes in order to become useful for the general use but around 95% of the archetypes included in the OpenEHR CKM are assigned to the orphan team. Consequently, the number of contributors in team review and draft archetypes is very small compared with the contributors in published archetypes.

Although OpenEHR plans to increase the number of archetype editors over the course of next year (McNicoll, 2010), it has to be accompanied with the increment and strengthened of the community of experts. This conclusion is aligned with the ideas expressed in the 1st ISO/EN 13606 Workshop (CEN/ISO EN13606 Workshop, 2010) where experts involved in the development of EHR based on this standard agreed on the need of creating a community of users to identify the best practice based on real implementations.

5.2.2. ARCHETYPE DEVELOPMENT PROCESS EVALUATION

The results obtained show than the ADP has not been a homogeneous process for all archetypes. Some archetypes present a higher number of contributors than others. There are differences in the number of contributors between published and other archetypes but this does not appear to be a consequence of an heterogeneous community. Archetypes inherited from NHS repository and also those that are explained in training courses could have an increased participation that results in a more mature development.

One original goal of this research was to predict the time required to achieve published status for archetypes included in OpenEHR CKM but the small amount of published archetypes made it impossible identify any statistical correspondence between the factors that impact the development process such as number of contributors, number of nodes per archetype, number of modifications with the resulting development time. The number of published archetypes is small and archetype development has

proceeded at a very slow pace, with only two published archetypes in the last 7 months at time of writing. (February – August 2010).

Most of the draft archetypes analysed have a very small number of contributors and they have a large period of time without modifications. Although these archetypes didn't achieve the published status, they could satisfy the local needs in the implemented systems based on the OpenEHR approach. They can be applied successfully to communicate different EHR systems.

5.2.3. Archetype Quality Evaluation

As it has been stated before, the results from the archetype quality evaluation shows that OpenEHR CKM, results in a very high quality in the published archetypes. EuroRec requirements are a good source to identify possible improvements in the ADP. The individual mapping of archetypes to EuroRec requirements shows the importance of an exhaustive documentation within the ADP, where references are highly important and they should be linked to individual nodes.

Currently the ADP performs the terminology binding task when the archetype has achieved the published status. This could be the reason why only two of the seven published archetypes have some of their terms mapped to international recognised terminology systems. The relationship between archetypes and terminology systems has been recognised by different authors as a field for further research (Kalra, 2008b, Markwell, 2008). In order to solve this problem openEHR and IHTSDO started a Collaborative Work Program with the objective to harmonise the integration of openEHR archetypes and SNOMED CT (IHTSDO and OpenEHR, 2009). In addition, OpenEHR has recently added a new feature within the openEHR CKM to handle termset (Garde, 2010).

There are recommendations about how to use post-coordination in order to establish a consistent framework to model the clinical knowledge. These recommendations are based on NHS experiences in the integration of SNOMED CT with their Logical Record Architecture (Sato, 2008). It is important to study how similar strategies can be applied to the ADP and add those requirements to the AQC. The AQC is a field where the Continuous Improvement Cycle can incorporate new recommendations based on the experiences learned from the implemented systems.

5.3. Proposed actions

5.3.1. Clinical Knowledge Definition

A common definition for clinical knowledge could facilitate sinergies between the ADP and other contemporary EHR initiatives. As Kohl affirms, multiples committees of experts responsible for modelling the clinical knowledge could be shared with different approaches (Kohl, 2008). There is a need to identify possible duplication of work between the different approaches related to the EHR communication. This research has identified many factors that impact the ADP such as community organisation, assigment of roles and teams to the people involved in the development, archetype review strategies, application of quality criteria to verify that models satisfy the policies and governances. Most of these issues could be applied to the definition of any semantic structure e.g. Detailed Clinical Model

(DCM) or Logical Record Architecture (LRA). Given that there are a great number of similarities between archetypes and DCM, the lessons obtained from the ADP are clearly relevant to DCM.

If the DCM project finally defines a new model and obtains acceptance between the different organisations involved in EHR communication, it would be possible to create a place where experts can define the semantic requirements in a format that can be translated to openEHR, ISO/EN13606, LRA and HL7 CDA. Although there are many barriers that could make it impossible, the potential benefits of the establishment of shared clinical knowledge between the different approaches make it highly desirable.

Until this goal is achieved, the community of experts involved in the ADP have the openEHR CKM as a place where they can discuss the definition of archetypes, but other parts of the clinical knowledge that have high impact on the EHR implementation are not included:

I. PROCESSES

The OpenEHR approach provides to clinicians the capability to create local templates that are useful for their daily practice. They are able to edit electronic forms and computer displays to facilitate information recording and presentation. This level of flexibility can increase the system adaptation level to the clinician's needs based on archetypes which are approved through review process that ensure the semantic interoperability of the recorded items. In contrast to this freedom provided to clinicians when they are recording information, the support for clinical processes is not fully addressed.

Evidence based medicine uses clinical guidelines to represent the processes that clinicians have followed to provide the recognised highest quality of care and improve the patient safety (Lohr et al., 1998). There are examples like Map of Medicine that implement clinical guidelines in a computable format in order to increase the efficiency of clinical practice.(Map of Medicine, 2010) Although there is a consensus about the benefits of clinical guidelines and they can be integrated with archetypes, the openEHR community keeps this point out of its scope.

The importance of the integration of guidelines within EHR systems is covered within the ISO 18308 requirements because they provide contextual information associated with events. Beale explained in the document ISO 18308 Conformance Stament that guidelines are integrated via the CARE_ENTRY.guideline_id attribute within the openEHR approach (Beale, 2006).

In this field, Medical Objects (Medical Objects, 2010) provide an example of how 13606-2 archetypes can be combined with guidelines defined in GLIF and decision support rules defined in GELLO (McIntyre, 2010). The great flexibility of the Medical Object approach allows to clinicians adapt their workflows and modify the presentation depending on their needs.

Currently there is no place where the community involved in the ADP can discuss the implementation of clinical processes within EHR systems based on archetypes. The community experts could discuss and agree the guideline definition through a process similar to the archetype revision process. Although it could be argued that guidelines are highly dependent on the local context, once the guidelines are published and made available for international use they can be adapted to local context in a process similar to the template definition. Another benefit of this approach is that it can help implementers to choose between the large number of guideline modelling languages.

II. DECISION SUPPORT

The same arguments that have been explained for the discussion of guidelines can be applied to the decision support rules. They are part of the clinical knowledge that can be discussed and shared within the community of experts. They are covered within ISO 18308 architectural requirements and Beale

affirms that further experience and testing is required to determine the integration of Decision Support Systems within the openEHR architecture. From the experiences of the Medical Object approach it can be inferred that decision support rules are important for presentation, for setting default values and for providing recommendations but they are expressed in GELLO a programming language that is not enough user friendly enough to be directly used by clinicians.

5.3.2. SHARED PATIENT SUMMARY

In the relationship with other approaches, the large number of standardisation initiatives created for EHR communication complicates the communication between systems based on different standards. The definition of a commont patient summary to share information between EHR systems could be the first step to the interoperability between the different approaches.

In this field, the Continuous Care Record (CCR) is a good candidate to define the minimum of information that can be shared between EHR systems. As it has been explained before this standard is implemented in different PHR systems and also HL7 has created a mapped version in CDA called Continous Care Document (CCD). Although it is possible to create archetypes that cover the information contained within the CCR, the different attempts to achieve this in the OpenEHR foundation and the ISO/EN13606 community haven't obtained finalised yet.

Another candidate specification for patient summary definition is called the Patient Care Coordination (PCC) profile which is defined by Integrating the Healthcare Enterprise (IHE). This organisation defines its patient summary based on CDA as an extension of CCD. In addition, IHE has a profile called Cross Enterprise Document Sharing (XDS) contained within the IT infrastructure specification that defines how different organisations could share patient summaries.

The problem of creating a mapping between different patient summaries specifications as CCR or PCC is that these specifications cover many areas of the medical field. Although it would possible and easier the creation of one large archetype including all the fields required within the patient Summary, as Moner did for the epSOS patient Summary (Moner, 2010a), this solution doesn't apply the full semantical capability of the archetype approach. In order to satisfy the AQC there is a need to define archetypes as a single concept. Although this strategy requires more time of development, the semantic level of interoperability obtained would be bigger than other approaches.

5.3.3. EDUCATIONAL RESOURCES

In order to increase the acceptance of both OpenEHR and ISO/EN 13606 and strengthen their community of experts it is important to facilitate the new user incorporation. Nowadays anyone is free to join the OpenEHR community or participate within forum of the ISO/EN 13606 official website but the vast amount of information required to understand how to apply these standards is a barrier that delays the growth of the community. There is a need for additional educational resources that present the information in a more comprehensive way and more complete supporting material to guide the ADP.

The educational resources available have a lack of exercise and examples that are essential to facilitate the understanding of new users and increase their confidence in ADP. Given that archetypes could be

applied to multiple RM and different fields outside healthcare, examples from outside of the medical field and with modified versions of RM could be created.

For instance on possible exercise could ask for creating archetypes to model the fruit concept in order to implement an Electronic Record of a farm. The solution could be that the fruit archetype includes type of fruit, cost, preferred consumed before date, retail price, etc. These examples from outside the medical field can improve the learning process because not all people involved in health informatics have clinical background.

The Reference Model explanation can be simplified in the explanation for clinicians by presenting only the clinical classes that they are going to model (Composition, Section, Entry, Element and Cluster) avoiding other classes that are important for attestation and authoring or demographics.

In order to promote the adoption of systems based on the archetype approach, there is a need to facilitate the choice of authorities. Additional resources could be created focused in the point of view of health authorities to make more comprehensible the benefits of this approach and help them in definition of procurer requirements.

5.3.4. USE THE REPOSITORY AS A LEARNING TOOL

The OpenEHR repository has become the central community tool that provides the means for discussion and collaboration between different experts in order to achieve a consensus in the definition of shared clinical knowledge. Additional functionalities could be added to the repository in order to facilitate the understanding of new users.

In some cases there are archetypes that model concepts with the maximum level of abstraction (e.g. Problem and Diagnosis). It is important to notice that when novel users try to search within the OpenEHR CKM for any symptom (e.g. Fever or Flu) they don't obtain any result. The search engine should advice to use the archetype created for a more generic concept for recording this symptom or diagnosis. As a possible solution the search engine could have a database with the most common concepts included in an archetype, for instance for the diagnosis archetype this proposed database could include a list of diseases. This list of diseases could be easily identified with the integration with a terminology system, for example in SNOMED CT the concept *Disease (disorder)* with ID 64572001 provides a list of terms that can be associated recorder with the same archetype.

Given that the size of archetypes and templates is relatively small (less than 25KB), it wouldn't be difficult allow that every user could have 1 MB free archetype hosting within the repository for learning and testing purposes. Users could also pay for additional functionalities and services.

5.3.5. ARCHETYPE QUALITY

This research has highlighted the importance of implementing AQC to promote the quality in ADP. Currently the repository is able to verify that archetypes and templates uploaded are conformant to the Archetype Model and the Template Object Model. Likewise, some of the requirements identified within the AQC can be integrated within both development tools and archetype repositories, to identify possible inconsistencies in the archetype definition.

Although not all the requirements described within the identified AQC could be checked by software, it is possible to implement automatic verification of some of them. For instance it is possible to detect whether an archetype definition has any empty fields. In case of the archetype doesn't satisfy the AQC, the corresponding recommendations can be shown to the archetype author.

Development tools and archetype repositories can provide support to perform the terminology binding. It would be possible to perform automatic mapping between the archetype concepts and different terminology systems, to propose possible terminology bindings.

The current development tools could be improved with the integration of the supporting material identified in this research. The identified diagrams for selection between RM classes can guide the development to provide decision support in the ADP. This feature could be activated as a Wizard design mode. The selection algorithm that provide support to in the selection between RM classes (OpenEHR Decision Algorithm, 2010, Moner, 2010b) described in chapter 2.3 are useful to minimise the subjectivity in the ADP and one additional recommendation could be added to the AQC to verify that the ADP methodology is conformant to these diagrams.

5.4. Research Questions

5.3.6. Why are there so few published archetypes?

The answer to this question suggests that there is a combination of different factors that makes the number of published archetypes so small. The archetypes that are not published are perfectly useful to facilitate communication between different EHR systems, they can satisfy local needs in systems already implemented. The analysed published archetypes were created in 2008, therefore ADP is still a new technique and archetypes didn't have enough time to receive inputs based on real implementation. Also the community of experts is not sufficiently large to provide support to all archetypes included in the repository. Although the clinician acceptance of the archetype paradigm is growing there is not enough support from Medical Organisations.

5.3.1. What are the requirements must be satisfied by an archetype to affirm that it is a "good" archetype?

In order to provide the maximum level of interoperability archetypes must conform to the archetype principles described by Beale and ISO/EN13606-2. Given that the recommended best practice aims to archetype definition aims to be universally applicable and understood EuroRec requirements can be applied to promote the exhaustive recording and documention of an archetype. All of these recommendations are presented in the chapter 2.3

5.4.1. How can be the AQC applied to the ADP?

In order to achieve the best practice, the Archetype Development Process (ADP) needs to be supported by quality criteria that evaluate the archetypes. This ensures the robustness and safety of the systems based on archetypes, while increasing their level of interoperability.

The experience from experienced archetypes editors can lead for further scientist research in the Archetype Development Process and identify Key Performance Indicators of this process. The Archetype Quality Criteria establish the minimum level of these Key Performance Indictors in order to ensure that the ADP satisfies the quality level needed in implemented systems.

Some organisations such as EuroRec can certify the quality of archetypes based on their performance against AQC. It allows that consumers can minimise possible risk and increase their level confidence on systems based on the Two Level Model paradigm.

6. CONCLUSIONS, LIMITATIONS & FUTURE WORK

6.1. CONCLUSIONS

This research has identified the different initiatives based on the Two Level Model approach and their methodologies. Based on the information obtained in the literature review, the openEHR Archetype Development Process (ADP) has been analysed in detail. The results from the analysis show that:

1- There are still a large number of draft archetypes and they are not expected to become published in the near future. The ADP is a long process that requires the implication of high number of experts to provide inputs based on their background. Therefore, there is a need to increase the community of experts because there are a large number of archetypes that don't have enough inputs.

2- The analysis of the state of the ADP shows that the current community of experts can't provide enough input to address all the archetypes contained in the OpenEHR repository. As a result there are long periods without modifications for most of the draft archetypes analysed. Therefore, there is a need to increase the size of the community of experts to cover more archetypes included within the repository.

3- The ADP is highly dependent to the number of archetype editors and the number of inputs from the community of experts. It reflects the importance of the organisational settings in the ADP.

4- The archetype editor role has successfully preserved the quality in the openEHR ADP. The evaluation of the quality of OpenEHR published archetypes against the EuroRec requirements shows that most of these requirements are fully satisfied.

5- In order to preserve the quality in the ADP there is a need to verify that the resulting archetypes satisfy organisation governance and policies. The establishment of Archetype Quality Criteria (AQC) ensures that archetypes that don't conform to the requirements are identified and they are modified before their application in EHR communication. The Continuous Improvement Cycle recommends continuous research in ADP methodologies to identify the Key Performance Indicators (KPI) in this process. These KPI are added to the AQC, which establish the required level of conformance.

6- Based on the results obtained, the author proposes the creation of additional educational resources that use the repositories as a learning tool. Additionally there is a need for strategies to cover other parts of the clinical knowledge such as processes and decision support rules within the Clinical Knowledge Manager. In future, if DCM obtains the acceptance between the different organisations it could be possible to create a place where experts can define the semantic requirements in a format that can be translated to openEHR, ISO/EN13606, LRA and HL7 CDA.

7- This research highlights the importance of the AQC and proposed its integration within the development tools and archetype repositories. In addition, it is proposed that the AQC could be integrated with supporting material to provide support in the selection between RM classes.

6.2. LIMITATIONS

Despite a number of informal communications and meetings with various players in the Archetype Development Process, the author of this research don't have any liaison to any of the organisation whose content or work have been analysed in this dissertation.

As it was previously stated the small number of archetypes in published and team review stage is a limitation that has made it impossible by time of writing to establish any linear relationship between the number of contributors, number of modifications or number of nodes in an archetype and the expected time of development.

The study has been performed using based on the state of the OpenEHR CKM in January of 2010. At the time of presentation of this dissertation (summer 2010), there are small changes as two team review archetypes have been published.

6.3. FUTURE WORK

It is recommended to study the effects of future changes in the size of community of experts and the number of archetype editors to the ADP.

Extend the study to the rest of Draft archetypes to identify their number of modifications and how are distributed in time.

Further research is necessary to improve the algorithm for decision between RM classes in order to minimise possible inconsistencies in the selection between multiple Entry classes and their relationship with Element.

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8. APPENDICES

8.1. LIST OF ARCHETYPES INCLUDED IN THE STUDY

Archetype	Archetype Status	Archetype Type
Medication	Draft	Action
Laboratory test	Draft	Observation
Diagnostic report	Draft	Section
Patient Admission	Draft	Admin
Procedure instruction	Draft	Instruction
Alert	Draft	Evaluation
Diagnosis	Draft	Observation
Vital signs	Draft	Section
Dignostic Report	Draft	Section
Apgar score	Published	Observation
Body weight	Published	Observation
Body mass index	Published	Observation
Body temperature	Published	Observation
Height/Length	Published	Observation
Blood pressure	Published	Observation
Respirations	Published	Observation
Macro_findings - Prostate cancer	Team review	Cluster
Macro_findings - Colorectal cancer	Team review	Cluster
Macro_findings - Melanoma of skin	Team review	Cluster
Macro_findings - Lymphoma	Team review	Cluster
Macro_findings - breast cancer	Team review	Cluster
Macro_findings - Lung cancer	Team review	Cluster
Heart rate and rhythm	Team review	Observation
TNM staging - Lung cancer	Team review	Cluster
Adverse reaction	Team review	Evaluation
Clinical Synopsis	Team review	Evaluation
Problem	Team review	Evaluation
Person name	Team review	Demographics
Postal address	Team review	Demographics
Pulse oximetry	Team review	Observation

Table 15. General information about the archetypes included in the study

8.2. DEVELOPMENT TIME IN THE ANALYSED ARCHETYPES

Archetype	Total days of development	Started	Finished
Heart rate and rhythm	449	7/21/08	10/13/09
Pulse oximetry	495	7/23/08	11/30/09
Macro_findings - Colorectal cancer	82	7/31/09	10/20/09
Macro_findings - breast cancer	46	6/29/09	8/13/09
Macro_findings - Lung cancer	75	7/28/09	10/11/09
Macro_findings – Lymphoma	216	1/17/09	8/20/09
Macro_findings - Melanoma of skin	70	6/3/09	8/12/09
Macro_findings - Prostate cancer	120	6/28/09	10/26/09
TNM staging - Lung cáncer	15	7/28/09	8/12/09
Adverse reaction	345	7/23/08	7/3/09
Clinical Synopsis	165	7/27/09	1/8/10
Problem	450	7/21/08	10/14/09
Person name	104	8/27/09	12/9/09
Postal address	104	8/27/09	12/9/09
Apgar score	305	7/21/08	5/22/09
Blood pressure	404	7/15/08	8/23/09
Body mass index	514	7/15/08	12/11/09
Body temperature	243	5/15/08	1/13/09
Body weight	514	7/15/08	12/11/09
Respirations	405	7/15/08	8/24/09
Height/Length	386	7/15/08	8/5/09
Medication	243	01/07/08	01/03/09
Diagnosis	32	02/07/08	03/08/08
Vital signs	86	02/05/08	27/10/08
Alert	0	01/07/08	
Laboratory test	183	01/06/09	01/12/09
Procedure instruction	304	01/05/08	01/03/09
Patient Admission	304	01/05/08	01/03/09
Diagnostic report	0	01/03/08	

Table 16. Detailed information about the development time in the analysed archetypes

8.3. AVERAGE OF DAYS BETWEEN STEPS IN THE ANALYSED ARCHETYPES

Archetypes	Average days between steps
Respirations	24
Macro_findings - Colorectal cancer	27
Macro_findings - breast cancer	15
Macro_findings - Lung cancer	25
Macro_findings - Lymphoma	36
Macro_findings - Melanoma of skin	12
Macro_findings - Prostate cancer	30
TNM staging - Lung cancer	5
Adverse reaction	345
Clinical Synopsis	27
Problem	90
Person name	26
Postal address	26
Heart rate and rhythm	225
Pulse oximetry	124
Body mass index	103
Body temperature	20
Body weight	73
Apgar score	51
Height/Length	64
Blood pressure	27
Medication	243
Diagnosis	7,75
Vital signs	86
Laboratory test	91,5
Procedure instruction	300
Patient Admission	304

Table 17. Detailed information about the average of days between steps in the analysed archetypes

8.4. ARCHETYPES DISTRIBUTION BETWEEN TEAMS

Team	Archetype Class	Number of archetypes	Published	Team Review	Draft	Examples
AEG	Observation	5	5	0	0	Blood Pressure, Body mass
Weight Team	Observation	1	1	0	0	Body weight
Demographic team	Cluster	7	0	0	7	Address, Organisation
	Demographic	1	1	0	0	Person name
Adverse Reaction Team	Evaluation	1	0	1	0	Adverse Reaction
Pathology synoptic Report	Cluster	14	0	8	6	
	Observation	1	0	0	1	
Danish Review Team	-	0	0	0	0	.
Orphan Team	Cluster	90	0	0	90	Device Details, Auscultation
	Composition	6	0	0	6	Referral Document, Medication List
	Evaluation	21	1	1	20	Clinical Review, Problem
	Action	6	0	0	6	Medication Action, Transfusion
	Instruction	10	0	0	10	Imaging Request, Medication Order
	Observation	63	2	3	58	Body Temperature, Indirect Oximetry
	Admin	1	0	0	1	Patient Admission
	Structure	8	0	0	8	Imaging data, Procedure
	Demographic	25	0	0	25	Birth date, Third person payer

Table 18. Relationship between archetype teams and the archetype status of the archetypes that they have assigned

8.5. CORRELATIONS AND LINEAL DEPENDENCES

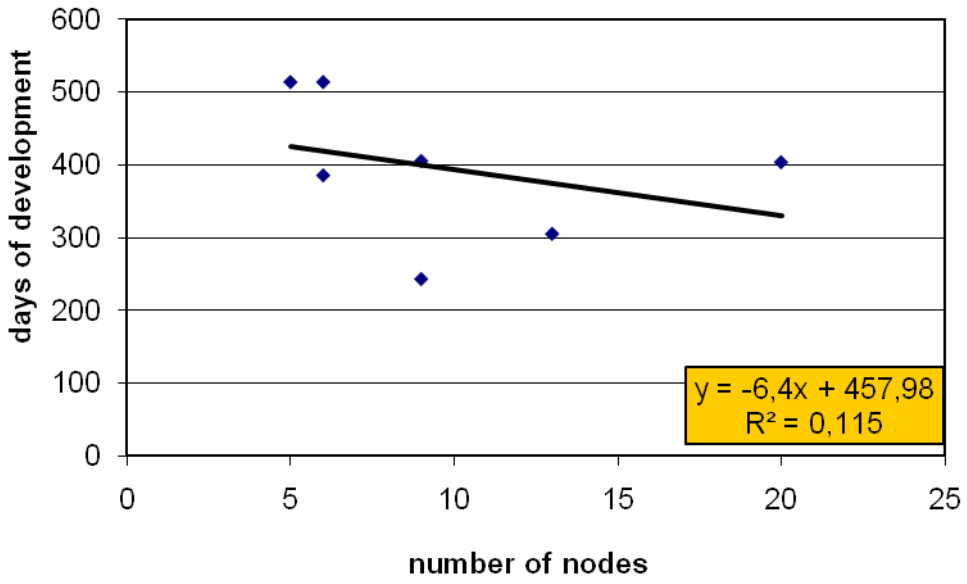

Figure 15. Correlation between days of development and number of nodes in published archetypes

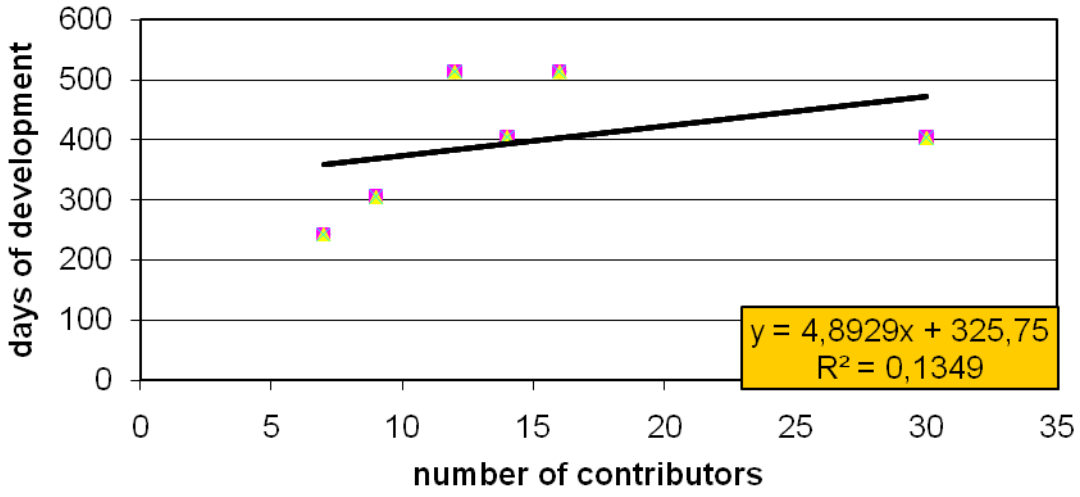

Figure 16. Correlation between days of development and number of contributors in published archetypes

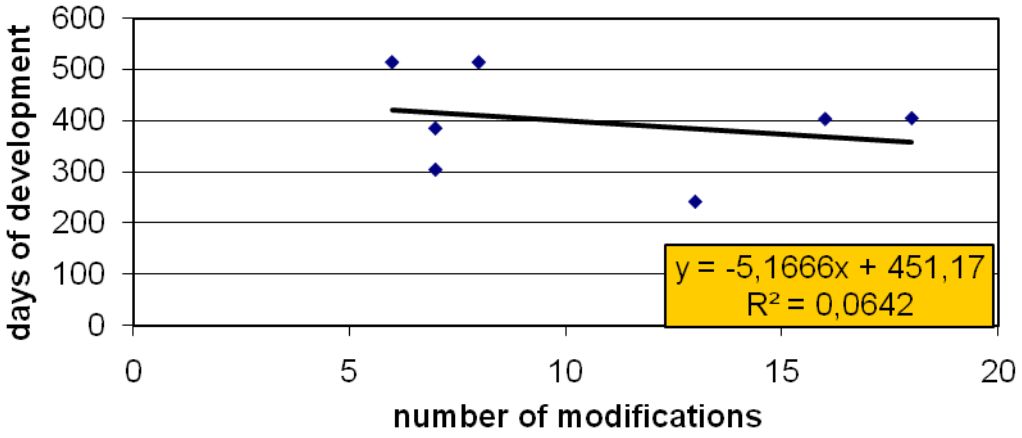

Figure 17. Correlation between days of development and number of modifications in published archetypes

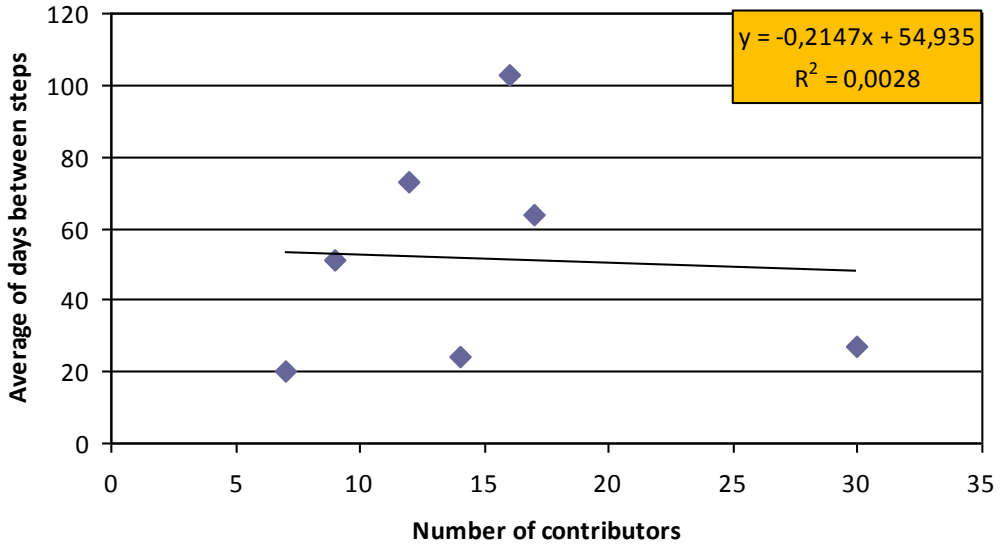

Figure 18. Correlation between the number of contributors and the average of days between steps in published archetypes

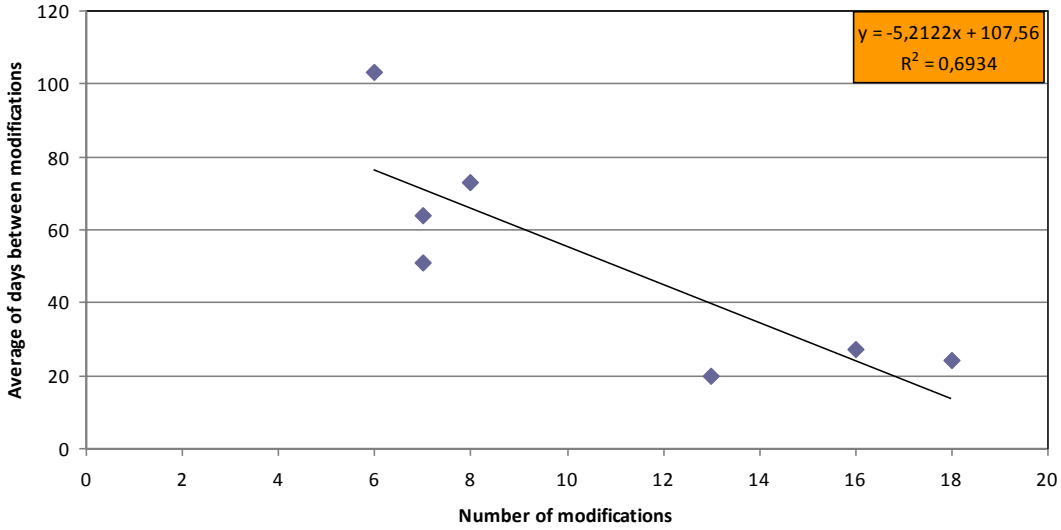

Figure 19. Correlation between the number of modifications and average of days between steps in published archetypes

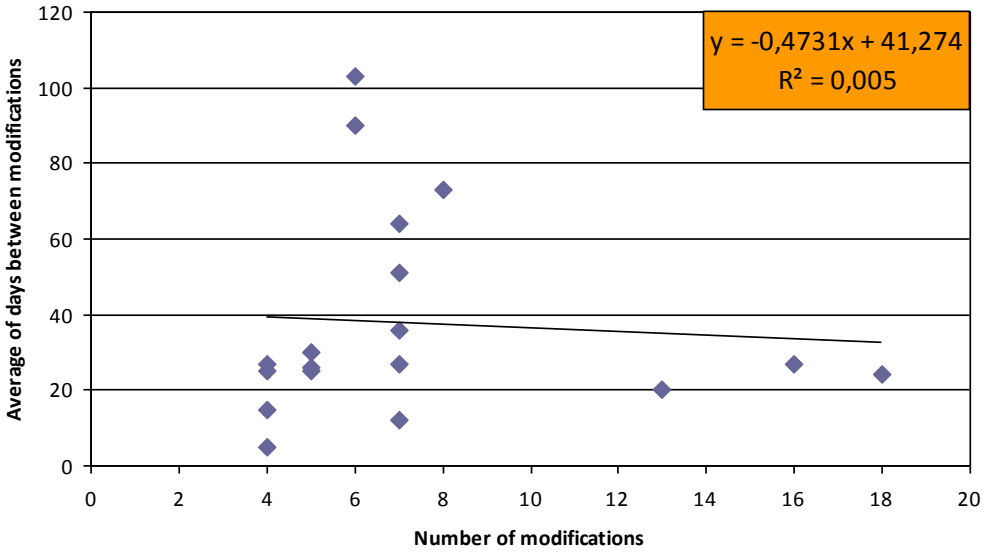

Figure 20. Correlation between the number of modifications and average of days between steps in published and team review archetypes