EHR*land* Final Report

Version 1.0

December 14, 2010

Guide for Readers

International experience has shown that the development of a national electronic health record (EHR) is an ambitious goal that is difficult to achieve. A truly national scale electronic record is multifaceted and involves major technical challenges and organisational changes. The question then arises: why would you go through with a process that is obviously so expensive, both financially and in terms of health service resources? It is difficult to provide an evidence-based answer to this question, simply because the shared electronic health record is a relatively new phenomenon and there hasn't been enough post-implementation experience of EHRs to measure the benefits.

However, if it is health policy to embrace a shared care model, there is an accompanying responsibility to also embrace the secure sharing of reliable and high quality information about the subject of care. This secure sharing of high quality information is what the electronic health record seeks to provide. This report reflects the multifaceted aspects of electronic health record implementation. The report is broken up as follows.

Chapter 1 Introduction to the EHR, gives a brief introduction to some of the main aspects of the modern electronic health record.

Chapter 2: Background to the introduction of an EHR for Ireland, discusses issues that relate to the development of an EHR in Ireland including the likely size of a system of this type, the opinions of stake holders before any EHR implementation, the EHR development process as it would be with EN13606, International experiences of EHR implementation, and a summary of architectural technical choices made by other countries and regions.

Chapter 3: The EHRland Approach, goes into more detail about the project team's experience of two-level models, the conceptual foundation for the EN13606 standard, and then adopting a more technical view, discusses some of the key elements of the two-level EN13606 information model.

Chapter 4 EHRland Architecture, describes an architecture for EHR services based on experiences gained in the project.

Chapter 5: Implementation Experiences, outlines the circumstances and outcomes of the various implementation streams from a top down(national) perspective and bottom up (site or scenario specific) perspective.

Chapter 6 Conclusions and Recommendations, contains a general discussion of the issues facing those charged with implementing an EHR for Ireland and provides specific recommendations for a way forward for Ireland towards EHR implementation.

TYPES OF READER

Health service management: should read the following chapters.
Chapter 1, Chapter 2 and Chapter 6

Health information strategists: are encouraged to take the following path through the report.
Chapter 1, Chapter 2, Chapter 3 and Chapter 6

Technical readers who have familiarity with detailed technical aspects of EHR implementation: should read.
Chapter 1, Chapter 2, Chapter 3, Chapter 4, Chapter 5 and Chapter 6

Note:

The Health Information and Quality Authority who have funded this work is referred to as "the Authority" throughout this document.

Document Editor

Damon Berry
TeaPOT Research Group, School of Electrical Engineering Systems, Dublin Institute of Technology, Ireland.

Contributing Authors

Damon Berry
TeaPOT Research Group, School of Electrical Engineering Systems, Dublin Institute of Technology, Ireland.

Fabrice Camous
TeaPOT Research Group, School of Electrical Engineering Systems, Dublin Institute of Technology, Ireland.

Xu Chen
TeaPOT Research Group, School of Electrical Engineering Systems, Dublin Institute of Technology, Ireland.

Yu Sheng
TeaPOT Research Group, School of Electrical Engineering Systems, Dublin Institute of Technology, Ireland.

Pamela Henry
Henry School of Nursing, Dublin City University.

Sebastien Pardon
TeaPOT Research Group, School of Electrical Engineering Systems, Dublin Institute of Technology, Ireland.

Allen O'Neill(formerly)
Helix Health.

John McGrory
TeaPOT Research Group, School of Electrical Engineering Systems, Dublin Institute of Technology, Ireland.

Frank Clarke
School of Biological Sciences, Dublin Institute of Technology, Ireland.

Kuba Chrzanowski
DMF Systems.

Gabriel Garus
School of Electrical Engineering Systems, Dublin Institute of Technology, Ireland.

Contents

List of Figures

List of Tables

Chapter 1

INTRODUCTION TO THIS WORK

Despite a good track record in health informatics research in Ireland and some notable individual involvement, as a country we have not participated in a systematic way in the European health informatics standardisation process until quite recently. The emergence of a cooperative process between the National Standards Authority of Ireland (NSAI), the Authority and HSE in the area of standardisation is a welcome and long-anticipated milestone.

Participation in standardisation activities can be seen as a two way process, organisations such as the International Standards Organisation (ISO) and its European equivalent, Committee European Normalisation (CEN) can only function when supported by the combined expertise, national perspectives and national experience of its members, while the experts and their home countries benefit by,

- being able to influence the standard to match national interests
- attaining early understanding of the underlying concepts and opportunities to disseminate them
- forming direct links to the primary authors of the standards with possibilities for a more interactive standards experience at national level

The dissemination of ideas from standardisation is further enhanced by the presence of national expert mirror panels that are organised by the appropriate national standards organisations such as the NSAI. The function of these panels of experts is to review and comment on the standards on behalf of member countries as they become available for review.

Many of the standardisation ideas in health informatics have come from research projects. The work on the 'cradle to grave' Electronic Health Record (EHR) which will shortly be described in more detail, is a case in point. Some of the key innovations that are incorporated in the current round of EHR standards were influenced by the work of Dublin-based researchers in the late 1990s. [4] [5] Features such as those found in the current family of Electronic Health Record standards are not to be found in existing health information products. Obviously, the concepts move forward over time, so there is a need for constant refreshing of knowledge at national level to keep abreast of developments and to be able to participate in standardisation. In order for the mirror panels and the CEN delegates to contribute to the fullest extent and to be ready to contribute to the

current and next family of standards, it is useful or even necessary that they (we!) have practical experience of the development implementation and consequences of sometimes new and elusive concepts.

Apart from the contribution to the standardisation effort, if we are to develop a well ordered health information infrastructure in Ireland, there is a need to understand the current state of the art and to be in touch with international best practice. This project has provided a mechanism for a group of Irish experts with an interest in and experience with the EHR, to work with leading-edge concepts relating to the EHR. In anticipation of a National EHR Framework, this work has also promoted the use of best practice in EHR development and selection in Ireland. This has been achieved by promoting at a national level, the emerging international consensus on EHR user requirements, EHR security, EHR architectures and technologies, and raising awareness of the dependencies on underlying technology such as an agreed national person identifier system, agreed clinical terminologies and data sets, and scaleable and secure information transfer.

It is important to stress at this point that EN13606, the specification that is the primary focus of this work is about EHR communication (hence the informal name EHRcom). In other words this specification deals with the transport of parts of an electronic health record that are worth sharing, between individual information systems in various health provider organisations. Such individual systems are often referred to as electronic patient record or EPR systems. The standard does not specify how EPR systems should be reworked to become part of the EHR community. Nor does it specify how new EHR systems will be built in the future. EHRcom is solely concerned with an agreed approach to communicating EHR extracts between EN13606-compliant EHR systems. It is envisaged that much of the industry response to the standard, will focus on transforming information from their internal representations into EHRcom form. Consequently, one focus of this work has been on attempting equivalent activities i.e. integration of EHRcom representative compatibility into legacy EPR systems or facilitating transformation from legacy format into EN13606 format using components that are external to the existing applications. The sharing of information in the EHR can be accompanied by direct or indirect human interaction. For this reason, the project team also attempted to look at EN13606 in the context of multi-disciplinary and distributed team based care.

1.1 An Introduction to the Electronic Health Record and Associated Technologies

1.2 EHR Definitions

The term Electronic Health Record is used to describe all of the useful clinical information that has been collected and stored about a patient from the cradle to the grave. The EHR has yet to be realised except in isolated cases. Perhaps this is not surprising if you consider that in a country the size of Ireland, to build a true EHR you would need to provide access to terabytes of data on thousands of discrete information systems and among other things, integrate the records of millions of citizens with just under one

million medical concepts, while providing access rights for tens of thousands of health professionals in hundreds of subtly different roles.

Durable (shared) EHR systems must be adaptable, but they must also include a mechanism to facilitate transfer of agreed and tightly constrained information. Currently dominant message based approaches do not match these needs. To fulfil these somewhat conflicting goals, specifications for a new breed of EHR system are in final stages of development. The resulting EHR systems will feature powerful and general (for health) information models, a set of concepts that can be used in a wide variety of ways to build information artefacts in the electronic health record. Archetypes and Templates (from openEHR and CEN TC251), and their HL7 counterpart, CDA Templates, restrict the ways in which the concepts from the generic information model can be combined to form sensible, and agreed EHR constructs.

For over ten years, the central thrust of the health informatics standardisation has been towards a European and international ISO standard for health record communication called EN13606. This five-part standard which was developed by a working group within CEN TC251. It features two information "layers". The first, normative layer is the so-called Reference Model. This is the information model that is referred to above, which defines the generic information building blocks for the EHR. A second optional layer, Archetypes, allow the general constructs from the Reference Model to be specialised, moulded and constrained into understandable, useable and generally agreed information constructs that are recognised by health professionals. The archetype layer is optional within the EHRcom standard to allow legacy EHR systems to comply with the standard. However, the real power of the standard comes from the inclusion of Archetypes. Archetypes can be constructed by groups of domain experts in the same way that national organisations currently specify messages for exchange of health information. At a national level, a group of Biomedical Scientists, led by (say) the chief consultant at the National Virus Reference Laboratory (NVRL) might develop agreed archetypes for *electronic laboratory reports* arising from inter-organisation lab referrals to the NVRL. Once the archetypes for lab reports had been developed, they would be incorporated into the EHR systems of the client hospitals and the NVRL, so that record extracts could be exchanged between the EHR feeder system at NVRL and the receiving EHRs systems of the client health organisations. A useful resource for this work would be the existing GP messaging work that has recently been done at national level.

In the same way, nationally agreed Admission and Discharge messages could be a guide for another group of domain experts to produce a national set of ADT archetypes. These nationally agreed archetypes would in the future be loaded into EHRcom compliant Hospital EHR and GP-based EHR systems to allow EHR extract messages to be seamlessly transmitted, accepted and merged into the GP's view of the patient's EHR. Archetypes can be used as the basis for constraints at both ends of an EHR communication link to form (at the sending end) and check (at the receiver) the communicated information. Reference models and Archetypes will be discussed in more detail in Chapter 3.

The idea of an electronic health record as a shared information resource has been introduced above. Before proceeding further, it is necessary to provide an additional explanation of what is meant by the term electronic health record. A large number of definitions for different types of electronic health records and electronic health record systems can be found in the literature. For example,

- (the EHR) can be seen as incorporating an inventory: "a representational artifact built out of singular referring terms such as proper names or alphanumeric identifiers." [6]

- "The basic requirement is that (the EHR) must be a faithful record of what clinicians have heard, seen thought, and done." [7]

For the purposes of this work, and in line with the standard EN13606, we adopt a definition that focuses on a type of electronic health record that can be communicated between organisations over a large geographic region as well as within health provider organisations.The ISO Technical Report ISO DTR 20514 Health Informatics: Electronic Health Record: Definition Scope and Context (ISO/DTR 20514) has provided authoritative definitions for the electronic health record.

- "electronic health record (EHR) - for integrated care (ICEHR): a repository of information regarding the health of a subject of care in computer processable form, stored and transmitted securely, and accessible by multiple authorised users. It has a commonly agreed logical information model which is independent of EHR systems. Its primary purpose is the support of continuing, efficient and quality integrated health care and it contains information which is retrospective, concurrent and prospective." [8]

- "electronic health record (EHR) - basic generic form: a repository of information regarding the health status of a subject of care, in computer processable form."

NOTE 1: The definition of the EHR for integrated care should be considered the primary definition of an electronic health record. The definition of a basic-generic EHR is given only for completeness and to acknowledge that there are still currently many variants of the EHR in health information systems which do not comply with the main (ICEHR) EHR definition (e.g. a Clinical Data Repository complies with the basic-generic EHR definition but not with the ICEHR definition). [8]

NOTE 2: For the purposes of this work, and in line with the previous discussion, the basic-generic EHR or a single organisations share of the electronic health record will be also referred to as an electronic patient record (EPR). This work focuses on the ICEHR which for convenience will be referred to as an electronic health record (EHR).

1.3 EHR "Building Blocks"

Before an integrated care electronic record system of the type described in the last section can be developed, a number of fundamental information services need to be established. The first goal is so called *technical interoperability* which in health informatics is the ability to transport health information between health provider organisations. This requires the most fundamental service, namely,

- Communications infrastructure to support the sending and receiving of personal health information.

In Ireland, the Healthlink project has delivered a communication infrastructure which could be said to support technical interoperability, as it facilitates passing of information between sender and receiver. The next set of services helps support this communication infrastructure to facilitate secure and high quality health information, that is human readable at the destination. Systems which support information exchange of this type are said to support *technical and syntactical interoperability.* [9] These include,

- Identity management services for subjects of care, individual healthcare providers, healthcare provider organisations, and technology resources such as information systems and medical devices.
- Access control facilities to facilitate secure access to confidential health information.
- Agreed "structure" for messages that convey personal health information.

In order to improve on functional interoperability to produce EHR communications that are computer processable at their destination - or *semantic interoperability* [9], it is necessary to add another type of service to the above set.

- Terminology services to assist in the preservation of meaning in EHR communications by allowing commonly understood coded terms to be added to messages.

Terminology services can help systems to exchange health information that is computable or "understood" by a receiving software application. It also offers the possibility of increased efficiency through greater automation, alarms and alerts, improved data quality and offers more opportunities for assessing the healthcare process. Systems that support computable communication of this type are said to support semantically interoperability. The ultimate objective of this innovation is better and safer healthcare.

One interesting comment about the above prerequisites for the electronic health record is that these services are fundamental for high quality management and communication of health information of many types. For example, they are also appropriate for widespread single-purpose messages which support communication of health information. This report will discuss approaches to these services that are compatible with the ISO standard for electronic health record communication - ISO/CEN EN13606. However, much of what is discussed in this report, particularly in relation to the above fundamental services could equally be applied to an HL7-based approach.

1.4 Why not just a messaging system - why do we need integrated messaging?

Large scale national e-health projects such as the NHS Connecting for Health [10] and Canada Health Infoway [11] have each adopted a highly-coordinated approach to the development of a large-scale integrated health information system with support for an electronic health record. The population of the United Kingdom is nearly 62 million in 2009 [12] while the population of Canada in January 2010 was 34 million [13]. The budgets for the above-mentioned national e-health projects are large and there are economies of

scale associated with the large number of organisations which need to be linked. By comparison, the Republic of Ireland has a comparatively small population which was estimated to be 4.4 Million [14] in 2008 (more on this in Chapter 2). However, despite the comparatively smaller scale of the Irish health system, there is a natural concern that many of the development costs of a regional shared system would be borne by a Irish health information network with similar features.

Nevertheless, the health information network has continued to evolve in Ireland. It is fair to say that this evolution has been somewhat fragmented. To maximise the benefit accruing from new developments, it is important that any future incremental development of systems and services to support and extend health information communication solutions in Ireland does not rule out the prospect of high quality electronic health records.

Single-purpose health messaging is a practical strategy for the longer term if it is based around the development of the above fundamental infrastructure. If expedient ad-hoc messaging solutions are adopted, it is possible that they may work well in the short term. However, if they are not designed to take account of future needs such as the evolution of the healthcare process, increased connectedness, or if they duplicate resources that have been developed elsewhere, they are likely to require refactoring, a process which can be difficult, time-consuming and expensive.

If at all possible, it is better to aim for an integrated system for the communication of health information which is supported by

- an open resource of nationally agreed and approved message structures and data sets with indications about the mandatoriness and data types of all data elements,
- coherent identity services which simplifies the use of identifiers for the communication of health information,
- terminology services using agreed term sets at a national level.

With this infrastructure in place or underway, it would be possible to develop an electronic health record system of the type discussed in this report. Recommendations in relation to these prerequisite services will be presented and discussed in Chapter 6.

Chapter 2

Background to the introduction of an EHR for Ireland

2.1 Introduction of an EHR for Ireland.

Before embarking on any large ICT project, it is useful to get a sense of the existing infrastructure, the level of support for the project and the understanding among stake holders of the issues involved. It also makes sense to develop an accurate estimate of the scale of the project and to identify issues that might need to be addressed. While the gathering of relevant background information of this type is not central to the EHR*land* project, the project participants believed from the start that background information would inform the technical work and lead to a more multi-dimensional set of recommendations. For this reason, early on in the project it was decided that a number of supporting investigations would be undertaken either directly by the project participants, or under their direction by postgraduate students. This chapter outlines some of the outcomes of this work as well as outcomes from other existing work in the field. This chapter also references experiences of EHR implementation in other countries, to understand the main factors involved.

2.2 Scale of a future EHR system for Ireland

There is insufficient current information available to the project team to produce comprehensive and accurate figures for the possible scale of future EHR activity in Ireland. However, some estimates can be made as follows from latest available Figure 2.1.

2.2.1 Estimate of total number of EHRs

The last available measurement of the population of the Republic of Ireland comes from the 2006 census [15]. It put the population of the state in 2006 at 4,239,848. The CSO estimated in April 2009 [16] that the population had reached 4,459,300, by 2009 despite a net outward migration. They associated this increase with the large number of births in that year. Based on this figure and assuming that there are no duplicate records and that everyone accepts an electronic health record, the estimate for the total number of national EHRs that would have been required if it was introduced in 2009 was,

Estimate of electronic health records required in 2009 4,459,300

2.2.2 Estimate of number of individual health providers in the public health sector who would be users of a future EHR

According to Department of Health Key indicators 2009, 111,062 people were employed in the public health sector in 2009. This figure can be broken down as follows.

Grade/Category	Numbers of Public health staff 2009
Medical/Dental	8,090
Nursing	38,282
Health and Social Care Professionals	15,957
Other Patient and Client Care	18,548
Management/ Administration	17,777
General Support Staff	12,428

Excluding the last two categories of public health employee who would not under normal circumstances have read access to an EHR, we get an upper estimate of
Estimated number of EHR users in public acute care sector with read access 80,877

2.2.3 Estimate of number of individual health providers in primary care sector

The Primary care strategy [17] envisaged 700 to 1000 primary care teams of various size would be required, each delivering care to between 3000 and 7000 people. This estimate was based on a population of 3.8 million. Based on the revised estimate for the population in 2009, this range would have risen to between 800 and 1100. One of the benefits of this initiative was to simplify the ICT by allowing general practitioners who would formerly occupy different sites to occupy a single shared site with a shared ICT infrastructure. Nevertheless, the number of general practitioners is estimated to be about 2,500 [18]. So assuming that general practitioners are the only primary care users with authorisation to view electronic health records.

Estimated number of primary care EHR users with read access in 2009 2,500

Note: Anecdotally, it is understood that there may be as many as 3,500 general practitioners in the state, but it wasn't possible to verify this figure.

2.2.4 Estimate of record "activations" in Public Acute Care Hospitals

Based on Department of Health and Children Acute Care Summary Statistics, there were 591,618 in-patient admissions, 558,814 day cases and 1,245,001 Accident and Emergency

attendances in 2006. [19] We will make an assumption that the total number of acute care episodes can be roughly estimated by summing these figures. 591,618 + 558,814 + 1,245,001 = 2,395,433.

Estimated number of acute care patient episodes per year in 2006 2,400,000
Assuming the worst case scenario of a record per patient episode, this figure also represents the upper limit for the number of health record activations for in the publicly funded acute hospitals. Of course, due to the effect of patients having multiple episodes over the course of a year, the actual figure is likely to have been be much lower than this.
Estimated number of acute care record activations in public hospitals in 2006 2,400,000
On the other hand, the number of acute care record transactions would be substantially larger than this figure.

2.2.5 Estimate of record "activations in Primary Care

The Department of health and children estimated in 2001 [17] that there were 15-16 million consultations in general practice. Thomas and Layte estimated in 2009 [20] that there would be approximately 12 million consultations for the population aged 16 years or more in 2006. Thomas and Layte acknowledged that there was no measurement of the number of general practice utilisations from 2004 to 2009. Based on this estimate we could say that an upper limit on record activations in primary care would be somewhere between 15 millon and 20 million in 2010.
Estimated number of primary care activations in primary care 2010 15-20 million

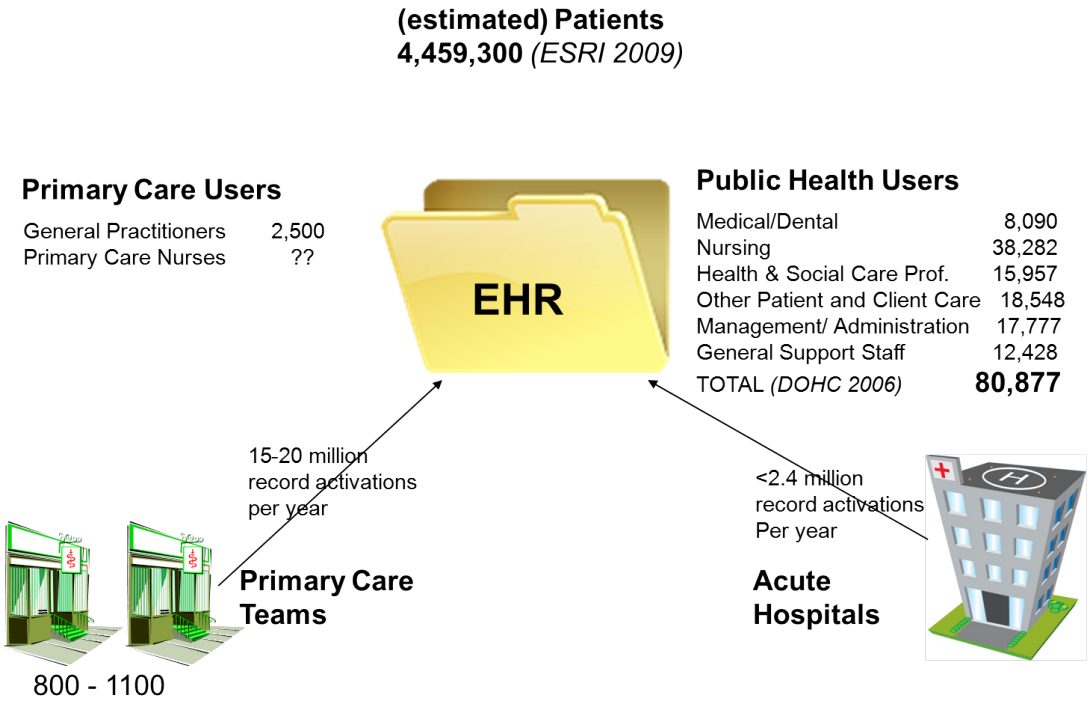

Figure 2.1: The scale of a future EHR system for Ireland.

The figures presented in this section are only rough estimates based on the information at hand. What is clear from this discussion is that there is an information deficit in relation to the demand for future ICT resources in the health sector. In terms of estimating the scale of future e-health in Ireland including the scale of a future national EHR system, there is a requirement for an assessment of the type of information that needs to be gathered followed by an appropriate information gathering exercise.

2.3 Attitudes to Electronic Health Records among Irish Health Service users

A second viewpoint on the introduction of an EHR is the reaction of various stakeholders. Two of the central stakeholders are the users, the health professionals who will contribute to and use the electronic health record, and the patients who are the subjects of the record. This section provides a general indication of the attitudes of these two sets of stakeholders to the introduction of a shared electronic health record.

A RedC telephone poll of 1002 people commissioned by the Health Information and Quality Authority in 2008 [21], found the following,

- 86% of respondents indicated that they would like their medical information from different sources to be linked up to improve patient safety.
- 96 % of respondents agreed that a single common patient identifier should be used to identify health information at different healthcare provider organisations (GPs and hospitals) to ensure consistency of care.
- 71% of respondents believed that linkage of health information was already happening in some fashion.

In relation to sharing confidential health information,

- 85% of respondents believed that information should be passed as part of a referral (e.g. to a physiotherapist).
- 77% believed that health information should also be accessible for those assessing the quality of care.
- 76% agreed that health information could be used for the purposes of health research.
- 74% believed that their health information could also be accessed by those seeking to improve Irish healthcare services.

The study by the Authority shows that Irish citizens are reasonably comfortable with the use of their heath information for various purposes and so the conclusion must be that they would welcome the introduction of a shared electronic health record system. The generally positive response may also be indicative of a need for more dialogue at a national level about the issues surrounding the sharing of information.

2.4 Attitudes to Electronic Health Records among Individual Health Providers in Ireland.

In a project in 2009 which informed and was motivated by the EHR*land* project, O'Malley (2010) surveyed 51 nurses and 23 doctors working in Irish health system about their attitudes to issues surrounding the introduction of an integrated care electronic health record (ICEHR) [8]. Six of the doctors and none of the nurses surveyed worked in primary care. 37% of nurses and 30% of doctors surveyed were involved in the Health Informatics Society of Ireland. The respondents for the survey were requested to read a description of the ICEHR which followed the definition from The ISO technical report Electronic Health Record: Definition Scope and Context [8].

The survey questions covered the following topics:

- Demographic Details
- Computer Skills
- How Patient Clinical Information is Recorded
- Expected Impact of Electronically Sharing Clinical Information
- Access to Patient Clinical Information
- Unique Health Identifiers
- Patient Confidentiality
- Trusting Shared Data
- Experience of a New Clinical Information System
- Support for an ICEHR System

2.4.1 Expected impact on care provision and patient safety

87% of doctors and 90% of nurses who responded, supported the introduction of an ICEHR system, and the majority indicated patient care and patient safety as the reasons for their support. A clear majority of respondents taken as a whole believed that there would be improvements in ability to make patient care decisions (92%), reduction in repetition of questions to patients (90%), enhanced timeliness of service provision (92%) and improved patient safety (96%) as a result of electronically sharing more detailed patient clinical information.

2.4.2 Expected impact on communications

The majority of survey respondents believed that an ICEHR would improve communications in a number of ways as follows.

2.4.3 Expected impact on data quality

There was also broad agreement about the impact on data quality. 100% of respondents were of the opinion that the introduction of an ICEHR would improve the legibility and clarity of patient care orders while 93 believed that the timeliness with which patient related data would be available would be improved or much improved.

2.4.4 Expected impact on work practices

O'Malley's study showed an interesting mix of opinions in relation to the expected impact on work practices (see pie charts in Figure 2.2 to Figure 2.7 below). The quoted benefits could be attributed to the introduction of both a local electronic patient record system or a cross institution integrated care electronic health record system. Broadly speaking, the respondents believed that the introduction of an electronic health record system would have a positive impact on different aspects of healthcare practice.

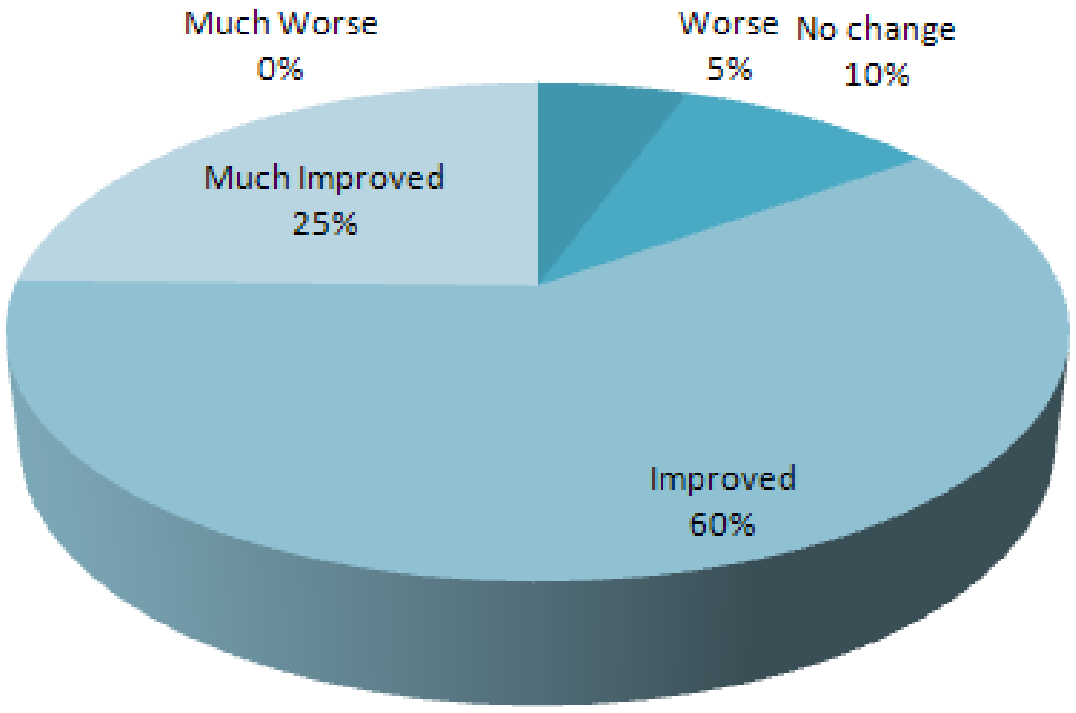

Figure 2.2: Expected impact of the introduction of an EHR-S on the efficiency of work practices.

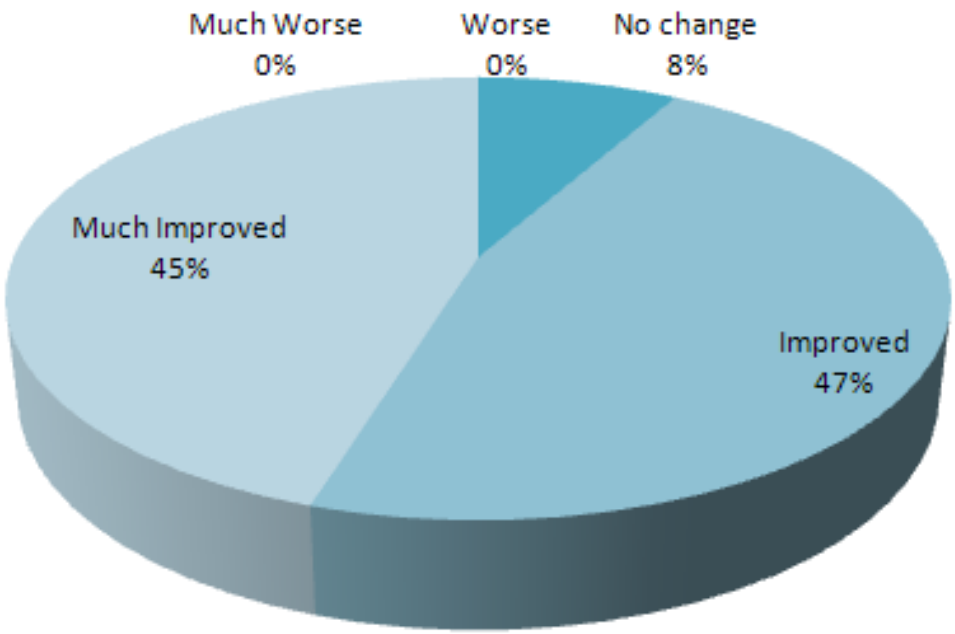

Figure 2.3: Expected impact of introduction of an EHR-S on the number of duplicate tests ordered.

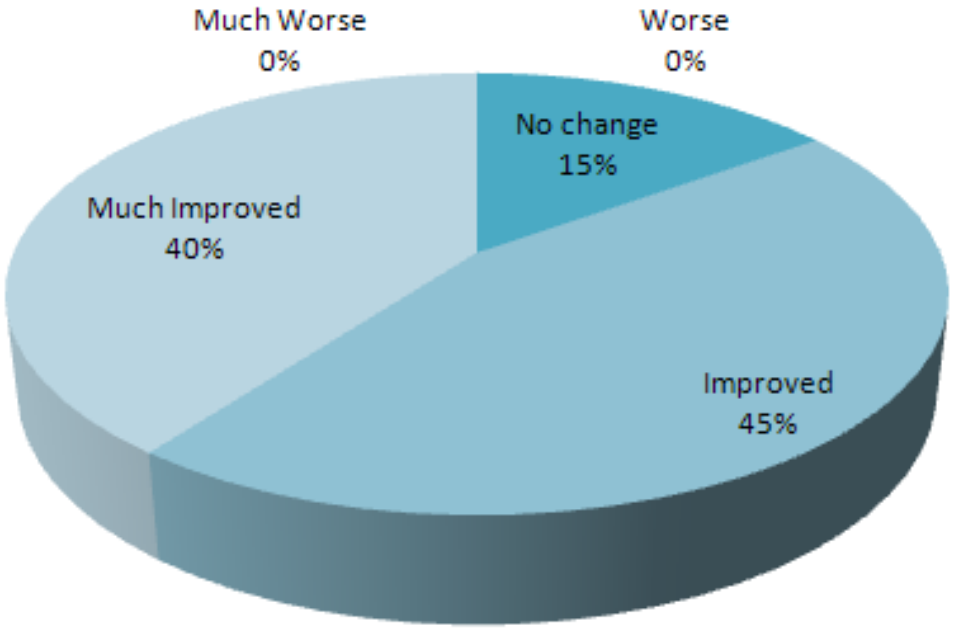

Figure 2.4: Expected impact of introduction of an EHR-S on the number of superfluous tests ordered.

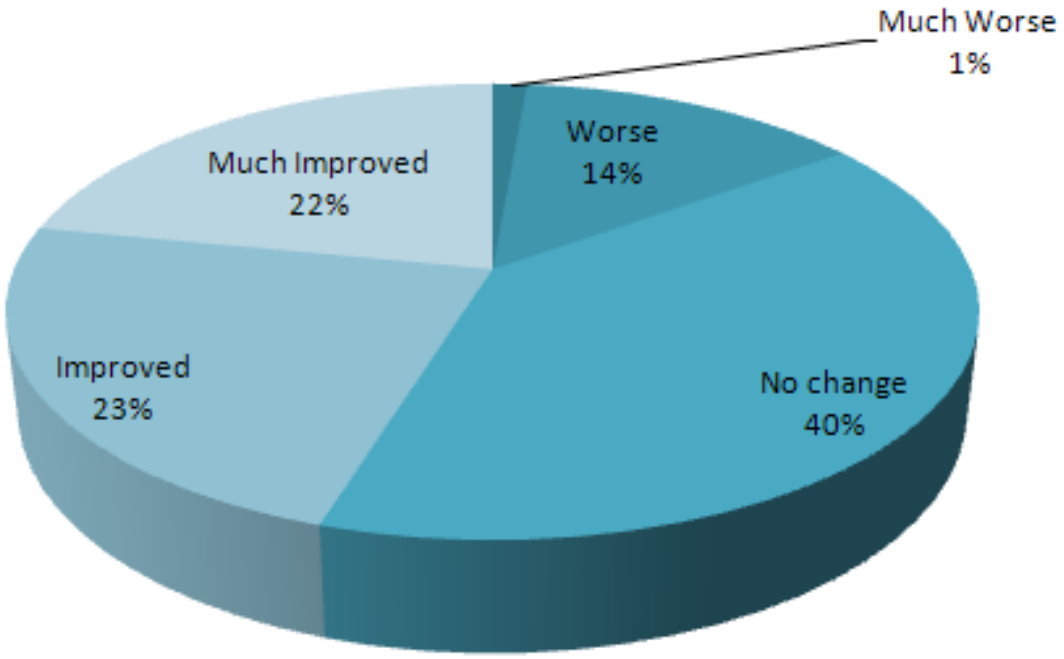

Figure 2.5: Expected impact of the introduction of an EHR-S on time spent documenting.

2.4.5 Access to Clinical Data

Survey participants were asked which information they would like to have more detailed access to. The majority of respondents indicated that they would like to have access to more detailed information for Patient Past Medical History, Patient Family Medical History, Clinical notes, Physical Examination Results, Observations,Prescribed Medications, Laboratory Results, Radiography Images, Diagnosis, Discharge Summary.

2.4.6 Unique Health Identifier

All nurses, and all but two doctors surveyed, agreed with the introduction of unique health identifiers for patients.

2.4.7 Patient Confidentiality

49% of Nurses and 61% of doctors thought that the introduction of an integrated care electronic health record might compromise the confidentiality of personal health data.

2.4.8 Trusting shared data

The respondents also expressed concern about the reliability of health information that is transferred between health organisations.

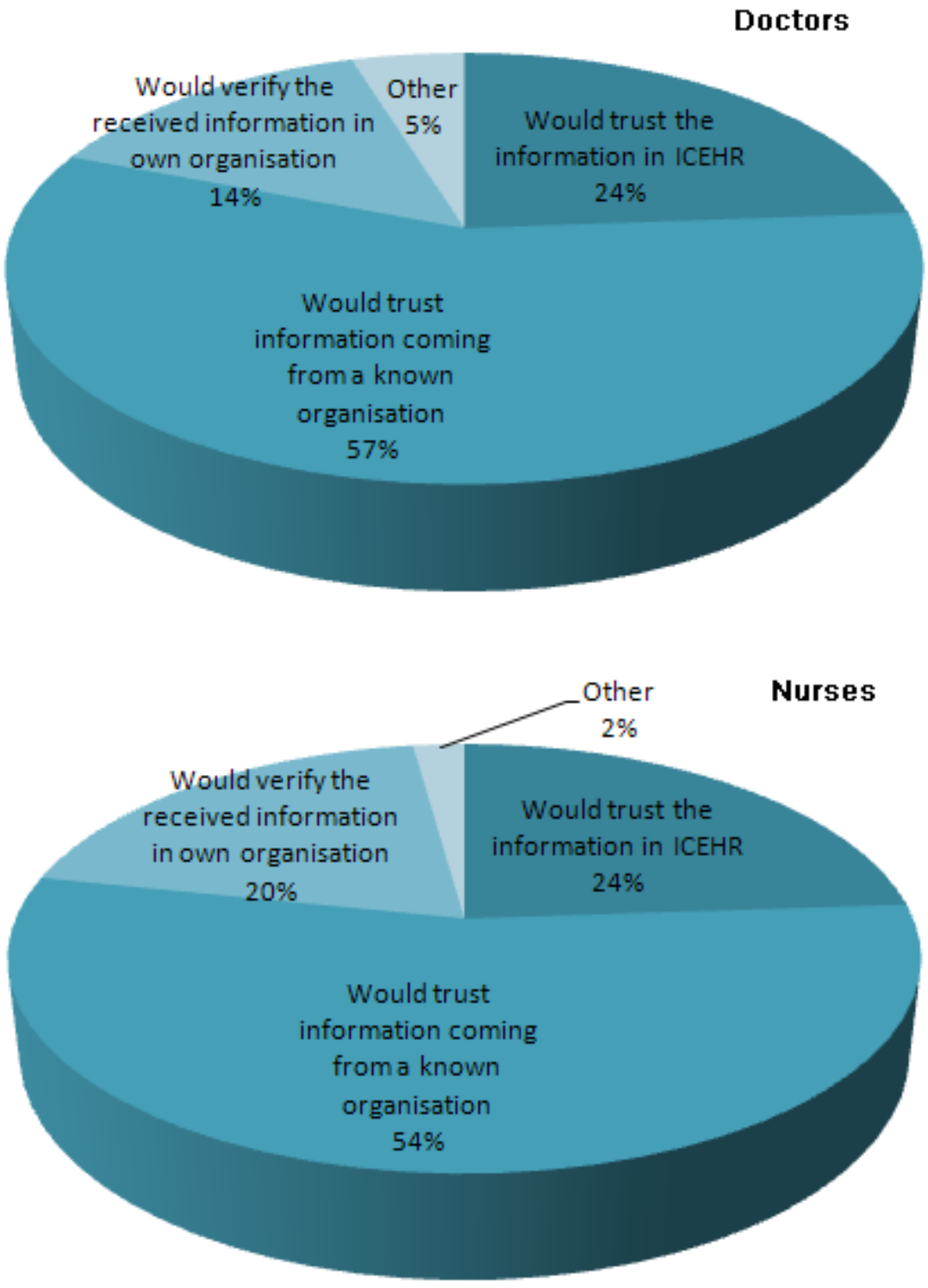

Figure 2.6: Extent to which Nurses and Doctors would trust data that has been shared by another health provider organisation as part of an ICEHR.

2.4.9 Attitudes to introduction of the ICEHR

Despite their concerns about these two issues the respondents believed that the ICEHR should be introduced

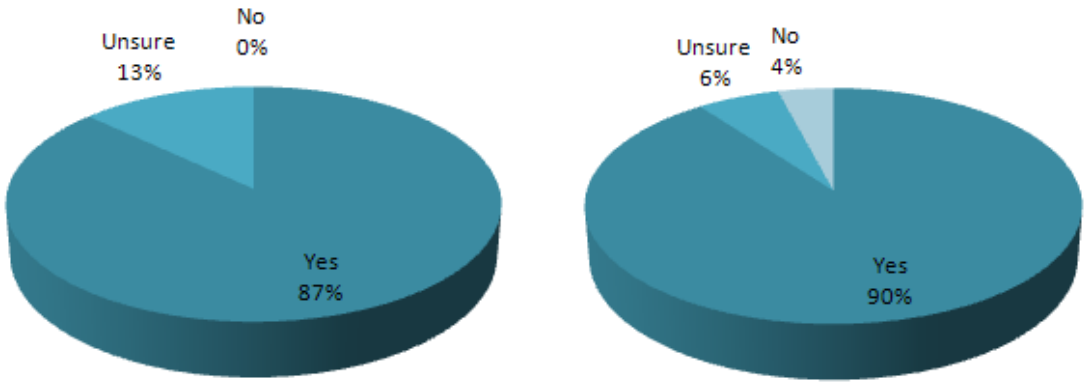

Figure 2.7: Attitudes of Nurses and Doctors in the study to the introduction of the ICEHR.

A comment from of one of the respondents neatly sum up the results of O'Malley's survey as follows "...It (the ICEHR) would be extremely useful in a variety of ways and would save significant amounts of time. Because of the all inclusive nature (of the ICEHR), it is likely to result in improved patient care. Must be balanced with the risks of breaches of confidentiality and deal appropriately with sensitive information...".

So it appears that attitudes of individual Irish healthcare professionals who would be another set of key stakeholders in the health information gathering process, does not present a serious barrier to the introduction of an integrated care electronic record.

Like the results of the 2008 RedC survey of health service users, the answers to some of the the questions suggest a need for continued dissemination of some of the issues and problems that surround the EHR.

2.5 National Implementations

It has already been noted that other countries have embarked on national EHR implementations. The EHR Implement [2]. consortium have researched the experience of EHR implementation across Europe. The practical and useful results of the EHR-Implement research focused on organisational and political issues that arise with largescale e-health implemenentations of this type. The EHR-Implement project consortium also attempted to document the factors that contribute to the success or failure of a selection of existing European projects in Table 2.5. The first two columns in the following table formed part of that report summarises some of the issues and controversies surrounding the introduction of the EHR in other countries a third column has been added here to show how this could relate to EN13606.

Table 2.1: A selection of existing European projects.

Countries	**Issue**	**Note on use of of EN13606 / standard**
Denmark, France, UK,	underestimation of work to be done resulting in unrealistic deadlines and delay (France) (UK)(Denmark had four tries at it over 15 years.)	not applicable
UK	scope creep	not applicable
France, Belgium	underestimation of cost and funding difficulties	not applicable
Denmark	hostile press	not applicable
	insufficient engagement with private firms involved. (France)	not applicable
Denmark, UK, Belgium	Insufficient clinical engagement - given the time pressure that HCPs are under they had little time to participate. This led to a lack of acceptance and resistance to change	clinical engagement could be supported and nurtured through the development of Irish nationals set of archetypes.
UK	systems designed by international suppliers for home markets not suitable for market	System would be designed by standard and allow local domain experts to develop lo cal archetypes etc.
UK	decommissioning of legacy (e.g. PAS) systems caused unforeseen problems as these systems often link other systems together.	EN13606 is designed to accommodate legacy systems
UK	centrally controlled projects were seen as causing a number of problems	EN13606 allows the interface to be defined without specifying the nature of the "wrapped" system. So in principle it allows for a federated approach.

Countries	Issue	Note on use of of EN13606 / standard
UK	development of local systems abandoned while the super system is implemented and then delayed etc.	EN13606 allows many existing local systems to coexist with the EHR.
France, Belgium	patient identifiers are a prerequisite for development of an EHR	Also the case for EN13606 as are health professional identifiers.
France	Masking of data, confidentiality, consent and "sealed envelopes"	Support for masking is included in EN13606
France	undue focus on technical aspects	not applicable (but relevant)
France	problems with static representation	EN13606 allows clinicians representing each health provider organisation to collaborate to produce dynamic views of the EHR.
Belgium	problems with centralised storage of data and resulting access issues	EN13606 can operate in centralized or distributed mode
Belgium	various security privacy related issues protection of content, authentication and identification, care team based access management	EN13606 has features to protect privacy of the patient.

Based on the accumulated experiences of its member countries and from a survey of EHR implementations in other countries, the EHR Implement Project also published the following list of practical and sensible recommendations for countries or regions who are considering or already pursuing EHR implementation. [2].
"...

(EHR-Implement) Recommendations concerning the strategy and vision

- *The large-scale implementation of EHR systems needs to be part of a clearly defined vision and strategy and integrated into the national strategy for the health sector.*
- *The vision should encompass the future of the relevant national, regional and local health economies, and make allowances for healthcare organisational needs that change over the course of the implementation of EHR.*

- *However, the implementation of EHR should not be used as the main or only instrument for healthcare reform. It could be an enabler of reform but not the goal as such.*

(EHR-Implement) Recommendations concerning the governance of the project

- *The vision of the future system must be held by a sponsor/leader with enough power, influence and awareness.*
- *The national implementation of EHR should have strong government support for the effort and for the relevant bodies involved, such as decisionmakers and policymakers. However, no pressure should be exerted on the management of the initiative.*
- *Governance should be established to define clear roles for decision-making and for agreement, monitoring, follow up, sanctions, legitimacy, roles, and means.*
- *Stakeholder engagement is vital throughout the EHR selection, decision and implementation processes. Stakeholder involvement ensures system ownership and motivation towards supporting and using EHR.*

(EHR-Implement) Recommendations: General principles to guide large-scale EHR-implementation

- *There should be a clear and consensual agreement on the goals to be reached and the tools to be developed, focusing on the added value for healthcare and citizens. Different and confused ideas among stakeholders should be avoided.*
- *A clearly defined privacy policy should be decided on beforehand and implemented. The discussion should involve all relevant stakeholders. The implementation of EHR systems should be in accordance with established laws and legislation.*
- *In the event that clear-cut laws regarding EHR systems were not in place, they should be established, especially regarding data sharing and shared responsibility.*
- *Projects should be realistically conceived in terms of complexity, resources, timeframe, and pressure placed on staff. A flexible schedule and process should be adopted.*
- *The use of strategic tools and the continuous evaluation of an EHR implementation initiative allow for feedback that leads to changes and adaptation to accommodate emergent needs.*
- *Funding should be provided and secure, and responsibilities for sustainability clearly defined.*
- *Change management should be considered as an essential issue and tools should be developed to accompany the changes (including education and training).*

(EHR-Implement) Recommendations concerning the implementation process

- *Realistic implementation plan and well thought out change management.*
- *The adoption of a senior executive-led change management programme and the involvement of researchers and analysts are vital for gaining full benefit from an EHR investment.*
- *Implementations should be flexible and step by-step; big-bang approaches should be avoided.*
- *Projects should not be longer than 12-18 months, and budgets, milestones, resources and deliverables should be set for this time.*
- *Continuous evaluation of EHR implementation initiatives should be used, allowing for feedback that leads to changes and adaptation to accommodate emergent needs.*

(EHR-Implement) Recommendations concerning the technical issues

- *Change should be properly managed and as limited as possible.*
- *Attention should be paid and commitment made to the required process and workflow changes in parallel with the implementation of EHR, in order to ensure the full realization of potential benefits.*
- *All EHR projects should be the subject of a clearly defined business case based on benefits and outcomes assessment across the health organisation to which all stakeholders subscribe. The clear definition of a business case allows for a sustainable change process where benefits outweigh the costs.*

(EHR-Implement) Recommendations concerning the relationships with vendors and the vendor selection

- *Good relationships between the public sector and industry should be established.*
- *Vendor selection should follow a thorough due diligence process to ensure that both the EHR software and vendor organisation are fit for the purpose.*
- *The selection should be submitted to detailed user evaluation to ensure that local processes, workflows and functional needs are taken into account.*
- *Vendors should have local and international knowledge of the market concerned and relevant experience with the health industry and the national health system*

(EHR-Implement) Recommendations concerning change management

- *All relevant stakeholders should be involved in all parts of the implementation process, so as to enhance communication and understanding between IT staff, healthcare professionals, policy / decision makers and management. During the process,*

stakeholders provide feedback, communicating their needs and concerns which result in application and service improvements.

- *Involvement raises awareness, establishes user acceptance and commitment of senior staff, and promotes public relations and trust among clinicians, citizens, IT specialists and politicians.*

- *Partnerships allow for the continuous identification of needs and concerns. Stable partnerships between key professional stakeholders, such as private-public partnerships focused on transparent governance of action plans and a defined strategy, facilitate implementation processes.*

- *Professionals should be encouraged with a clear motivation system and an explicit presentation of realistic envisioned benefits. Professional drivers should be taken into account when defining the required incentives.*

- *The leader is responsible for building a coalition of supporters and for promoting the measures necessary for overcoming anticipated as well as unexpected obstacles.*

- *Leaders must be aware of stakeholder needs, flexible to react and respond to real events, sensitive to stakeholder experience feedback and adequately autonomous to be able to resist political pressures.*

- *Education and training for professionals and all users involved should be established at an early stage to maximise the use of the system and ensure the quality of data input and of the content of patient records.*

- *Training should be regarded as even more important than software functionality as it allows for familiarity with EHR and facilitates change.*

..." [2]

Finally, and again based on the experienced of the participating countries and the results of the surveys, the EHR-Implement Recommendations report outlines the following 10 factors that impact on large-scale EHR implementation with accompanying explanations in Table 2.2.

"...

Table 2.2: Factors and explanations impact on large-scale EHR implementation. [2]

FACTOR	**EXPLANATION**
Leadership Governance & Vision	• *Large scale implementations of EHR systems need to be part of a clearly defined vision and strategy agreed within the healthcare sector.* • *The vision should encompass the future of the relevant national, regional and local health economies and allow for healthcare organisational needs changing over the lifetime of the EHR implementation.* • *There should be a clear definition and acceptance of ambition level for the use of EHR (short and long term) to avoid different and confused ideas among stakeholders.* • *The vision of the future state must be held by a sponsor/leader with enough power, influence and awareness.* • *The leader is responsible for building a coalition of supporters and for promoting the necessary actions to overcome anticipated as well as unexpected obstacles.* • *Leaders must be aware of stakeholder needs, flexible to react and respond to real events, stakeholder experience feedback and adequately autonomous to be able to resist political pressures.* • *National EHR implementations should have strong government support towards the effort and the relevant bodies involved such as decision makers and policy makers.* • *Governance should be established to define clear roles for decision making, processes of agreement, monitoring, follow up, sanctions, legitimacy, roles, and means.*

Clear Definition of business case, objectives, benefits & outcomes	• *All EHR projects should be the subject of a clearly defined business case based on benefits and outcomes assessment across the health organisation to which all stakeholders subscribe. A clear definition of a business case allows for a sustainable change process where benefits outweigh the costs.* • *Outcomes, impact and quality should be considered at various levels such as clinical, financial, public health system and others.* • *As the implementation proceeds, there should be a formal assessment to evaluate whether the expected benefits are obtained or to understand why they are not reached.* • *There should also be a clear and consensual definition of the goals to be reached and the tools to be developed focusing on the added value for healthcare and citizens.* • *Quality assurance of the applications and the related services and project reporting need to be based on the business outcomes - not on the mechanics of delivery.*

Realistic Implementation plan Change Management Health System Reform	• *Projects should be realistically estimated in terms of complexity, resources, timescale, and pressure placed on staff.* • *Expectations for the EHR implementation need to be set appropriately and all stakeholders informed.* • *Implementations should be stepwise and big-bang approaches should be avoided. Projects should be broken up in manageable sub projects of not longer than 12-18 months, and budget, milestones, resources and deliverables should be established for this time.* • *Implementation plans should be flexible to allow for adjustments, unforeseen circumstances, time for dialog with stakeholders and a step by step process.* • *Change should be properly managed and as limited as possible.* • *EHR implementation should not be used as the main and/or unique instrument for Healthcare reform but as an enabler of reform. Introducing EHR systems in parallel with other important procedural changes for the health system can result in significant delays and/or failure.* • *Attention and commitment to the required process and workflow changes should be made in parallel with EHR implementation in order to ensure full realization of potential benefits.* • *Adoption of a senior executive-led change management programme and involvement of researchers and analysts, are vital for gaining full benefit from an EHR investment.*

Evaluation & Assessment of similar initiatives	• *Knowledge should be gained in EHR implementation initiatives through extensive evaluation and assessment of similar initiatives.* • *Documentation of success and failure of National, Regional or International initiatives should be used in future EHR design and implementation.* • *Use of strategic tools and continuous evaluation of an EHR implementation initiative allows for feedback that leads to changes and adaptation to accommodate emergent needs.*
Vendor selection	• *Vendor selection must be the subject of a thorough due diligence process to ensure that both the EHR software and vendor organisation are fit for purpose.* • *Selection should be the subject of detailed user evaluation to ensure local processes, workflows and functional needs are taken into account.* • *Vendors should have local and international knowledge of the market and relevant experience with the health industry and the national health system.*

Stakeholder involvement	• *Stakeholder engagement is vital throughout the EHR selection, decision and implementation process. Stakeholder involvement ensures system ownership and motivation towards supporting and using the EHR.* • *All relevant stakeholders should be involved in all parts of the implementation process to enhance communication and understanding between IT staff, health care professionals, policy/decision makers and management. During the process, stakeholders provide feedback communicating their needs and concerns which result in application and service improvements.* • *Citizens should also be involved in the process to ensure acceptance from the consumers' point of view.* • *Involvement raises awareness, establishes user acceptance, commitment of the senior staff, promotes public relations and trust among clinicians, citizens, informaticians and politicians.* • *Power struggles are carefully managed to establish a creative balance among stakeholders.* • *Partnerships are established allowing a continuous identification of needs and concerns. Stable partnerships between key professional stakeholders such as private public partnerships, focused on transparent governance of action plans and a defined strategy, facilitate implementation processes.* • *Professionals should be encouraged with a clear motivation system and an explicit presentation of realistic envisioned benefits. Professional drivers should be taken into account when defining the required incentives.*

Infrastructure & Information-structure	• *EHR systems should be delivered on an established coherent well-defined infrastructure and information-structure build on existing international health standards.* • *Security and privacy should be major components of the established architecture. Components include, identification services, based on a unique patient identification or equivalent, authentication services based on reliable and for free accessible authentication sources, routing services and others.*
Education & Training	• *Education and training for professionals and all involved users should be established at an early stage to maximise use of the system and ensure quality of data input and content of patient records.* • *Training should be regarded as even more important than software functionality as it allows familiarity with the EHR and facilitates change.* • *Education and training should be introduced in medical curricula and in vocational training. Only when health professionals understand the importance of EHRs in improving health care will they be able to incorporate them into their daily practice and become active advocates of EHR systems.* • *Training should also be established for citizens, in order to reduce the technological gap.*

Resources	• *Implementation, use and maintenance of applications and services should be backed up through the guaranteed flow of steady or structural resources for medium and long term time spans.* • *Funding should be provided and assured, while responsibilities for sustainability clearly defined.* • *The internal cost of a healthcare organisation's resources must be allowed for and the magnitude not underestimated if the EHR implementation is to be successful.*
Legislation	• *EHR systems implementation should be in accordance with established laws and legislations. In the case that clear-cut laws and legislations are not in place regarding EHR systems, they should be established especially regarding data sharing and shared responsibility.* • *Methods for practical implementation of laws and legislations should also be considered.* • *A clearly defined privacy policy should be decided in advance and implemented. The discussion should involve all relevant stakeholders including citizens.*

..." Having considered EHR implementation summaries of experiences other countries, the next sections focus on the EHR infrastructure that is in place elsewhere. The following sections briefly describe key infrastructure in seven countries that are progressing towards national or regional electronic health records.

2.5.1 Study of EHR Infrastructure in other countries

In order to understand the diversity of EHR and e-health architectures in other nations, a review of the literature and consultation with experts involved in national implementations was conducted as part of this work. The goal of this investigation was to establish whether key technological and infrastructure choices that underpinned implementation of EN13606 were generally applicable for the implementation of EHR systems in other jurisdictions. Particular emphasis was placed on technological elements or choices that the EHR*land* project team considered to be key ingredients of a successful implementation of an EN13606 as follows:

- national register of patients associating patient identifiers with a set of demographic traits
- national register of health professionals associated national health provider identifier with a set of traits and information on professional qualifications
- directory of health organisations and health organisation units.
- use of OIDs to provide global identification of assigning authorities and additional resources.
- use of key mature terminology systems to help promote semantic interoperability.
- deployment of a unified technological solution for conveying and representing EHR content.
- approach to access control and consent.

2.5.2 Austrian e-health / EHR project

The Austrian e-health project is of interest from an Irish viewpoint because they have only recently embarked on their e-health project. The Austrian work has been underpinned by development of identification of patients using social and health cards and associated identifiers. The identification approaches have been designed and are now under implementation. A registry based on IHE identity management profiles is also currently under implementation. Also under implementation in Austria is a mechanism for exchanging certain types of health messages, using IHE XDS and CDA as a transfer mechanism. Permission to access health information is intended to be given through use of a pair of e-cards. The patient, by inserting an e-card with their details an health identifier into a reader during a medical encounter gives consent for the health provider, who also produces an e-card with their details and number to subsequently access their record. Each citizen has at least one e-card that can be used for this purpose. Citizens with private health insurance, do not use their social insurance card but it is intended that they will use their citizen e-card or something similar.

The approach has been to focus on essential building blocks with a key change in the last four years towards adoption of international standards that have been proven to work. The project is also implementing 'proven' coding systems such as LOINC. This work cannot yet be considered as a full EHR, but the project is adopting the pragmatic approach of developing the key ingredients of an EHR system.

2.5.3 Norwegian e-health project

Norway already has a national patient identifier and a mature national OID registry. Norway has had a long history of using identifiers and has identifiers for both patients (four different types of unique patient identifiers!) and for certain types of health professional. There are two linked registries for individual health providers. One of these registries is a professional register with competencies. Most of the activity on this registry is for doctors and nurses, the second register records roles for each health professional. This is

also linked to a directory of health organisational units so the roles can be associated to organisational units. This system does not rely on the use of cards.

There is some use of IHE XDS (for instance in the western region of Norway) as a base communication layer for health information. On top of this and other infrastructures, they have developed a national system that is based on a variant of the predececessor of EN13606 called ENV13606. This has become a national standard that is used for exchanging health messages of different types, lab requests and results, admission and discharge etc. The adoption of this earlier standard has presented some problems for Norwegian standard authorities who are slightly out of line with the revisions that accompanied the transition from ENV13606 to EN13606. The western region of Norway are promoting conversion to HL7-based messages with CDA in some cases. Norway has developed its own national terminologies and terminological systems. However, these systems are not unified so it could not be stated that there is a Norwegian national shared EHR system. But many of the building blocks are already in place.

2.5.4 Brazilian e-health project

Background: Brazil has a population of 200 million people. Their national health system is well conceived but deployment is uneven. 160 million Brazilian citizens rely on the public health organisation (SUS). Brazil has a well-developed e-society. For instance, they have a fully functional e-voting system for 135 million voters, Brazilian IRS submission is electronic only and they have a very high per-capita rate of Internet usage. Brazil has 160 voluntary experts who are actively involved in health standards development. This activity is supported at national, local authority levels and by commercial funding. The work on e-health began many years ago with fragmented systems. The Brazilian authorities are now focusing on getting the 250 silo-ed health information systems to interoperate.

At a national level in Brazil, standards have been selected for unique ID and cards for individuals (patients) and for individual healthcare providers, leading to the development of a national registry of healthcare providers - their roles and affiliations to healthcare organisational units. These roles and connections are themselves the subject of a directory in some regions of Brazil.

The goal of this work, which is out for consultation, is to develop a full map of resources, which records relationships between procedures, healthcare professionals, equipment and organisations based on the above registries. In all there are twelve standards in translation. In addition the following EHR-related standards are at a more advanced stage for national adoption and implementation.

Standards undergoing public consultation in Brazil

- ISO EN13606-1 EHR Communication
- ISO27799 Information security management
- NBR database of individuals that is based on DTS22220
- ISO TS29585/2010 Deployment of clinical data warehouse

- ISO TR 22221 Good principals and practices of a clinical data warehouse
- Brazilian National standard - Health Summary records for hospital discharge

Already adopted and published Brazilian standards

- TR12309 Health informatics - Guidelines for terminology development organizations
- TS17117 Health informatics - Controlled health terminology Structure and high-level indicators
- ISO TR 17119 Health informatics profiling framework
- ISO TS 18308 Requirements for an EHR architecture
- ISO TR 20301 Health cards - General characteristics
- ISO TR 20514 EHR - Definition, scope and context
- ISO TS 21667 Health indicators conceptual framework

There is also an extensive certification programme for EHR systems and their components against appropriate standards. Two example Brazilian projects are of interest as representative implementations:

Minas Gerais state EHR (20 million people) in July 2010 launched an RFP for EHR systems, that required adherence to ISO IS 13606. As a result many Brazilian health IT companies are working on OpenEHR archetypes, although not many are finished applications yet.

They have developed demographics archetypes based on ISO/DTS22220 Identification of Subjects of Care and ISO/DTS 25757 Health Provider Identification.

SIGA Saude IT model (and EHR) in Sau Paulo (population 22 million) The Sao Paulo system uses ICD 10, ATC medication codes and LOINC for lab codes Technology used is HL7 3.0, CDA R2V3 XML messages using thin clients.

Statistics associated with this implementation

- 20 million people in system with unique ids
- 1,200,000 primary care appointments/month
- 200,000 specialised care consultations/month
- 2,200,000 prescriptions/month
- 15,000 users trained on the system.

2.5.5 Swedish e-health project

Sweden has a population of 9 million people. There are 21 independent county councils and 290 municipalities. The EHR is completely implemented in 92% of hospitals, 100% of primary care facilities and 96% of psychiatric sites in 2008. The Swedish health system has been using health identifiers for many years. Identifiers exist for patients / health system users and for health professionals. An access control system for the summary record is currently at the procurement stage. Health information of Swedish citizens is currently managed through a third generation health record, i.e. rather than practice or hospital records, Swedish healthcare professionals already have an integrated care record for primary care, psychiatric care and for hospitals.

Swedish authorities are now working towards allowing the patient to interact with their record and extending the scope of the record using EN13606 with OpenEHR tools. (The OpenEHR tools are being used for reference archetypes and templates. This is because, as of October 2010, they believed that tools for EN13606 development were not mature yet). The focus of the Swedish e-health effort is towards an implementation that involves EN13606 and OpenEHR. They are developing reference archetypes and templates with embedded SNOMED-CT terms. They are also using the WHO ICF structure.

The OpenEHR reference model is being used for the reference archetypes while the EN13606 EHR reference model is intended to be used for the actual communication. In relation to terminology. ICD or other term codes are mapped to SNOMED-CT codes, which are then mapped into archetypes. The impressive array of international health informatics standards relating to the EHR are proposed for this design. These standards can be grouped into three layers.

Use of standards at the Swedish generic business/clinical layer

- EN12967 HISA part 1, Enterprise Viewpoint
- EN13940-2 Contsys Part 2 health process and workflow
- FDIS 21667 Health indicators conceptual framework

Use of standards at the Swedish reference information layer

- EN12967-2 HISA
- EN13606-2 Archetypes
- OpenEHR RIM and specifications
- SNOMED-CT concept model
- PrEN13940-2 Contsys
- ICF (WHO classifications for disabilities and functions

Use of standards at the Swedish clinical applied layer

- EN13606-1 Reference model for healthcare record communication
- EN13606-4 Electronic healthcare record communication part 4
- EN13606-5 Electronic health record communication Part 5 Interface specification
- PrEN13940-2 Contsys part 2: healthcare process and workflow
- SNOMED CT, ICD, ICF terminologies

2.5.6 French e-health project

In France the EHR project has sought, despite significant difficulties, since 2004 to produce a system that included patient health information while promoting coordinated shared health care. The "Dossier Medical Personnel-DMP" (personal medical record) allows patients to prepare their own medical data such as medication histories and other summary information for consultation with their general practitioner and other healthcare providers. This system is expected to be delivered at the end of 2010. An extended "Dossier Medical Patient" is also under development for delivery in a few years time. This more comprehensive second record is expected to be shared by authorized healthcare professionals.

One early practical impediment to the development of the DMP was the fact that France didn't have a national health identifier for patients. This problem was accentuated by a national debate on issues related to access to private health information, and the rights of the patient in this respect. One approach that was considered to solve this problem was that access to health information would be governed by the use of two smart e-cards. The Sesam Vitale-2 which commenced roll-out in 2007 contains a photograph of the health system user a summary of vital medical information and a secure patient identifer. Using this approach, a clinician could get an overall view of the patients record. However, each healthcare professional would only be permitted to access information strictly related to their domain of expertise as represented on their health professional CPS card. The authorization to access the patients record would also require patient consent and this must match authorization on central access control resources. Following relaunch of the DMP programme emphasis shifted to the introduction of national identifiers and in November 2009, ASIP Sante published a specification for calculated national health identifier. (Esante 2010) [22]

Interestingly, rather than imposing the DMP system on the health system, the development of the electronic health record was promoted by creating comsumer demand to influence general practitioners, labs and other users. A developer API for the system has now been published to further encourage the community to adopt the system.

The French authorities also announced that they had developed a French translation of the Biology subset of the LOINC Codes set which has been incorporated into a new higher quality way to report lab results. [23]

2.5.7 Canadian EHR project Canada Health Infoway

The estimated population of Canada at time of writing in 2010 is just over 34 million. The Canadian health system provides care to this population with the support of 700 hospitals, 40,000 general practitioners, 315,000 nurses, 29,000 specialists, 26,000 pharmacists and 1,600 long-term care facilities.

Canada Health was created in 2001 to progress the development of information systems in Canada and is now engaged in the large-scale development of a community of regional message-based peer-to-peer e-health systems. These large cooperating systems allow eligible users to access the health information that they manage and include an HL7-based EHR "view". Canadian informaticians have participated in the development of the HL7 v3 models and tools. In turn, the XML-based HL7 v3 messaging specification and the HL7 Clinical Document Architecture are used in Canada for the exchange of messages for laboratory, pharmacy, patient and provider registries, clinical content in the EHR, insurance claims and also for health surveillance.

Canada also utilises LOINC for coding lab concepts and SNOMED CT for problem lists, procedures, and other clinical observations. The Unified Code for Units of Measure (UCUM) is used for units of measures whereas Canadian diagnostic Imaging communications are based on DICOM and IHE XDS-I.

There is also some recent discussion around the development of a single unique identifier for health providers that cites similar developments in USA and Australia. [24] This work mirrors similar work in Ireland that has been led by the Authority. [24]

2.5.8 Dutch e-health project

The National e-health infrastructure in the Netherlands is called AORTA and it facilitates exchange of data between healthcare providers and uses HL7 v3 and SOAP. Another key ingredient of the national system is the employment of a unique identifier called the Burger Service Number (BSN) which following the "Use of Citizen Service Number in Healthcare Act", healthcare providers organisations have been obliged to use from January 2008. The approach also involves each healthcare professional in Netherlands having a smart (UZI) card with personal identification. And they have defined requirements for local systems to be connected to a national e-health infrastructure. The Netherlands is also a member of IHTSDO, who are responsible for SNOMED-CT and the planned e-health infrastructure includes this large terminology.

In recent years, the Dutch Government has sought to introduce a national EHR called het Electronisch Patientdossier (EPD) but this project has been opposed by some of the stake holders including almost one third of doctors who refused to participate. Objections have focused on the perceived lack of security and the notion of guaranteed privacy. More recently the project at time of writing the project has been put on hold for at least one year after the Dutch Senate voted to make changes to the national programme. Many Senators felt that the wrong technological model (a form of federated EHR) had been used and also due to large number of amendments to the legislation. [25]

2.5.9 National Patient Identifiers

The table below summarises the style adopted by different countries for their national patient identifiers.

Table 2.3: The summary of National Patient Identifiers. [3]

Countries with National identifiers that are specifically for health	**Countries with national identifiers that are used for purposes other than health**
Australia, United Kingdom, New Zealand, The Netherlands (Quantin et al 2007)	Germany, Canada, Finland, Luxembourg, the United States, The Netherlands (Quantin et al 2007)

2.5.10 Summary

Consideration of the above examples of national implementations shows similar components of an e-health architecture are emerging in different jurisdictions as follows.

- patient identifiers and demographics profiles stored in a registry either with or without health card and either linked to social security numbers or with separate health identifiers,
- directory of health care organisation units and assets which can be linked to individual health providers,
- identifiers for health professionals with links to qualifications and demographics also stored in a registry,
- (in some countries) a registry of roles and affiliations to health organisation units,
- use of mature terminological systems such as LOINC, SNOMED-CT and ICD with the intention of embedding term codes into e-health applications,
- use of a transfer mechanism based on technologies such as IHE XDS (or at a lower level SOAP) to pass information between health provider locations,
- use of OIDs to distinguish between different types of identifiers and to uniquely identify resources across the e-health infrastructure. OIDs are necessary for implementation of HL7 V3 and EN13606.

As we shall see, EN13606 requires a similar set of resources to be in place for satisfactory operation of a system that is based on the standard.

Another issue arises from the results of the EHR-Implement Report: That of capability and skills to support the EHR. The development and support of a national EHR system - a substantial ICT project by any measure, will require significant and widespread EHR related skills. Such skills include: system architecture, distributed identity management, clinical terminology, clinical information modelling, legacy system integration, data migration, data quality management, workflow management and business process

modelling. Many of these skills are not prominent in the Irish Health community. So the question arises, how will these skills be fostered? The project team have helped promote some of these topics - notably clinical information modelling, through running a series of archetype workshops. This type of dissemination is clearly not sufficient. There is a need for a strategically guided and comprehensive advanced skills programme to generate enhanced and more widespread home grown expertise in these areas.

2.6 The road to the EHR

In the case of one of the skills mentioned above, clinical information modelling; skills development must accompany the development of a national set of clinical models. In order for the two-level modelling paradigm to be fully productive, detailed archetype models for a large number of concepts such as blood pressure, body weight and Apgar score and many many others is required. This would allow those who adopt the two level approach at healthcare provider organisations to use graphical tools and templates to gather the archetypes that they require and deselect the optional parts that they do not require. Estimates given by experienced practitioners for the number of archetypes required to document the key elements of healthcare provision range from hundreds to thousands. While the number of draft archetypes is in the low hundreds, the number of published archetypes is very low indeed, so work is really only beginning at time of writing. Another piece of work by Moreno Conde [26], that underlines this fact was motivated in part by EHR*land* and was designed to fit cohesively with the work of the main project. Moreno Conde's work investigated the various elements of the archetype development process.

His findings include the following.

The pace of archetype development: As mentioned above, although hundreds of draft archetypes have been developed in the online openEHR clinical knowledge manager environment, only a very small number have been published and the remainder are still in draft or team review stage and are not expected to be published in the near future. Although there was not enough information available to estimate the time required, at the current pace of development it will take years rather than months before the number of fully mature archetypes reaches hundreds. This appears to be due to a number of factors. Moreno Conde notes that the following are contributing factors to this slow pace of development,

1. The archetype development process as it currently exists, even for a single archetype, is a relatively long and labour intensive one that requires the support of many domain experts. These experts voluntarily provide inputs based on their background in healthcare.

2. The role of archetype author/editor is relatively tightly controlled within the openEHR community. This measure has successfully preserved the quality of archetypes in the openEHR ADP. However, the small number of archetype authors is also likely to have influenced the slow pace of the ADP. It is worth noting however, that the interest in archetypes is continuing and there is a capacity for increasing the numbers of experts involved in the process.

Archetype Validation: Moreno Conde also notes that in order to preserve the quality in the ADP there is a need to verify that published archetypes satisfy organisation governance and policies. Preparations for the addition of this step to the process are already underway. The establishment of Archetype Quality Criteria (AQC) such as those published by the EuroREC [18] ensures that archetypes that don't conform to the requirements are identified and they are modified before their application in EHR communication.

The work evaluated the quality of all published OpenEHR archetypes against the EuroRec requirements and showed that most of these requirements are fully satisfied by the published archetypes.

Educational Resources: Based on the results obtained, he proposes the creation of additional educational resources that use Archetype repositories as a learning tool. Additionally he asserts that 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.

Moreno Conde's findings suggest the following way forward for the ADP.

1. *There is a clear need for recruitment or other measures to increase the size of this community of experts in order to accelerate the archetype development process.*

2. *Assuming that the number of contributing experts can be increased, the small number of experts who act as archetype authors should also be increased. The introduction of an archetype style guide and tools to support good design practice in archetype development would be a positive development. While the recruitment of additional archetype editors would also help increase the pace of development.*

3. *If EN13606 is to be used in Ireland as the basis for a national or regional EHR system, it would not be sufficient to rely on the international effort as we would be likely to have our own national priorities which are not the same as priorities of other regions. An Irish ADP would therefore need to be established with archetype authors working on strategically important archetypes supported by local experts from the Irish health system and working in cooperation with their counterparts in other countries.*

4. *Another very specific enhancement that Moreno Conde refers to in his study, relates to the introduction of what we will call here a "concept selection wizard" which could help a prospective archetype author to select the appropriate base concept from the reference model for the specific clinical concept that they wish to model. He cites two existing sets of rules that could be used for this purpose.*

5. *EuroREC AQCs or equivalents should be formally incorporated into the archetype development process.*

6. *To help ease the relatively steep learning curve for experts, additional educational resources and smart tools should be developed and made available to the community of experts*

2.7 Legacy Data Integration Challenges

The electronic health record involves "legacy system integration" on a large scale. Many existing information systems, while they may function well in stand-alone mode, will not have the capacity to exchange health information. In Ireland, when information systems do have this capability, they often use HL7 v2 messages. In the case of the former type of information system, it is necessary to either modify the application in some way in order to facilitate secure communication or in extreme cases, to replace it with an application that can communicate. If on the other hand, the information system already supports Hl7v2 messages, additional functionality to support 13606 could be added, or the HL7 messages could be transformed into EN13606 form. These technical scenarios will be examined further in chapter 5 based on experience gained in the project.

On the other hand, if the information system natively supports two-level models as in the case of Helix Health's HealthONE product, then the integration challenge is much diminished and this may even be possible without writing code.

Apart from the not insignificant challenge of achieving 'low-level' interoperability, it is necessary for stake holders and data custodians to come to an agreement about the format in which data can be shared. This is where the two-level approach is supposed to provide significant advantage. Corrigan [27], conducted an investigation on this aspect of the integration challenge that has contributed to the EHR*land* outcomes. He investigated the use of the OpenEHR architecture - an approach which is closely related to EN13606 - to create dynamic views of a two-level shared EHR for multidisciplinary teams. He focused on archetypes to satisfy the requirements of multidisciplinary care of Cystic Fibrosis (CF). Corrigan's work involved the use of many existing archetypes from the OpenEHR CKM archetype repository. He also contributed his own novel CF archetypes to the OpenEHR community which have been absorbed into the general development effort in the OpenEHR project.

This study found OpenEHR to be sufficiently expressive for the above mentioned task from a data modeling point of view, whereas the graphical representations of the data were found to require further evolution. OpenEHR tools fulfilled the goal of the work in being capable of producing new and pre-existing archetypes and templates which represented the full extent of the data chosen for the study. Corrigan noted the dependencies that exist from templates through archetypes to reference model constructs, which have a number of consequences including a reduced ability to make changes if they are required at the reference model level. He felt that the most successful aspect of the openEHR approach was the ability to select from a menu of carefully designed and "maximal" archetypes and then construct templates based on them. Corrigan also presented a detailed step by step methodology for creating archetypes and templates. In conclusion, he found that openEHR and by extension two-level modelling is a very positive initiative which has potiential to address challenges in implementing clinical information systems, if the following issues can be addressed. "...

- *the further development and use of the OpenEHR Clinical Knowledge Manager*
- *streamlining the data governance process to speed up development and publication of completed archetypes and templates*

- *the further development of archetype design methodologies specifically incorporating archetype design patterns to guide good design*

..." [26] It has already been noted that there are a number of prerequisites for the establishment of a national EHR system, including,

1. identifiers for patients, for individual healthcare providers and health provider organisations,
2. terminology and coding systems
3. a secure communications infrastructure
4. access control mechanisms
5. agreed structures for the communication of health information

In the next chapter, it will be seen that functionality corresponding to the above items is required to satisfy EN13606. It is worth noting that the first four items on the list will generally improve e-health infrastructure and should be considered as intermediate objectives that are independent of the introduction of the electronic health record. These objectives will also have their own business cases. For example a certain level of coding leads to semantic interoperability for EHRs, but is also associated with more accurate assessment of healthcare activity. Likewise it is difficult to imagine a scalable EHR without national identifiers, but the introduction of such identifiers will help reduce the possibility of mis-identification with the associated side effects. For this reason the above "building blocks" of the EHR should be developed as part of a plan to develop the EHR but which also bring benefits that are independent of the EHR.

2.8 Terminologies and Ontologies

2.8.1 An introduction to the use of terminologies

Another skill that was mentioned above relates to the use of clinical terminologies to support semantic interoperability. This is an area where Ireland lags somewhat behind other developed countries. The concept of interoperability was introduced in the last section. The goal of semantic interoperability in the e-health domain is an elusive, but worthwhile one that both the industry and the research community have pursued. In the absence of semantic interoperability, heterogeneous systems have the potential to cause integration difficulties and possible mis-interpretation of information during data exchange. This is a recurring issue in the current e-health environment.

The SemanticHEALTH project [9] has provided the following definition of interoperability.
"... Health system interoperability is the ability, facilitated by ICT applications and systems,
- to exchange, understand and act on citizens/patient and other health related information and knowledge
- among linguistically and culturally disparate clinicians, patients and other actors and

organisations
- within and across health system jurisdictions in a collaborative manner..."
They further classify a number of different levels of interoperability as follows
"...
Level 0: no interoperability at all
Level 1: technical and syntactical interoperability (no semantic interoperability)
Level 2: two orthogonal levels of partial semantic interoperability
Level 2a (quality): Unidirectional semantic interoperability
Level 2b (quantity): Semantic interoperability of meaningful fragments
Level 3: full semantic interoperability, sharable context, seamless co-operability
As the level of semantic interoperability increases, better integrated terminologies are required to address issues that arise when data exchange happens between heterogeneous EHR systems..." [9]

As the development of various Electronic Health Record (EHR) systems progresses, the need for a standardized mechanism to share and exchange commonly understandable health information increases. The Electronic Health Record is not merely implemented as a replacement of the paper records but also seeks to adopt an approach that utilises a sharable and reusable data model to promote this common understanding between users of different systems that exchange health related information. This is why EHR standard development organisations such as CEN TC251 have been engaged in long term data modelling activities which aim to provide a generic and flexible data structure for recording clinical information.

In contrast to and concurrent with development of structural characteristics in the data model of the electronic health record, symbolic representations of the meaning and context of the clinical information are developed as "Terminology" in health care. A medical terminology is the terminology relating specifically to topics in medicine. It has many aliases such as "controlled vocabulary", "clinical terminology" and "coding system". Terminology in health care is regarded to be as old as computers, because initially shorthand codes and terms were invented and designed to minimise disk space usage. For example, a textual description of "Diabetes Mellitus" can be shortened by simply using a term like "DM" or even a code that can be understood by the computer. The history of using codes pre-dates the origin of digital computers. The idea of coding lies in the use of symbolic or alphanumeric representations to refer to agreed concepts or real world objects. Terminologies at the beginning served the same purpose as any other codes being used in a computer system: to save precious memory/disk space and for the ease of processing data. These obstacles are long gone since the computing power and storage technology has been increasing dramatically.

Research and development work into clinical terminologies has become of great importance now because it attempts to classify a wide range of clinical phenomena. The introduction of electronic health record and EHR systems opens the possibility that some level of automated clinical process can be achieved by embedding terminology from terminological systems such as SNOMED-CT within e-health information systems. Given this great potential, electronic health record approaches such as EN13606 are designed to work seamlessly with terminology systems. Studies have shown that [28]the growth in use of coded information and terms and the amount of terminology training undertaken by healthcare professionals is continuously rising. Perhaps this is related to the fact that

many forms, screens and coding frames for e-health applications have adapted medical terminologies and it also reflects the popularity of terminologies among the majority of system vendors. Huge effort has been invested by these vendors to improve the human computer interface to cope with terminologies [29]. However, perhaps the existence of systems embedding medical terminologies convinced the users to adapt to them without asking why.

2.8.2 The origin of terminology

During the expansion and accumulation of our knowledge of medicine, medical terminology has evolved to allow us to achieve many clinical tasks. Common functionalities can be classified as the following [29]:

1. Clinical data capture and presentation - letting healthcare professionals enter, store, and review what would otherwise be written in the clinical notes

2. Information integration, indexing, retrieval - linking clinical records, decision support, quality assurance, and other information.

3. Messaging between software systems - linking laboratory and hospital information systems or sending prescriptions from prescriber to dispenser to the Prescription Pricing Authority

4. Reporting - providing the official returns in whichever coding system is required

However the need for terminology in medicine did not develop spontaneously. For a long time the use of natural language was (and continues to be) predominant for clinical note-taking and for other medical documentation. The natural language represented an incredibly expressive tool until it came to the electronic health record. Some obvious drawbacks are the ambiguity of human language and number of languages and dialects worldwide. The words we use to describe a situation or phenomenon depend heavily on the context. We exchange ideas and meanings in conversation - not the words. Free text that is used in health data or clinical note-taking may suffice within a small environment such as personal use or an office. But it soon becomes problematic when health professionals wish to exchange clinical information. As the desire for exchanging reusable clinical data arose, a controlled and commonly agreed vocabulary was needed. When people first attempted to classify and index clinical phenomena, they experienced difficulties in expressing those using natural languages: there are many ways of expressing the same meaning while even with the same phrases can be understood and interpreted in different ways if the term is short. Codes were developed to resolve this situation. The difficulty of processing natural language related information has also acted as a barrier to the rapid development of a meaningful digitised clinical record. By comparison, codes consist of numbers and letters are very easy to process. Codes can also reduce risks in health care by removing ambiguity. In general, the partition of clinical information being coded is increasing in many medical fields such as clinical noting, clinical data entry and documentation.

The development of code system experienced different stages and spawned different types of code systems over decades. First single purpose code sets were developed which

tied to the area where these codes can be applied. Examples of these coding systems are the UK READ codes and LOINC codes [30]. Another common problem is that the meaning of a term may change over time due to the evolution of medicine while the words used do not. It could also be the case that the description of one concept has to change because of new findings of the disease. And these circumstances could occur simultaneously. This leads to a solution that introduces persistence of meaning by using codes. A code acts as an anchor to a particular concept or meaning in medicine.

In order to design such a medical thesaurus, one must consider an vast set of commonly used words and phrases in medicine. To avoid terms overlapping with each other, a more sophiscated type of code system is required. Codes or terms in the system exist as concepts. Relationships are created between concepts to form a classification. International Statistical Classification of Diseases and Related Health Problems (ICD) is an example of this approach. Because each code/term in a release persisted a concept, the code/term is acting just a symbol to that concept. Multiple releases over ICD give the benefit of allowing one easily and distinctively identify and specify a concept, for instance, the manifestation of hepatitis through the history of studying and researching such disease. However despite the countless clinical terms for describing medical phenomena, many dialects exist in local use by health professionals. The number of terms and concepts keep expanding in those classification code systems. A third type of code system emerged: a compositional code system. In this type of system, each code is a concept of mini-ontology. Expression of new concept can be composed by existing concepts. The system contains axioms that will not violate the logic of reality in medicine. A nice feature of this system is to have the ability of inferring and reasoning. This can greatly facilitate interoperability especially where it requires communications between electronic systems with no human intervention. Other promising features such as decision support and AI in health are at the high end of research. An example of such a code system is Systematized Nomenclature of Medicine-Clinical Terms (SNOMED-CT) [31] developed by the International Health Terminology Standards Development Organisation (IHTSDO). A formal knowledge representation language called Description Logic (DL) [32] is applied when developing SNOMED-CT. SNOMED-CT is so far the most complicated code system for clinical use.

To summarise: the effort to produce reusable clinical thesauruses has led to the development of clinical terminology systems. A clinical terminology like SNOMED-CT is a semantic network of clinical terms that defines phenomena and health-related concepts [33]. When exchanging health related information, the data quality of information recorded in EHR can be improved by referencing unambiguous concepts from terminology systems. These concepts exist as codes or terms in various EHR-related applications. Terminological systems can be developed separately by clinical domain experts who model and build codes that can be used for encoding health information.

2.8.3 The ontology approach

Most coding systems cover only a specific area of medicine as they were designed for a single-purpose. MeSH (Medical Subject Headings) [34] is used for the purpose of indexing bibliography in medical databases. The 4 digit Read Codes, [35] were designed to be used by general practitioners for disease and service registers. As mentioned earlier about

the evolution of terminology, more recently developed controlled vocabularies tend to cover more medical concepts than their precedents and they span multiple purposes. For example, certain codes can be used for both messaging and information retrieval. New problems arise with the creation and management of bigger and richer terminologies.

- Standardisation for share and re-use: because of a need for larger terminologies to support multi-disciplinary care, merged sets of medical concepts are required to be logically correct and coherent. Concepts from different classification systems, which when viewed independently, were considered logically correct, may appear to be incorrect when brought together, due to differing classification methods. In addition, where classification systems overlap, a single concept can be classified in different ways in the original code systems. In order to address these problems, re-modelling of all the concepts may be required. The cost in terms of time and resources is a major barrier to the release of a mature and practical merged terminological system. Each time a terminology is modified and expanded, another iteration of re-modelling may be necessary. When building a large and coherent terminology, any modification of a basic feature of the classification has the potential to cause a significant change.

- Problems of expressing the item to a corresponding code: It is often discovered that in real medical circumstances, an item does not exactly correspond to the code in the terminology. This may be because:

  - the item is not classified or identified.
  - the item is not classified in a way that a user recognises.

  So in order to map the item to a code in the terminology a new code has to be introduced. However this cannot guarantee that,

  - the new codes can cover all the gaps in expressing variants of the item and
  - the new codes do not collide with the old codes.

This effect tends to make the offending parts of a code system unmanageable. Since the introduction of codes, the expressivity of terminology has been the primary concern when developing new terminologies. Difficulties have arisen when mapping a concept to an appropriate code in a terminology due to many classification approaches. To address this problem, multi-classification (expressing the same concept in different ways.) should be allowed in single terminologies.

This is where Ontology comes to the aid the development of modern terminology. A profound and full explanation of ontology is beyond the scope of this report. A brief definition will suffice: ontology in the flavour of medical information science can be seen as *a formal representation of knowledge in a domain of medicine by a set of concepts and their relationships.* [30] Ontology uses classes to describe groups with similar features i.e. the types of things (universals) and attributes to describe the properties and characteristics. There are other components such as relationships and assertions (Axioms). Ontologies have been used to model specific domains in medicine, such as anatomy and bacteria.

The primary motivation for the application of Ontology to information science is to enable computer-based reasoning. Medical information science takes advantages of ontology in various ways to enhance reasoning technologies viz. automated clinical workflow, decision support system, population health surveillance and others. Two distinct approaches are being used to develop strong links between terminologies and information models.

Object oriented modelling: Ontology facilitates more coherent modelling by allowing an information modeller to assign formal meaning to different types of information. For example, consider the introduction of "Class", "Object/Instance", "Attribute" and "Relationship". These basic elements provide a paradigm for designing and modelling many specific domains including the medical domain.

Hierarchical modelling: Another design pattern that has clearly influenced modern terminology is to conceptualise pieces of medical information and link them in hierarchical structures. This practice allows the term or code to be referenced in a medical document while it resides in a network of concepts which reflect reality. It also provides the opportunity for standardising the concept network so that the use of terminology always closely follows reality.

One positive feature of ontology is that they allow multiple forms to express the same concept. When this approach is applied to terminology, it permits medical concepts to be composed by different codes that act as smaller components of a bigger concept. While this composition property is not yet widely used in practice in health terminology, it does help to address the problem mentioned above of merging an ever growing list of codes into very large collections of terms.

Certain logic can be applied to assure the correctness of these composed expressions to minimise the number of codes. An example of a coding system which has this capability is SNOMED-CT and the logic used is Description Logic.

Ontology also influenced the development of EHR information models. Because the EHR presents as a structure to record clinical information to form a consistent electronic artefact, the resulting recording should be medically meaningful. The electronic equivalent should make sense in the medical field, for example a recording of observing blood pressure should become a "measurement" or "observation" but not "evaluation". To ensure such logical coherence, the design process needs to take ontological aspects into account. Figure 2.8 gives an example of how these views can impact on modelling in the medical domain. Major EHR information models have mature implementations of ontological views of medical domains yet a lot of effort is spent to elaborate them.

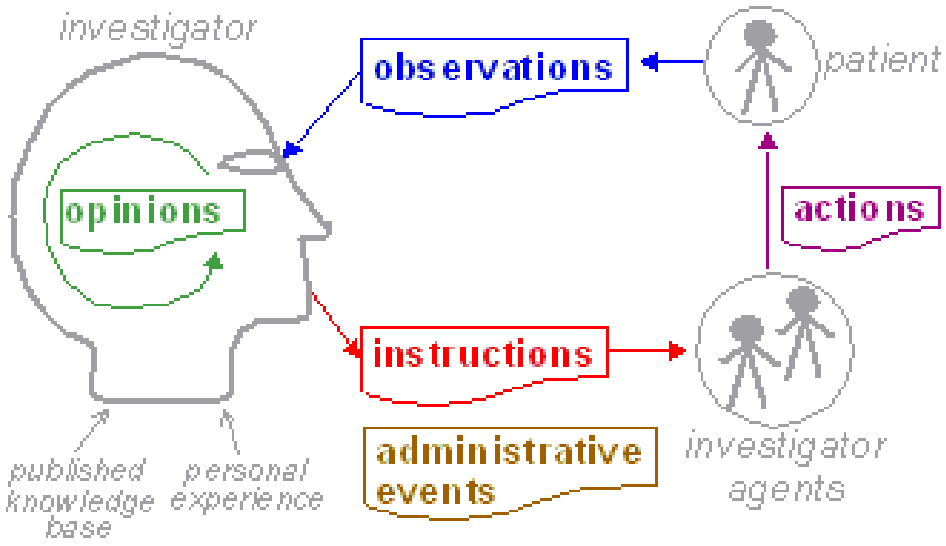

Figure 2.8: Example of ontological modelling in medical domain. [1]

However there exist many views of how the clinical information ought to be modelled. Sometimes these views were generated by survey or requirement based on a particular profile. Data stored in hospitals are significantly more complex than smaller clinics. Figure 2.8 is only a generic view of how to classify clinical information at an abstract level [36]. Different ontological views lead to different results of modelling. One proof is the subtle differences found in building blocks of EHR, reference models of many standards [37].

The archetype approach involves the use of a constraint model which allows specifying clinical content (also is regarded as clinical domain knowledge) that to be recorded in an EHR. The formalism of constraining clinical content can be seen as an ontology-like approach. Extended work is already on the way to expand ADL to ontology authoring language such as OWL [38]. Meanwhile, ontology influenced terminology e.g. SNOMED-CT is becoming more predominant. Collaboration between openEHR and IHTSDO to merge some properties of both information model and terminology is being carried out [39] recently. Movement towards an ontological structured EHR could be a future development direction.

Chapter 3

THE EHR*LAND APPROACH*

The previous chapters have provided a background to the development of an EHR in Ireland. This chapter provides an overview of two-level model approach that forms the basis of the EN13606 standard and comments on some of the decisions that were taken in relation to investigation and implementation of different parts of the standard and supporting works. It also discusses the EN13606 standard in detail before outlining some of the consequences of the standard for a national implementation. It finally goes on to discuss the general issue of identity and identifiers in the context of the current version of the standard.

3.1 One-level Models

3.1.1 Health messaging and "large" fixed models.

Traditional health messaging approaches such as those adopted by Hl7v2.x allow messages to be created by the message implementer who picks attributes from existing properties in the reference information model. The approach could be summarised as shown in Figure 3.1.

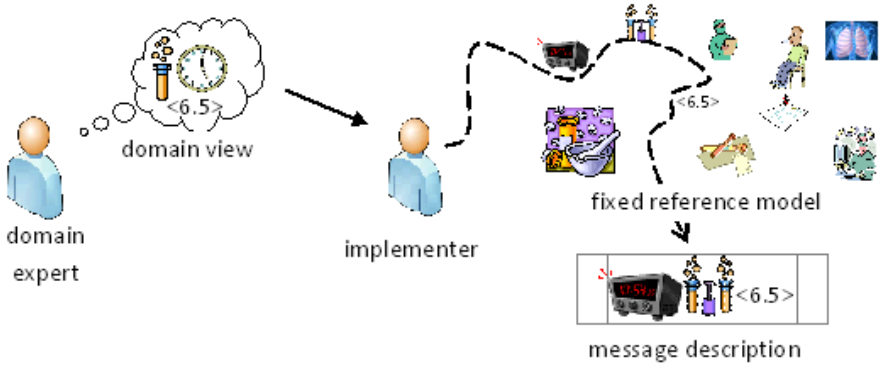

Figure 3.1: Fixed model approach.

Figure 3.1: Fixed model approach - domain expert explains what is to be conveyed to technologist who effectively selects concepts from a fixed model to form a message.

One often quoted difficulty that arises with this approach is that although the classes and properties in a given version of a v2.x model are fixed, there may be alternative ways to implement a given message and a fixed model such as HL7 v2.x provides no mechanism to limit this process. Also in the case of HL7v2.x the RIM is subject to slight but significant changes between different versions. HL7 in the introduction to HL7v3 MDF outline the following difficulties with creating messages using HL7 v2. *"...The process for building version 2.X messages is entirely ad hoc. There is no explicit methodology. Members receive no formal guidance in constructing messages. Trigger events and data fields are described solely in natural language. The structural relationships among data fields are not clear. Segments are re-used in many messages and message definitions are reused for many trigger events. In order to accommodate this extensive re-use, most data fields are optional. Chapters are inconsistent in their use of trigger events versus status codes. There is no specification as to when a specific kind of healthcare information system should be expected to honor a trigger event or accept a message. With version 2.x, a technical committee creates messages by editing word processing documents directly. The metadata is not available in a structured form until the staff and volunteers tediously extract it from the word processing documents after publication..."* [40]. Flores and Win in 2007 following a survey of previous HL7 implementations, identified another difficulty that relates to the scalability of the fixed model approach *"...In order to satisfy the (version 2.x) RIM, the (HL7) message should contain a basic set of fields, which must hold the critical information required to for exchange; additional information should be provided using the optional fields. This fact does not represent a real inconvenience for local implementations, however, this issue could increase the costs and efforts required during the development and redeployment of HL7 messages for inter institutional applications..."* [41]. HL7v2.x (and v3) models use internal codes in many places to allow a concept or property to be used in different contexts, but in order to cope with diverse use cases, it is sometimes necessary to allow to some level of flexibility / ambiguity at the field level in order to allow a model to be generally applicable. Of course, for a well-designed and safe electronic health record, ambiguity needs to be minimised. It must be noted that HL7 v2.x was never intended to be used for EHR communication. As one senior and experienced project team member noted during the course of the work, HL7 v2.x "is what it is", a somewhat flawed but ultimately successful messaging approach that has found wide acceptance and has been very useful for certain types of health messaging.

3.1.2 HL7 V3 RIM a more flexible and general model

HL7 have recognised the limitations of the v2.x implementations, and began work on HLv3. The HL7v3 model is quite general and can be specialised, not with archetypes as in the case of EN13606 but with artefacts called RMIMS and DMIMS. However, HL7 RIM is intended to be multipurpose; it is not specifically designed for the EHR. Fores and Win in 2007 note that "...at the actual level of development, the most intractable barrier for the use of HL7 has been the lack of standards for exchanging fine grained highly heterogeneous structured clinical data among information systems that had been implemented under different platforms..." [41] They also note that version 3 RIM has been variously reported as being unable to represent complete model structures for nursing information systems [42], general practice [43] and for the exchange of referral and discharge letters. (Heitmann

2003). The HL7 Clinical Document Architecture (CDA) level 3 and CDA templates, form the core of the HL7 approach for EHR communication. CDA templates form a 'bridge' between the EHR and the RIM. Smith and Ceusters [6] observed that careful use of language is required in description of a reference information model and note that the underlying assumptions and the definitions associated with HL7V3 RIM lead to confusion. They point out one serious source of confusion that relates to whether RIM concepts represent the actual observed concepts or recording of the information associated with the concepts. Two-level approaches such as EN13606 and openEHR avoid this confusion by firmly orient their models towards the recording of health information. The next few sections describe some of the main features of two-level model based systems.

3.2 Two-level Models

Two-level models were briefly introduced in chapter 1. Before delving into the detail of the EN13606 later in this chapter, it is useful to reflect on the main conceptual elements of this approach. First it must be said that two-level models represent a change in the way that health information is represented. Practitioners of this approach are given a reference model that is composed of general, reusable and very well thought out concepts. The reference model should also provide certain general constraints about how concepts can be combined and used without dictating their use in particular clinical contexts. The reference model concepts for EN13606 and the general constraints on links between them have been the subject of intense debate and scrutiny over a period of 15 years by a large international community of health information modelling experts. The various iterations of reference models in the previous ENV12265 [44], and ENV13606 [45] specifications have been used within research projects and certain products and national and regional implementations. The reference model for EN13606 has been modified based on feedback from implementation of the previous version and so the basic concepts and some of the properties could be considered as mature and tested. On the other hand, certain new attributes and classes have been introduced for EN13606, for instance from experiences within the openEHR project and so need to be assessed by design and implementation experience.

3.2.1 Data types for two-level models

Reference models do not typically include definition of data types, but data types are an essential prerequisite for the application of reference models. There may even be a need for certain systems to support multiple sets of data types. (e.g. one set of data types for persistence, another for communication) The issue of transformation between data types within health information is likely to become the topic of debate with the ISO/CEN community under the topic of "software as a medical device". At time of writing it seems likely that any health information system that requires certain types of clinical information to be converted between data types is likely to be considered as a medical device and subject to the same assessment criteria as a medical device, prior to use. The project team used a relatively simple set of data types that had been provided by CEN [46] for this purpose, and these were found to be sufficient for the situations that

arose during the course of the work. However, a more comprehensive set of "harmonised" data types ISO prEN 21090 [47], have been working their way through the ISO process and at time of writing are due for a final vote to become a full international standard in early 2011. These data types are intended to be used for communication of EHR data but are not intended to be used internally in individual EHR providers. The harmonised data types are intended to bridge differences between data types that are consistent with the two level model approaches of openEHR and EN13606 and a larger set of data types that support HL7 v3. There has been some controversy in the two-level modelling community about whether the ISO prEN 21090 data types are fit for this purpose. Concerns focus on the large size of this harmonised set of data types and the addition of a number of HL7 centred data types.

3.2.2 Archetypes and two level models

The power of the two-level approach begins to emerge with the introduction of archetypes into the mix. The two-level modelling approach provides an archetype object model (AOM) and a scripting language called the archetype definition language (ADL) for representing archetypes in tools and as exchangeable documents respectively. The intention is that domain modelers can use convenient graphical tools based on the AOM and ADL to define, manage and share archetypes. Archetypes allow domain experts to define detailed high quality and very specific models to represent information that is commonly found in the electronic health record. The domain experts construct archetypes with building blocks that mirror the concepts of the reference model.

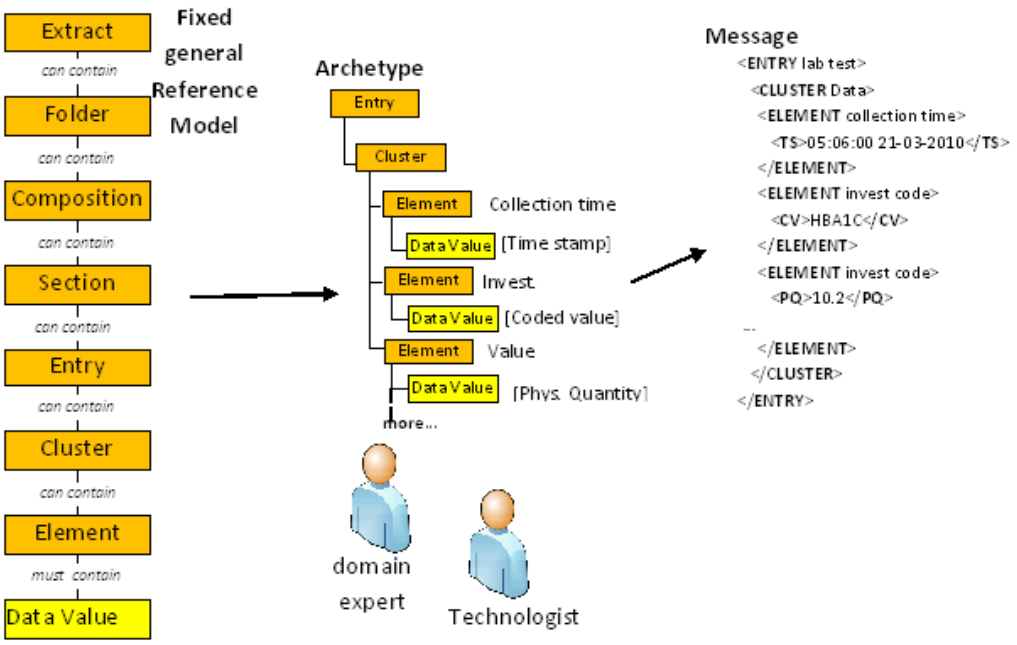

Figure 3.2: Two-level model approach - domain experts and technical experts working in a team - apply constraints to linked concepts from the reference model to produce archetypes - formal description of the information content in the message. (*Note the portrayal of the archetype in this example has been simplified for the purposes of describing the process.*)

The archetype defines the permissible way in which concepts from the reference model are connected together to produce a detailed clinical concept. A well-designed archetype encapsulates a set of strong and appropriate constraints that are applied to a specific concept in addition to the more general constraints from the reference model. Examples of the types of constraints that can be applied include cardinality, naming, value ranges, permitted coded values and optional sets of codes for particular nodes. To illustrate the types of archetype constraints that commonly occur, consider Figure 3.3, showing simplified blood pressure measurements with and without the types of constraints that can be contained in an archetype.

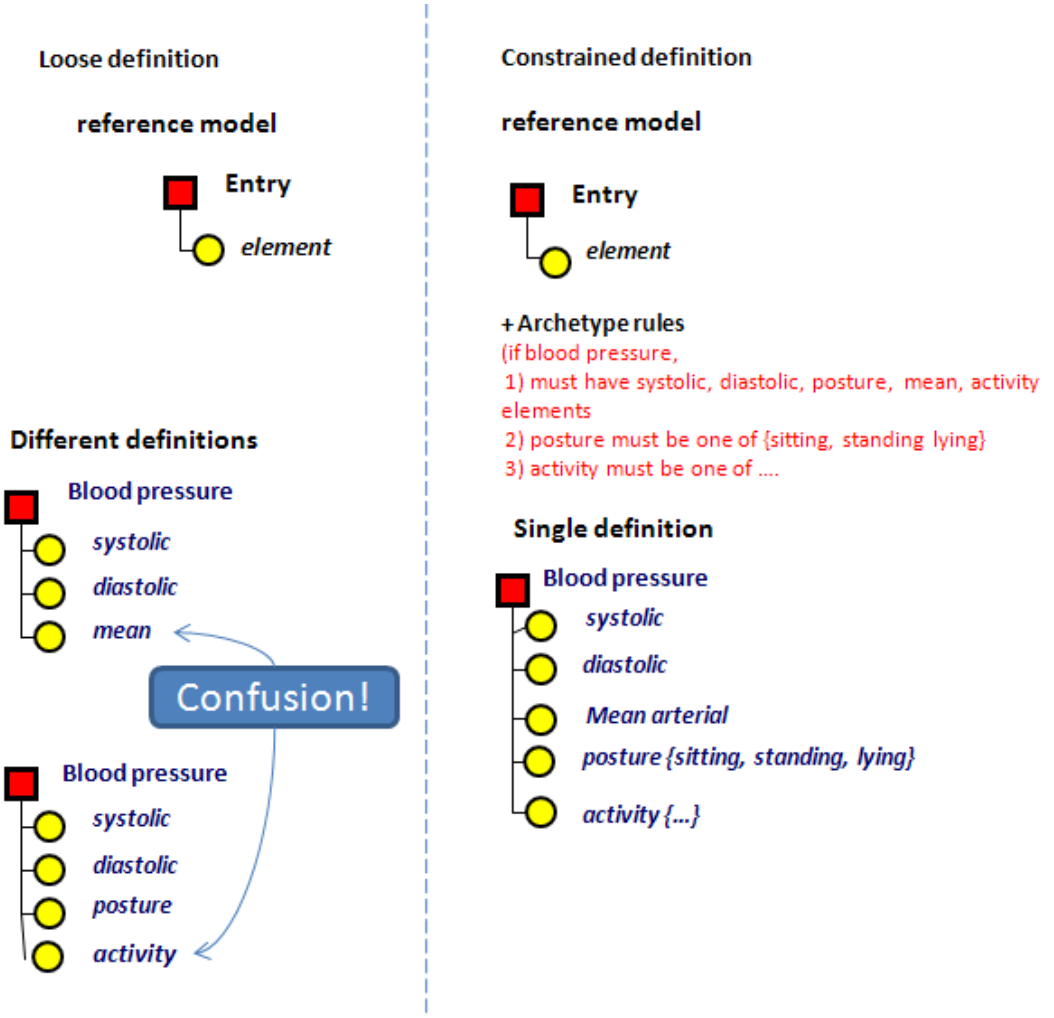

Figure 3.3: The effect of archetypes on shared record components.

The scenario on the left hand side of the diagram is an exaggeration of what happens with fixed-model based message implementations when there is no specific guidance in relation to representation of a particular information. The reference model only applies the general constraints that apply to all uses of the model. Different message implementations if they stay within these general guidelienes can choose different approaches with perhaps different ideas about the important pieces of information. On the right hand side of the diagram a blood pressure archetype contains additional problem specific constraints of the type indicated in red text, to ensure more uniformity between implementations of blood pressure. Implementers can use software libraries to apply the general constraints of the reference model but in principle at least, are not obliged to implement the specific constraints for each and every archetype but rather employ an archetype parser for this purpose to support the archetype-conformant creation of the corresponding record components. Archetypes can also be referenced by objects or messages associated with EHR communications. Archetypes referenced in EHR record components can be drawn down by EHR source systems to guide the creation of EHR extracts and by EHR recipients to evaluate incoming EHR communication. Archetype designers draw on traditional legacy sources of metadata when looking for raw materials to supplement their domain exper-

tise in guiding their designs, including paper forms and documents, database schemata, graphical user interfaces of end user applications, health information standards, clinical data sets and assessment 'instruments'. The creation of archetypes at time of writing is led primarily by the clinical perspective. One interesting feature of archetypes that has been adopted, perhaps in an attempt to limit the number of archetypes that need to be developed, is the idea of a maximal data set. So for instance, rather than defining an archetype for each and every laboratory investigation, the maximal data set approach would attempt to group families of laboratory investigations with similar characteristics (lipids, or blood gases) within a single archetype.

3.2.3 Archetype Slots

Archetypes can be joined together in certain ways that can be decided by the archetype designer. The mechanism that is used to do this is called an Archetype Slot. An archetype slot can be added by an archetype designer and then "filled" with the unique identifiers of a selection of archetypes that can fill that slot. So for instance, an archetype slot called referring party, could be filled by either an Individual health professional archetype or a health provider organisation archetype. Figure 3.4 shows a simplified example of a slot within a arterial blood gas archetype. This slot has been filled by a specimen type cluster archetype. Note that an archetype that fills a slot should obey the rules of the underlying reference model.

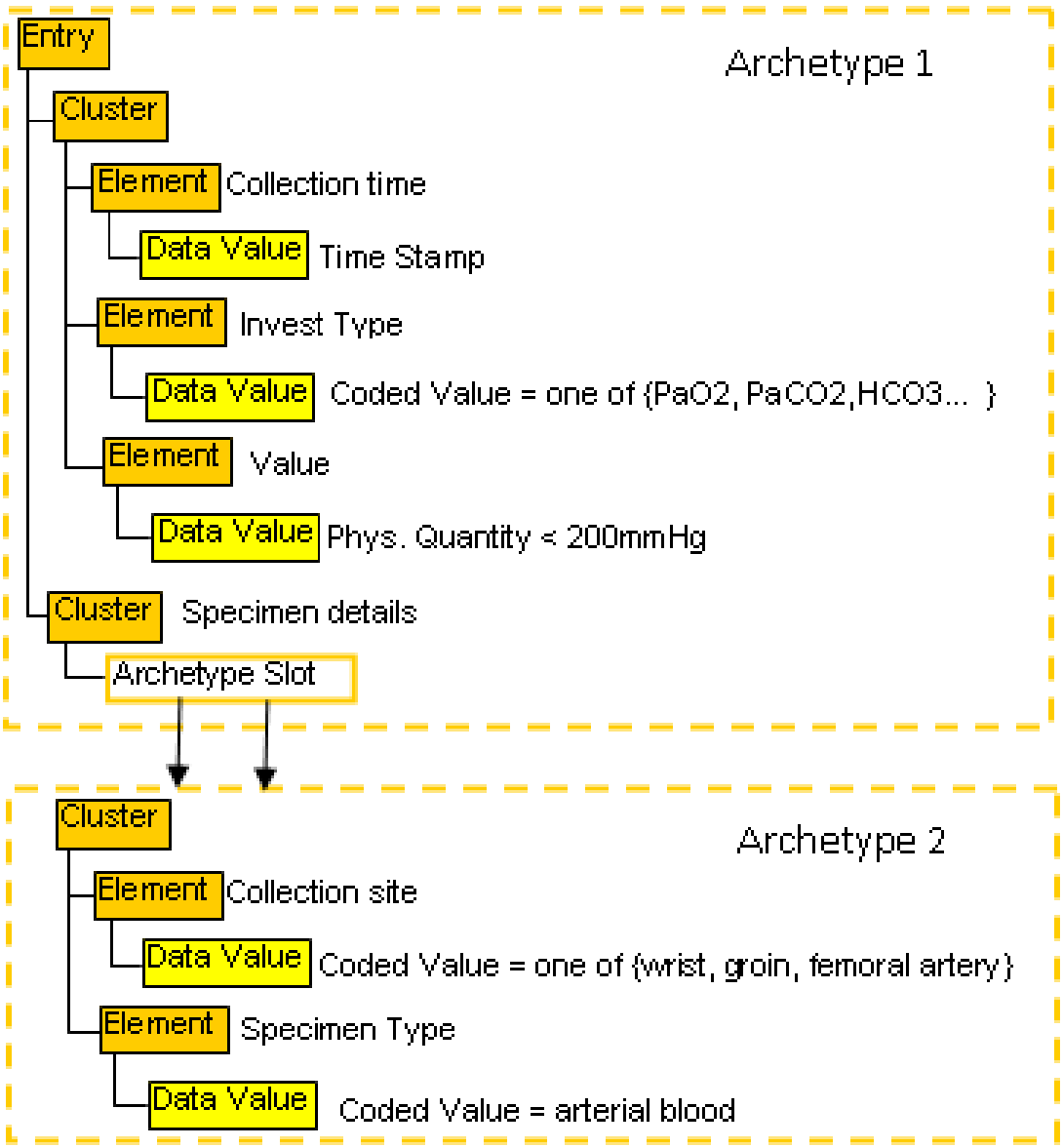

Figure 3.4: Archetype slots are a feature of archetypes that allows other archetypes to be optionally embedded at particular nodes. It is possible to have more than one archetype at each archetype slot.

3.2.4 Templates for two-level model systems

At this point, another essential ingredient of the two-level model approach, Templates are introduced. Given a suitable collection of archetypes, templates allow system implementers to select archetypes for the concepts that they wish to convey. Each template can draw together multiple archetypes to create a composite cohort of health information. Templates also permit the removal of some of the optional nodes in the archetypes that they contain. In a mature two-level model based implementation, the production of templates is where most of the development work will occur. Where archetypes are used as a starting point for end user interface design, this development effort would be mostly codeless and could be achieved quite quickly if the underlying archetypes have already

been created, in which case, they can be downloaded from a public archetype repository. This would significantly accelerate the development process. The example below follows on from Figure 3.4. In this case, Archetype 2 Specimen Details, of Figure 3.4 has been placed into the place of the archetype slot of Archetype 1.

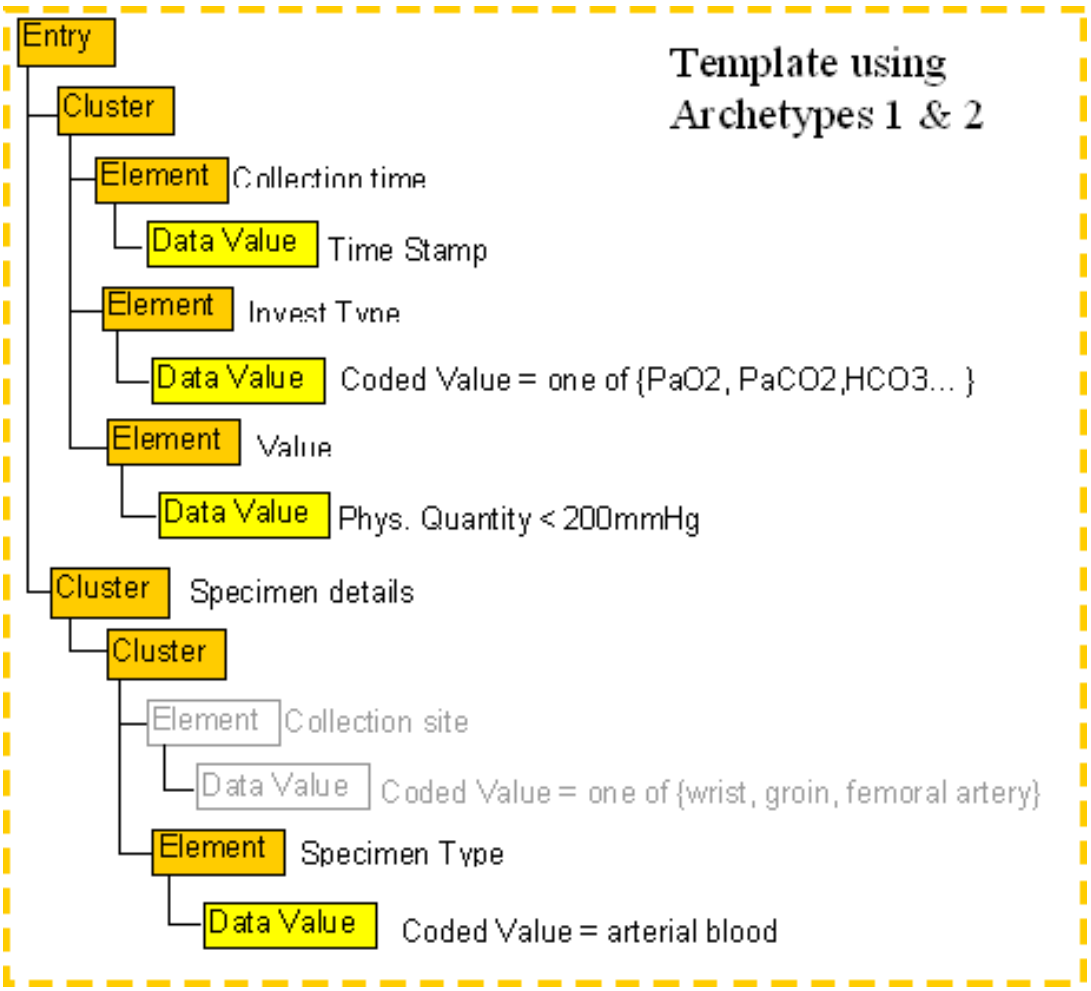

Figure 3.5: Templates can be used to combine archetypes and deselect certain archetype nodes according to the preferences of users at a particular site.

The Template designer has decided for one reason or another that the optional collection site archetype node is not necessary and has removed this node from the template. This is how the maximal data set approach of archetypes is brought back to something specific for a particular site. Unfortunately, although the project team consider them to be of pivotal importance for a realistic application of the two-level model paradigm, templates are not part of the EN13606 specification.

3.2.5 Terminology binding in archetypes

In the first chapter, the relationship between information models and terminology was introduced as well as some of the general issues around semantic interoperability. Terminological links can be added to archetypes with very little effort once the correct code

or set of codes has been agreed. This presents the interesting possibility that archetypes can come with their own miniature payload of universally recognisable terms. It also presents the possibility of adding terminology to EHR applications by including terms as part of the metadata. So when an EHR user creates a record component that has a link to a blood pressure archetype. If that archetype has bound SNOMED-CT concepts in the diastolic and systolic nodes, these codes can be resolved by a terminology server at the receiving end to unambiguously identify those nodes. So archetypes and terminology would seem to be natural partners. The project team, following a survey of over two hundred openEHR archetypes on the openEHR CKM archetype repository [48] found two hundred and fifty individual SNOMED-CT bindings. This figure is rather low, but number is likely to increase following a memorandum of understanding between openEHR and IHTSDO to develop term bindings among other activities.

3.3 OID/II Management

The use of identifiers is central to the quality of EHR communications. In common with HL7 v3, EN13606 relies on the existence of unambiguous identifiers for subjects of care, health professionals, EHR systems and EHRs. An EHR, by definition may have regional or national scope, spanning multiple information systems in different organizations. The identifiers associated with a national EHR must then be applicable at national level and this is made much simpler if they are unique. EN13606 endorses a particular approach for supporting unique identifiers. The idea is to prepend certain identifiers "extensions" with so called object identifier or OID root to form what EN13606 calls Instance Identifiers or IIs. The OID root in this scheme can identify a naming authority such as "the domain for Irish national patient IDs" or "the St James's hospital medical record number domain", The II Extension then holds the associated unique identifier. The combination of OID root as naming authority and Extension / identifier can in this way be made globally unique.

A position paper on the use of OIDs with EN13606 has been authored by members of the project team with support from other members of the EN13606 community has been submitted to the international EN13606 community. Additional guidance on use of OIDs is required with perhaps the development of implementation guidelines for use of OIDs with the standard. This position paper has been included in the appendices for this report.

One aspect of use of OIDs in the EN13606 standard that may need to be changed is the idea that IIs should be used to identify every record component in an EN13606 compliant electronic health record. There are concerns among certain members of the community that OIDs may not be the most practical approach. Other approaches for achieving globally unique identifiers, include UUIDs, which can be generated conveniently for any machine with a network card.

3.3.1 Benefits of two level models

Reference models and the language and models for archetypes are defined by the EN13606 and openEHR standards. Software applications can be developed in many cases to comply

with these specifications without requiring the pre-existence of archetypes. Archetypes can be added later in the process, particularly in the case of new EHR applications that don't need to be integrated with legacy systems containing clinical information. The situation becomes a little more obscure for legacy system integration. It is unlikely in the short term at least, that wholly codeless legacy system integration will be practical. It will be hard to avoid some hard-coded mapping of existing local concepts onto archetype-constrained EHR structure. Despite this difficulty, the process of creating archetypes can be controlled and executed by domain experts. The loose technical definition of "building block" concepts within a mature and highly refined general reference model gives communities of domain experts the flexibility to construct constraints that they require. They are in a position to commit their domain knowledge about what clinical information and supporting context needs to be recorded in different circumstances. As Atalag (2007) has noted about the two-level approach, *"Like the separation of data from structure in XML, the clear separation of medical information from knowledge is truly a paradigm shift."* [49] If archetype development is carried out on a national basis, the two-level approach provides a powerful platform for domain experts to develop high quality information artefacts. The concepts can be richly defined and constrained leading to better quality community-specified information artefacts in the record. This in turn leads to higher quality EHR messages. For instance, because a well-designed reference model permits increased expressiveness and the possibility of creating tight constraints using archetypes to suit multiple clinical scenarios, there is a reduced need to resort to the deliberate ambiguity of the fixed model approach in order to design for diverging use cases for a single information artefact. The archetype approach not only offers good separation of implementable reference models and the details clinical models, they also allow separate treatment of terminology through the use of bindings. Finally, the addition of templates allows archetypes to be reused on a large scale and in flexible ways.

3.3.2 Disadvantages of the two-level model approach

The application of the maximal model leads to archetypes that are multi-purpose. This in turn requires wide consensus if the archetypes are to be used. But while the development of an archetype to suit the purposes of a single site can be achieved quite quickly, arriving at consensus on archetypes that are to be shared at a national or international level requires substantial time and effort from domain experts. The two-level model communities around EN13606 and openEHR have not managed to mobilise a large community of domain experts to lead or participate in this work and as a result, the development of archetypes has proceeded slowly. This situation will be improved as more countries follow the example of Sweden [50] and Minas Gerais region in Brazil [51] in implementing two-level based records. The existence of the two models and the need for domain experts to understand how to use the reference model concepts represents a barrier to adoption.

3.4 CEN EN13606

While focusing on communication of the EHR, the EN13606 standard that is the subject of this work, further refines the thinking from previous pre-standards called ENV 12265

[44] and ENV13606 [47]. As described in the previous sections, the key innovation of this major step in the specification of EHR systems is the introduction of the two level information model. The two-level modeling approach allows high quality and generally agreed and understood information structures, Archetypes, to be conveniently defined by domain experts to represent concepts to be communicated between EHR providers within an EHR system. These definitions can be reused by the international e-health community to build interoperable EHR systems.

3.4.1 Parts of EN13606

The following is a summary of the five-part so of the EN13606 "EHRcom" standard:

Part 1: Reference model [52]

This document provides a detailed description of the reference model, the "first layer" model of EN13606. It is an ODP [53] Information Viewpoint Model, representing the global characteristics of health record entries. As outlined above, the EN13606 Reference model focuses on the generic "building blocks" of the EHR. These generic concepts can be specialised by archetypes of the second layer to form clinically meaningful content for the EHR.

Part 2: Archetypes [54]

Describes in detail, the mechanisms behind "second layer" model that is composed of archetypes. This part of the standard describes, formally, the information model for archetypes and also provides details of information model that can be used to describe Archetypes, to exchange them and to persistently store them. Part two also describes a language for expressing archetypes called ADL1.4. This language is completely identical to the ADL promoted by the OpenEHR consortium until recently. Since the publication of the standard, the OpenEHR consortium have published a new version of the language called ADL 1.5 which includes useful features such as the introduction of Templates. This is not a normative part of the EN13606 standard, but meaningful use of the standard in the way that it was intended to be used, requires compliance with this part of the standard.

Part 3: Reference Archetypes and Term lists [55]

This document contains a helpful set of reference archetypes and also a set of terms that arise as properties of the concepts that are expressed in the reference model in part 1 of the standard. These terms do not occur elsewhere and would be expected to be part of an EN13606 implementation.

Part 4: Security Requirements and Distribution Rules [56]

Part four of the standard describes a methodology for specifying the privileges necessary to access EHR data. It deals with access control to record components as well as

audit trail functionality. The standard does not take into account either encryption, or identity management. Nor does it prescribe a particular access control strategy (while it does suggest compatibility with role based access control). These aspects of security although necessary for safe operation of an EHR community, are considered to be outside the scope of the standard. The approach adopted by the standard is to give health providers and EHR system implementers flexibility to implement.

Part 5: Exchange Models [57]

The final part of the standard describes an exchange format for the EHR. This document describes a small number of relatively simple interface aspects of the EHRcom standard. In particular, this document focuses on message based and object based EHR communications.

3.4.2 Classes of EN13606 part 1

Most of the focus of implementation of the EN13606 standard focuses around use in one way or other with the classes of the EN13606 reference model. For this reason, this section discusses the corresponding concepts in some detail.

EHRcom Record Components

EN13606 employs record EXTRACTs as containers to convey parts or all of an EHR. EHRcom record components are the building blocks of the clinical data of the EXTRACT. They include record components for organising the extract (FOLDER, SECTION, and CLUSTER classes), and record components for containing the data (COMPOSITION, ENTRY, ELEMENT classes). Some record components are abstract (RECORD_COMP ONENT, CONTENT, ITEM), and they will never be instantiated. They only contain common properties for subclasses. Figure 3.6 gives an overview of the inheritance hierarchy of EHRcom component classes. Figure 3.7 shows additional EHRcom classes that are used as attributes of component classes. In both figures, arrows represent an is-a relationship between the classes.

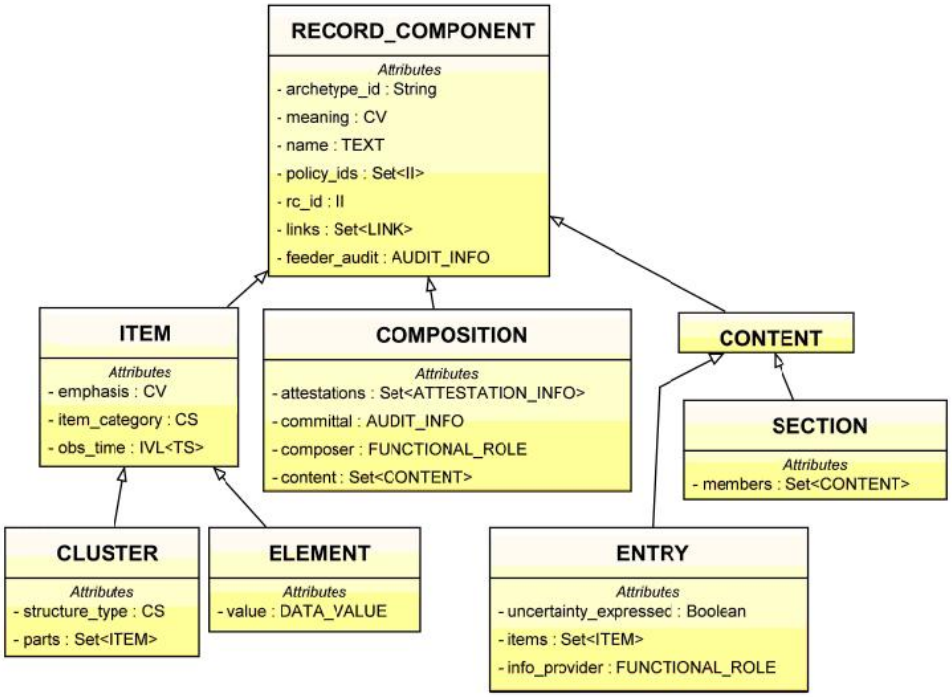

Figure 3.6: Overview of EHRcom components inheritance hierarchy.

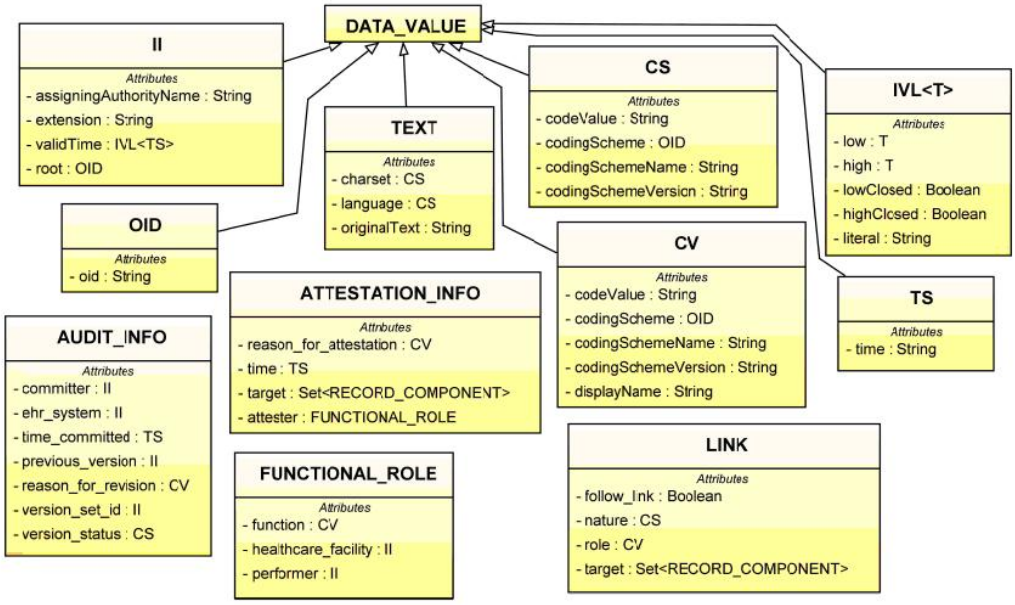

Figure 3.7: EHRcom classes found in record components.

As well as inheritance relationships, record components have compositional relationships, i.e. they can be composed of one another. For example, a COMPOSITION object can contain a SECTION object, which in turn contains ENTRY objects. Next, each ENTRY object can contain ITEM objects, with each one of them containing multiple

ELEMENT objects. Figure 3.8 illustrates such an arrangement. As an EHRcom compliant adaptor is required to return all kinds of record components, it needs to be aware of the compositional relationships between record components. More detailed information about EHRcom reference model is available in [52].

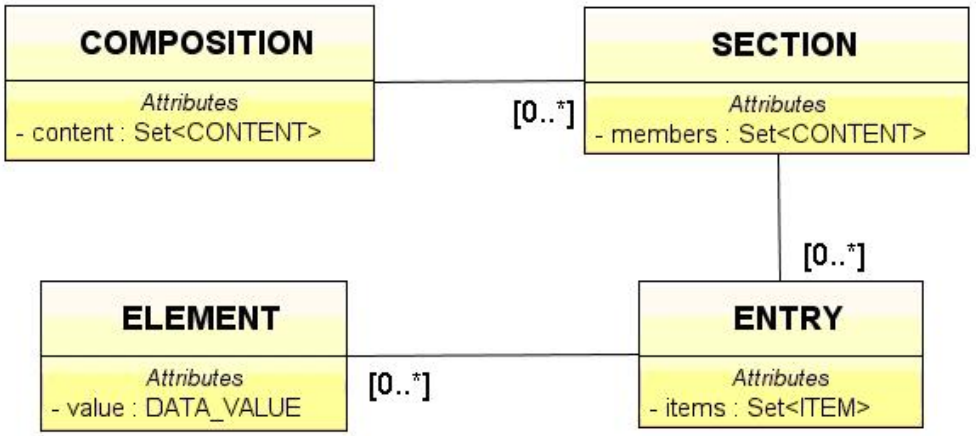

Figure 3.8: Example of class composition.

The RECORD_COMPONENT Class

The RECORD_COMPONENT class is abstract and contains attributes shared by all record components. The minimal requirements for all record components is to provide a name (name attribute), an ID (rc_id attribute), and indicate whether the component was synthesised in order to comply with EHRcom (*synthesised* attribute). Table 3.1 gives the type of the required attributes and their definition as given by EHRcom.

Table 3.1: Required attributes of record components.

Attribute	Type	Definition
name	TEXT	The name, expressed as a coded value or as plain text, specifies the clinical or administrative concept to which this EHR node corresponds, as labelled in the EHR system in which it was first committed.
rc_id	II	The globally-unique identifier by which this node in the EHR hierarchy is referenced in the EHR system to which the data were first committed. This identifier must be retained by the EHR Recipient and re-used whenever this RECORD_COMPONENT is subsequently included in another EHR_EXTRACT.
synthesised	Boolean	This attribute value must be TRUE if this RECORD_COMPONENT has been created in order to comply with this standard, but this point in the EHR hierarchy has no corresponding node in the EHR from which it was extracted.

The II Class

The instance identifer for globally unique identifiers was mentioned earlier in this chapter. The EHRcom II class that manages instance identifiers is a subclass of the DATA_VALUE class is shown in Figure 3.7. It is used for many IDs in EHRcom, including EHR ID, subject of care ID, EHR ID, EHR extract ID. Table 3.2 shows the required attributes for the class and their description as given by EHRcom. An important attribute is root, which is an attribute by association. This means that the value of root, and OID object (and OID is an Object Identifier according to ISO/IEC 8824-1), can be the same for several II objects. For example, the shared OID object could be the global ID of the EHR system managing the record component. Given a common root OID that is shared between components in this way, attributes *assigningAuthorityName* and *extension* give the necessary distinction to guarantee uniqueness of the II. The attribute *validTime* constrains the ID validity to an interval of time if necessary. In practice, the EHRcom standard suggests that "an EHR Provider system that has been issued with an organisational OID might use its internal references to construct unique local extensions to that OID and thereby construct globally-unique rc_id values."

Table 3.2: Required attributes for II class.

Attribute	Type	Description
assigning-AuthorityName	String	A human readable name or mnemonic for the assigning authority. This name is provided solely for the convenience of unaided humans interpreting an II value. Note: any automated processing must not depend on the assigning authority name to be present in any form.
Extension	String	The value of the instance identifier, unique within its assigning authority's namespace.
ValidTime	IVL<TS >	If applicable, specifies during what time the identifier is valid. By default, the identifier is valid indefinitely. Any specific interval may be undefined on either side indicating unknown effective or expiry time. Note: identifiers for information objects in computer systems should not have restricted valid times, but should be globally unique at all times. The identifier valid time is provided mainly for real- world identifiers, whose maintenance policy may include expiry (e.g., credit card, numbers.)
root (by association)	OID	A unique identifier that guarantees the global uniqueness of the instance identifier. The root alone may be the entire instance identifier, an extension value is not always required.

The TEXT class

The TEXT class is a subclass of the DATA_VALUE class as shown in 3.7. It is the default EHRcom data value for expressing free text. Table 3 shows the required attributes for the TEXT class. The originalText attribute contains the actual text value, while the additional attributes charset and language give the character set and the language used, respectively. The CS type means that the coded value used are constrained by EHRcom.

Table 3.3: Required attribute for the TEXT class.

Attribute	Type	Description
charset	CS	Specifies the character set and character encoding used.
language	CS	Specifies the language of text data. Code set defined by ISO 639:1988 (E/F) "Code for the representation of names of languages".
originalText	String	A string of indeterminate length.

Optional but Useful Attributes of the RECORD_COMPONENT class

Along the required attributes shown in Table 1, the RECORD_COMPONENT class has useful optional attributes for:

- implementing the access control of record components,
- storing relationships between record components,
- storing information about how they were originally persisted, and
- allowing the implementation of semantic interoperibility.

Table 3.4 gives the description of the attributes as provided by EHRcom. The attribute policy_id can store references (II objects) to access control policies. They can refer to local existing policies enforced by the feeder system or to policies to enforce globally and agreed between parties exchanging information.

The attribute *links* expressed semantic links (LINK objects) with other record components. Table 3.5 shows a subset of the possible link types defined by EHRcom. A full list of link types is available in part 3 of the standard.

Table 3.5: Subset of link types.

Code	Meaning	Description
LINK-A2	suggests (tentatively related to)	The interpretation expressed in the target component is a possible cause or outcome of the findings documented in the source component
LINK-B3	permits (sanctions, authorises)	The source component documents a permission or an authorisation of an action documented in the source component.
LINK-C3	evidence for	The observation or interpretation documented in the source component provides confirmatory evidence of the interpretation expressed in the target component.

The feeder_audit attribute is of type AUDIT_INFO. As described in Table 3.4, it corresponds to the committal of the record component in the original system, i.e. the

Table 3.4: Optional but useful attributes for the RECORD_COMPONENT class.

Attribute	Type	Description
policy_ids	Set<II>	This attribute identifies one or more access control policies that specifically pertain to this RECORD_COMPONENT and which need to be communicated to the EHR Recipient to govern future access to it. The identifiers may refer to policy information included in this EHR_EXTRACT as defined in Part 4 of EHRcom, or to policies held in external policy servers to which the EHR Recipient has access.
links (by association)	Set<LINK>	Any RECORD_COMPONENT may have zero or more semantic links to other RECORD_COMPONENTs.
feeder_audit (by association)	AUDIT_INFO	This association represents the committal and revision information specifically for this RECORD_COMPONENT in the EHR system in which it was originally committed. This association may be omitted if this RECORD_COMPONENT shares the same committal information as its parent RECORD_COMPONENT. In the case of a COMPOSITION, this association may also be omitted if the EHR Provider system is its originating system (since the data will be identical to that represented via the committal association).
archetype_id	String	The unique identifier of the archetype node to which this RECORD_COMPONENT corresponds, either in the EHR Provider system or as a mapping produced when this EHR_EXTRACT was created. The syntax for populating this attribute value is defined in Part 2 of EHRcom.
meaning	CV	The standardised clinical or administrative concept to which the name attribute has been mapped. In archetyped systems it will correspond to the archetype node name. In non-archetyped systems it might be a coded term from an appropriate terminology system.

feeder system. We will describe the AUDIT_INFO class in 3.4.2. The name attribute can be useful for a human to understand what the record is about. For example, "BP", "Blood Press.", and "blood pressure", even with typos, will be understood at the receiver end by a human who speaks English. Moreover, by looking at the structure to which the record belong, the human reader/recipient will be able to distinguish a record referring to a clinical encounter focused on a blood pressure observation, and a single blood pressure measurement. However, for machines to semantically process the data at the receiver end, more information needs to be included. For example, the meaning attribute of the record component could contain the SNOMED code referring to the "blood pressure" concept. This could help to solve the ambiguities caused by the use of acronyms, abbreviations, and unintentional typos. Nonetheless, the machine does not know what type of record this code refers to and what kind of content to expect in it. Such a description is available if a set of structures and constraints on the content of a blood pressure record has been agreed on. In EHRcom, this agreement is called an archetype [54] [58]. Archetypes are written by domain experts for national health organisations. For example, the NHS uses an archetype to describe what a blood pressure observation should look like. The ID of this archetype is ''openEHR-EHR-OBSERVATION.blood_pressure.v3''. The first part of the ID refers to the reference model used in the archetype. The EHRcom reference model corresponds to an early version of the openEHR reference model [58]. "OBSERVATION" is a subclass of an EHRcom ENTRY. The rest of the ID corresponds to the name of the archetype and its version. If an archetype is used for semantic interoperability,

- the full path to the node corresponding to the record component inside the archetype structure is assigned to the archetype_id attribute, and
- the code of the node corresponding to the record component inside the archetype structure is assigned to the meaning attribute.

The full path is expressed with a syntax derived from the XPath language. For example, ''openEHR-EHR-OBSERVATION.blood_pressure.v3/at0000'' corresponds to the root node of the archetype, (a blood pressure observation), while ''openEHR-EHR-OBSE RVATION.blood_pressure.v3/at0000/at0001/at0006/at0003/at0004'' is an internal node of the archetype (e.g. a systolic pressure measurement).

Organizing Record Components

Three different types of EHRcom record components are used for organisation and they correspond to three different levels, respectively, in the record component hierarchy:

1. the FOLDER class is used to organise the extract into a hierarchy of FOLDER objects containing a set of COMPOSITION objects,
2. the SECTION class is used to organise the extract into a hierarchy of SECTION objects containing a set of ENTRY objects,
3. and the CLUSTER class is used to organise the extract into a hierarchy of CLUSTER objects containing a set of ELEMENT objects.

Figure 3.9 gives an example of an extract structure using FOLDER, SECTION, and CLUSTER classes.

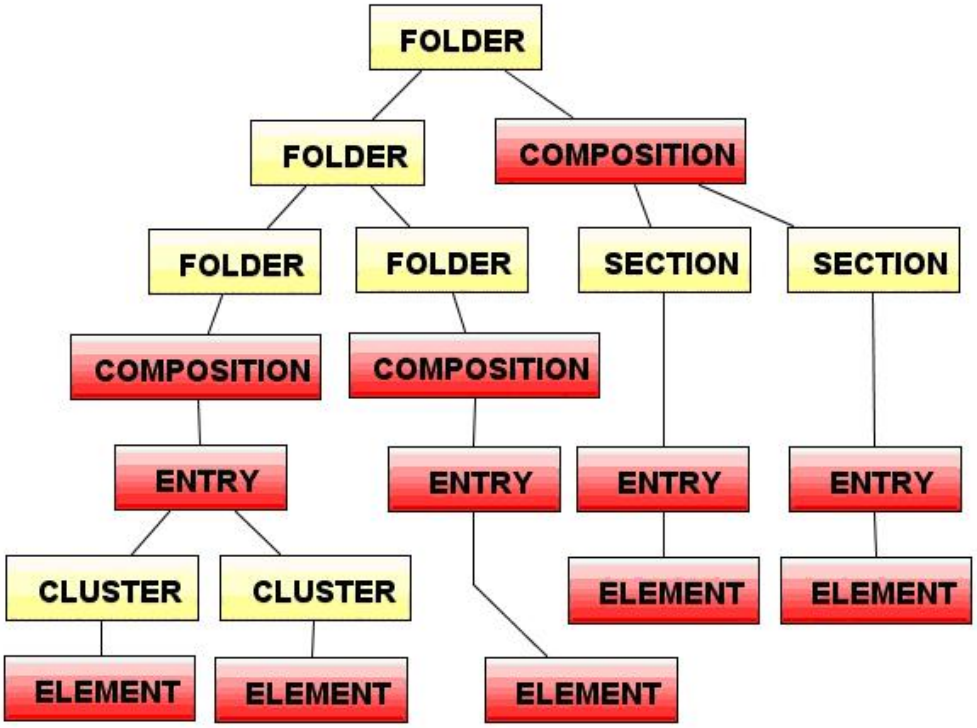

Figure 3.9: Example of extract structure.

The COMPOSITION Class

The EN13606 standard states that "a COMPOSITION represents the set of RECO RD_COMPONENTS composed (authored) during one clinical encounter or documentation session, and committed within one EHR." It is also the level at which the versioning of the data is implemented. The only required attribute is *committal* and it is of type AUDIT_INFO. The required attributes for the AUDIT_INFO class and their descriptions given by [52] are shown in Table 3.6. The versioning of the COMPOSITION is implemented by optional attributes of the AUDIT_INFO class shown in Table 3.7. A COMPOSITION object is also expected to use other optional attributes, such as content for example, so that it contains other record components of type CONTENT (SECTION or ENTRY objects). Also, the attestations attribute can be used to provide legal responsibility about the information found in the COMPOSITION object, and the composer attribute can be used to give details about the process of gathering data inside the COMPOSITION object. For further information about these attributes and their type, see [52].

The ENTRY Class

[52] defines an ENTRY object as "the information recorded in an EHR as a result of one clinical action, one observation, one clinical interpretation, or an intention, and is also known as a clinical statement." The only required attribute, on top on the one inherited from the RECORD_COMPONENT class, is the *uncertainty_expressed* attribute which indicates whether some uncertainty is associated with the information contained in the ENTRY object. However, we expect the items attribute to be used so that the ENTRY object may contain ELEMENT objects (CLUSTER or ELEMENT objects).

Table 3.6: Required attributes for AUDIT_INFO class.

Attribute	Type	Description
committer	II	The party responsible for committing this RECORD_COMPONENT within the EHR of this subject of care.
ehr_system	II	This attribute identifies the EHR system in which this RECORD_COMPONENT was committed.
time_committed	TS	Date and time at which this RECORD_COMPONENT was committed within the identifiedEHR system and therefore became part of that EHR of the subject of care.

Table 3.7: AUDIT_INFO attributes for versioning.

Attribute	Type	Description
previous_version	II	This attribute is the rc_id of the RECORD_COMPONENT of which the current RECORD_COMPONENT is a revision. If this attribute is null, there is no previous version (i.e. it is the very first version).
reason_for_revision	CV	A code for the reason for assigning the current version status.
version_set_id	II	This attribute value is the rc_id of the very first version of this RECORD_COMPONENT. This attribute may be null if this RECORD_COMPONENT is the very first version.
version_status	CS	The medico-legal status of this version of the RECORD_COMPONENT. The code set for this attribute is defined in [55].

The ELEMENT Class

The ELEMENT class is the leaf node of the hierarchy and has an optional attribute value of type DATA_VALUE. The DATA_VALUE class is the top abstract class of the data value hierarchy.

We already presented some data value types (II and TEXT classes). There are all sub-classes of the DATA_VALUE class, as shown in Figure 3.7. The DATA_VALUE class has only one optional attribute, null_flavour, of type CS (code value from an EHRcom defined code set) to give a coded reason for the value not being available. The data values can be used to express:

- free text (TEXT class),
- coded values given by EHRcom (CS class),
- coded values determined by a coding scheme outside the standard (CV class),
- time (TS class),
- intervals of ordered sets (IVL class), and
- identifiers (URI, II, OID classes).

The attributes required for the CS and CV classes are shown in Table 3.8. Additionally, the CV class has a mandatory displayName attribute of type String that corresponds to "a short, human-readable description of the concept that may be abbreviated for display purposes" as described in [52]. The TS class has a single mandatory time attribute of type String that correspond a calendar date and time conforming to the ISO 8601:2000 standard. The IVL class correspond to a set of consecutive values of an ordered DATA_VALUE type which can be discrete or continuous. It has no mandatory attributes and its optional attributes include boundary value containers (low and high attributes), and boundary inclusion indicators (lowClosed and highClosed attributes), and the literal form of the data type (literal attribute).

Table 3.8: Required attributes for both CV and CS classes.

Attribute	Type	Description
codeValue	String	String containing the value of the code
codingScheme	OID	An Object Identifier (OID) according to ISO/IEC 8824-1 that uniquely identifies the coding scheme to which the concept and code value belong. Example: "106.75.314.67.89.24," may identify the WHO classification of diseases
codingScheme-Name	String	A string containing a name of the coding scheme (e.g. "SNOMED CT").
codingScheme-Version	String	A string giving the version of the coding scheme.

[52] states that "the sub-types of DATA_VALUE shown here are those used as attribute types in the reference model. A fuller set of DATA_VALUE sub-types suitable as value types for element is given in CEN TS14796." For example, the Physical Quantity (PQ) class in standard CEN TS14796 is a specialisation of DATA_VALUE and its attributes are described in Table 3.9. The CS_UNITS type of the unit attribute is a child class of the EHRcom CS (the code values are constrained by a built-in code set) class and the CD type of the property attribute is a child class of the EHRcom CV class (the code values are not constrained by a built-in code set).

Table 3.9: Attributes for the Physical Quantity class.

Attribute	Type	Description
value	Real	The magnitude of the quantity measured in terms of the unit
unit	CS_UNITS	The unit of measure specified in the Unified Code for Units of Measure (UCUM) [http://aurora.rg.iupui.edu/UCUM]. NOTE: Equality of physical quantities does not require the values and units to be equal independently. Value and unit is only how we represent physical quantities. For example, 1 m equals 100 cm. Although the units are different and the values are different, the physical quantities are equal! Therefore one should never expect a particular unit for a physical quantity but instead provide automated conversion between different comparable units.
property	CD	Property being measured, e.g. "mass", "length", "time", "pressure", "flow rate"etc. The properties of atomic units are described in the UCUM specification (e.g. "s" = "time", "m" = "length", etc) but the properties of compound units are not (e.g. "ms-2" = "acceleration").
precision	Integer	Precision to which the value of the quantity is expressed, in terms of number of significant figures. 0 implies no precision

EHRcom Demographics Package

Part one of the standard includes a "fixed" (i.e. non-archetypable) demographics reference model. This package provides classes to contain information about entities (subject of care, healthcare agents, device, and software). Figure 3.10 provides an overview of the class hierarchy. The top class is the IDENTIFIED_ENTITY class and has one mandatory extract_id attribute of type II which is a unique reference for this object within

the EHR system producing the extract. Interestingly, an optional id attribute of type Set<II>contains other IDs used in other EHR systems. Additionally, a telecom attribute can be used to store service URLs giving contact telephone numbers.

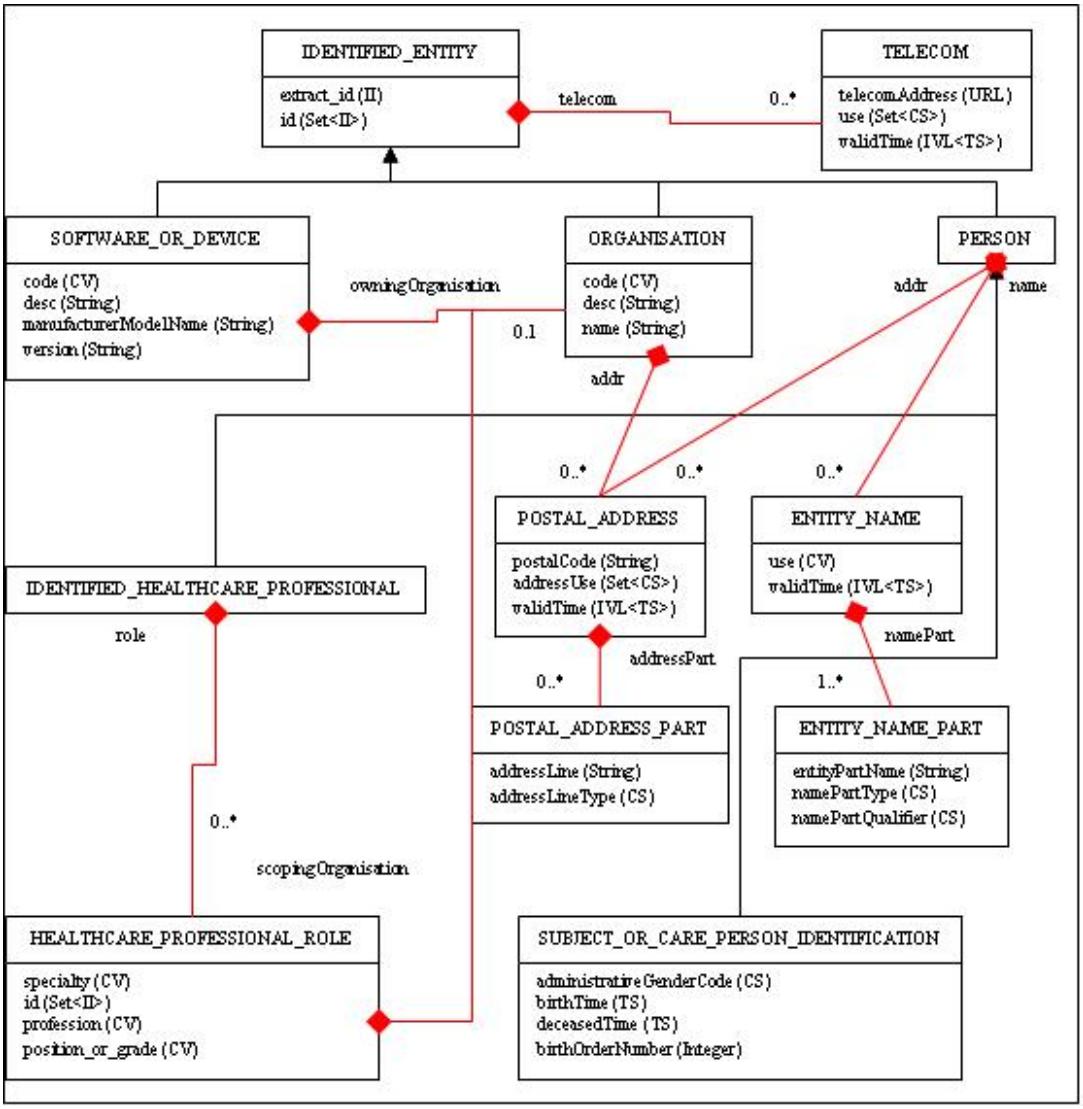

Figure 3.10: Overview of the Demographics package.

The IDENTIFIED_ENTITY class has three sub-classes: SOFWARE_OR_DEVICE, ORGANISATION, and PERSON.

SOFWARE_OR_DEVICE objects can be associated with an ORGANISATION object with their owningOrganisation attribute. Both ORGANISATION and PERSON objects can be associated with POSTAL_ADDRESS objects in their addr attribute whereas PERSON objects can also be associated with ENTITY_NAME objects. The PERSON class is further sub-classed by:

1. the IDENTIFIED_HEALTHCARE_PROFESSIONAL class, and
2. the SUBJECT_OF_CARE_PERSON_IDENTIFICATION class.

These classes are useful to send identity information in extracts about healthcare professional and their role, and about patients.

3.4.3 Classes of EN13606 part 2

The main class of part 2 is the ARCHETYPE class. Part 2 describes an archetype as "formal definition of prescribed combinations of the building-block classes defined in the Reference Model for particular clinical domains or organisations." It contains instructions about how to assemble record components into a particular structure. For example, the structure shown in Figure 5 could be expressed in an archetype. The instructions, or constraints, include optionality (whether a component is required or not), and multiplicity (whether one or more components can be expected in a set or list attribute. An archetype object has three main parts:

1. a description section containing information such as author details and original language,
2. a definition section where the constraints are found, and
3. an ontology section where ontological definition and constraints are expressed.

The definition section is organised into a tree of constraints at the top of which is a constraint on a record component also located at the top of the structure we wish to build. For example, a definition section to build the structure shown in Figure 5 will start with a constraint on a FOLDER object. The constraint classes used in the definition section are organised into a hierarchy at the top of which is the ARCHETYPE_CONSTRAINT abstract class. Figure 3.11 shows an overview of the constraint hierarchy of the archetype model. Two kind of constraint are apparent:

1. constraints on objects (reference model objects): C_OBJECT objects, and
2. constraints on attributes (reference model attributes): C_ATTRIBUTE objects.

Typically, the definition will start with a C_COMPLEX_OBJECT object, which will then contain one or more C_ATTRIBUTE objects (C_SINGLE_ATTRIBUTE or C_MULTIPLE_ATTRIBUTE objects), which will themselves contain C_OBJECT objects. As we reach the leaves of the record component tree structure we want to build, C_PRIMITIVE_OBJECT objects will be used to constraint primitive types such as Strings and Integers. Additionally, the C_OBJECT object can point to another archetype (AR CHETYPE_SLOTobject), or repeat an internal constraint structure (ARCHETYPE_IN TERNAL_REFobject), to a code set defined in the ontology section of the archetype (CONSTRAINT_REF), or finally to a domain-specific constraint (extensions of C_DOM AIN_TYPE class). A detailed description of the archetype object model is available in part 2 of EN13606.

3.4.4 Archetype Definition for a Simple Blood Pressure ENTRY object

In this section we determine an archetype definition to instruct the building of an ENTRY that records a blood pressure measurement. This blood pressure measurement includes

a systolic measurement, a diastolic measurement, and the posture of the subject of care during the measurements. The measurements must use the unit mm[Hg] and be within the range [0.0..1000.0]. Also, the posture is a list of coded text values defined locally, namely "Standing", "Sitting", and "Lying".

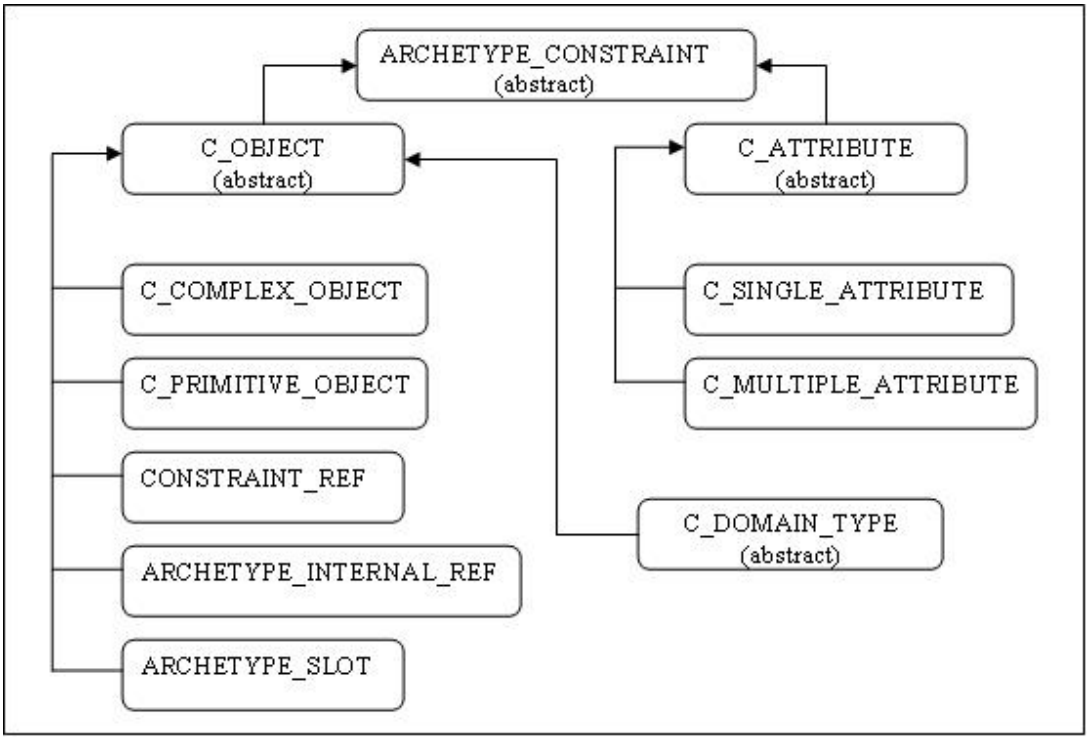

Figure 3.11: Overview of the archetype constraint hierarchy.

Figure 3.12 shows the definition constraint structure needed for the blood pressure ENTRY described in the previous paragraph. The definition always starts with a C_COMPLEX_OBJECT object. Its rm_type_name attribute is set to "ENTRY". Its node_id attribute is set to "at0000", and this code will correspond to "blood pressure" in the ontology section of the archetype. Then we associate its features attribute with a C_MULTIPLE_ATTRIBUTE object for the items attribute of the ENTRY object. We need a C_MULTIPLE_ATTRIBUTE object as opposed to a C_SINGLE_ATTRIB UTE object as the items attribute is set to a list of three ELEMENT objects. The rm_attribute_name and children attributes of the C_MULTIPLE_ATTRIBUTE object are set to "items" and a list of three C_OBJECT objects, respectively. The three C_OBJECT objects are actually C_COMPLEX_OBJECT objects as they are constraints on ELEMENT objects. The rm_type_name and features attributes of all three C_COMPLEX_O BJECT objects are set to "ELEMENT" and a C_SINGLE_ATTRIBUTE, respectively. However, distinct values, "at0001", "at0002", and "at0003", will be used for the node_id attribute of each C_COMPLEX_OBJECT objects. They will correspond to "Systolic", "Diastolic", and "Posture", respectively, in the ontology section of the archetype.

The first two C_SINGLE_ATTRIBUTE objects corresponds to the systolic and diastolic measurements. Each object points to a C_DV_QUANTITY object which in turns contains a C_QUANTITY_ITEM object containing the units and magnitude constraints.

C_DV_QUANTITY is an extension of the C_DOMAIN_TYPE class.

The third C_SINGLE_ATTRIBUTE object correspond the posture measurement. It contains a C_COMPLEX_OBJECT object constraining a DV_CODE_TEXT object (an extension of the DATA_VALUE class of Figure 3.7). The C_COMPLEX_OBJECT object contains a C_SINGLE_ATTRIBUTE object which is a constraint on the defining_code attribute of the DV_CODE_TEXT object. The constraint on the defining_code attribute is a C_CODE_PHRASE object (an extension of the C_DOMAIN_TYPE class) which contains a list of codes to be used by a CODE_PHRASE object. Note that "at0004", "at0005", "at0006" correspond to "Standing", "Sitting", and "Lying" in the ontology part of the archetype.

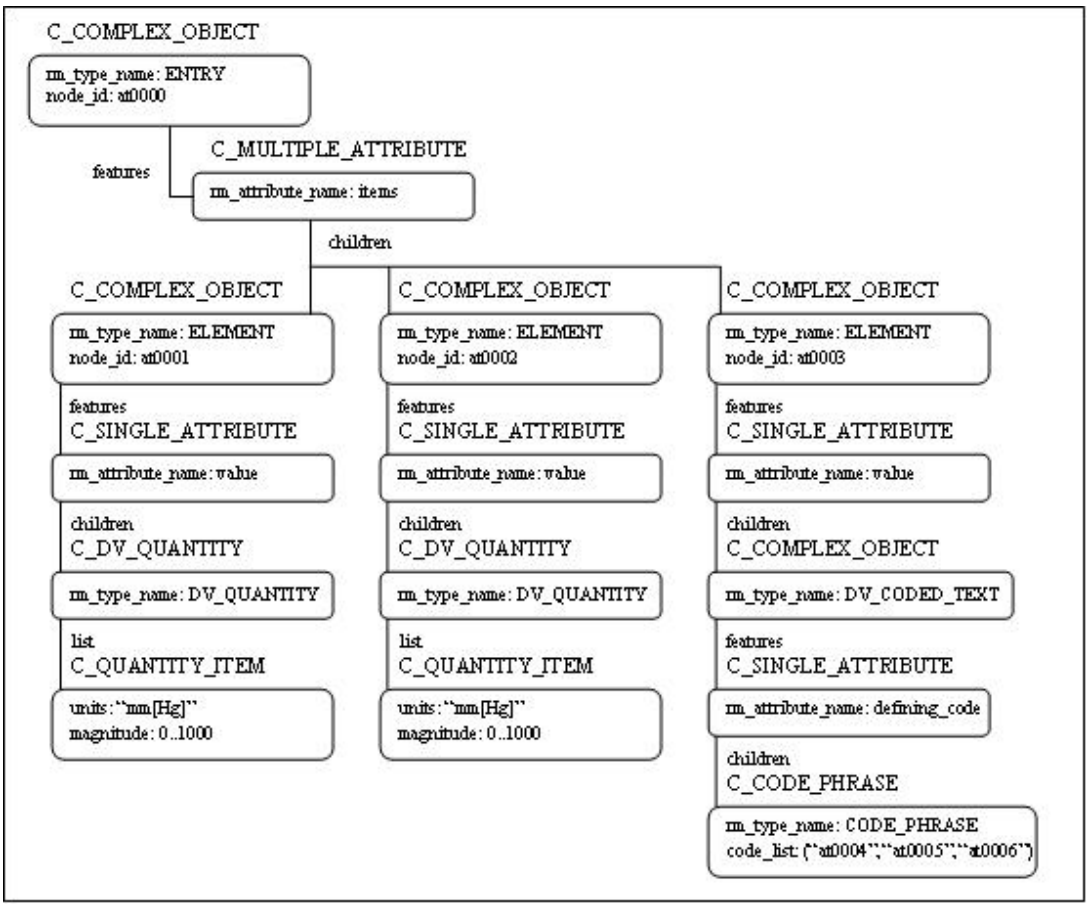

Figure 3.12: Example of a constraint structure.

3.5 Approach adopted in implementing EN13606

The EHR*land* project team has sought to investigate EN13606 from both bottom-up and top down perspectives.

- The project team have adopted a bottom-up implementation view, choosing to work on representative scenarios that 'exercised' different aspects and use cases of the standard.

- The top down service approaches adopted by other countries have been described in the previous chapter.
- Rather than focusing on a standalone record system the team adopted a top down approach that from the start assuming connectedness - it would not be an afterthought to be left to the end of the project. As part of the top down viewpoint, particular attention was paid to the types of services that would need to be provided as centralised resources for the participating EHR provider systems.

3.6 Identity and Identification

It has been mentioned earlier in this chapter that EN13606, although it introduces a demographics model, doesn't prescribe its use. The shared EHR discussed above assumes the merging of information from different domains and from different health provider settings. Sharing information in this way involves sharing and cross-referencing of corresponding identities. This problem of identity cross referencing is a non trivial task which is very difficult to achieve on a large (national/regional) scale unless there is a shared centralised identity management system to which all other identity domains can be aligned. From the survey presented in the previous chapter, it is evident that many countries and regions are either developing, or already have developed dedicated health information identifiers. For example, National Health Service (NHS) Number in UK, Unique Health Identifier (UHI) in Germany, Unique Patient Identifier/Client Registry (UPI/CR) in Canada [24], Individual Healthcare Identifier (IHI) in Australia. [59]

The need for unique identifiers in health care is necessary and widely accepted. However, if identifiers are used in a distributed system they must be unique at that scale, with distributed maintenance, and with supporting technical and the administrative structures. Application redevelopment in this context constitutes a substantial investment, nevertheless it is clear from the number of countries who are developing national identifier systems that it is generally believed that the benefits outweigh the difficulties and expense. On the other hand, the development of cross regional, cross domain or cross reference identification has long been problematic. Some hospitals don't have a patient identity management system, so they will randomly assign a ID to each patient. As an apparent result, the information services staff of the hospital can not find an association between the randomly assigned ID and a particular patient. Many hospitals do have identity management systems, but often they have a large number of duplicate records for the same patient. Although, the unique identifier for patient has been accepted and used, it doesn't solve the problem of redundant identities, mis-identification, inefficient identification. The current main technical specifications and the services used in relation to identity management in the EHR are listed below with short explanations of some of the key concepts.

3.6.1 Concepts associated with Identity Management

During the process of sharing and retrieving the EHR, there are a number of types of different standard formats for identities in different health systems, domains, geographical locations, and this heterogeneity makes the identification process difficult. As part of the

project work, members of the project team compared and analysed selected identity models (EIS, OpenEHR, EN13606, HL7 RIM, ISO DTS22220/DTS27527) [47] [60] [61] [62] to select their common features for proposed model. They were found to contain many conceptual components in common, leading to the possibility that they could all be represented by archetypes. Nevertheless, the demographics model of EN13606 is a fixed model and is not suitable for archetyping. The project team are currently engaged in a study to determine how a general identity model could be made to represent all other identity models for the different types of health related entities listed above.

The following terms are commonly used in describing general identity systems in the health domain.

Identity in EN13606

Each identity is typically associated with one or more numerical or alpha-numerical identifiers, traits which can be used individually and conveniently by a software application to select a single unique identity for particular entity within a particular set of such identities called an *identity domain*. The EHR*land* approach from the start assumes the presence of a national unique identifier for healthcare subjects. It will also require a national unique identifier for health professionals. To satisfy the requirements of EN13606 it will also be necessary to establish a national scheme for identifying information systems that contribute to the EHR community.

Identifiers

Each identity in an EHR system is typically associated with one or more numerical or alpha-numerical identifiers which are called different names (e.g. Medical Record Number, Patient ID, and Subject of Care ID) in different organisations.

Identity Domains

An Identity Domain is equivalent to the concept of domain that occurs in many places in the computerised world. An Identity Domain, whether it is for patients, health professionals, or other types of healthcare resources can be seen as a set of identifiers and traits for each identified entity which have been assigned by the different healthcare organisations with certain administrative policy. For example, in an acute care setting, a hospital information system (HIS) manages an identity domain and each identifier within this domain is unique. Different hospitals often have their own patient registries as well as registries for other types of entities (users, medical devices, software application etc.)., each with their own identity domains. Probably the most prominent identity domain is the enterprise master patient index (EMPI), that is at the heart of many hospital information systems and is one of the common identity domains in many hospitals. It is the Identity Domain that cross-references identity. Features to support sharing, linking and merging of identities are also often available and necessary. A typical medium-sized hospital would have identity domains which incorporate hundreds of thousands of identities.

Traits

Identifiers are used by software applications to identify particular people or resources that are associated with the EHR. Additional identifying traits or that can be associated with identities are very important components of identity management as they allow users to recognise the identity. The traits of an identity can be represented by the attributes of an associated identity object. Conceptually, a patient identifying trait has three parts which are like *traitName* "First Name", *traitType* "String" and *traitValue* "Paul". The different representing traits of demographics have been used by many EHR standards.

Information Models

The information model also defines an inheritance relationship between the node "Person" in a tree of identity types and more specialised nodes such as "doctor" and "nurse". Besides, modelling approaches have been used through information technology (IT) in healthcare by many standards development organisations such as CEN and HL7. For instance, part one of health informatics standard ISO EN 13606 which is used in this work, describes a reference model.

Identity Services

The Identity Cross reference Service (IXS) [63] is a general service specification that is being developed under a joint HSSP project between OMG and HL7 [64]. The IXS provides a set of service interfaces to identify the multiple types of entities (e.g. Patient, Health Professional, GP) not only within disparate enterprise environment but also across a group of collaborating health organisations and domains. This idea of generalised entities in the health domain has been adopted within the EHR*land* project as the basis of our work on identity.

The Person Identification Service (PIDS) [65] is a technical specification that has been adoped by Health Domain Taskforce of OMG in 2001. The PIDS provides the identity management on the particular identity domain for person but its use was extended to other domains.

The Personal Demographics Service (PDS) [66] is part of the NHS (National Health Service) Care Record Service and it provides a national demographic service of supporting access control and identity management for United Kingdom. The demographic information will form part of each personal electronic NHS Care Record and it allows a patient to be identified by NHS staff. Furthermore, the PDS provides secure, efficient and convenient access to demographic information for 50 million patient in UK within the NHS Connecting for Health Initiative which in turn is part of the National Programme for IT.

The Patient Identifier Cross-referencing (PIX)/ Patient Demographics Query (PDQ) [67] is the IHE (Integrating the Health Enterprise) [68] technical framework that aims at stimulating integration of healthcare information resources such as HL7, DICOM. Through the specified the standards and best practices, IHE defined several profiles for interdepartmental communication to achieve the maximum extent of sharing information in e-health. The PIX profile supports the cross-referencing patient identification within a number of health domains. The PDQ profile is used for inquiries of patient demographic

information. The consumers can query the patient's medical records respectively through the transaction of Patient Demographics Query and Patient Demographics and Visit Query by the service provider.

Taking inspiration from the generalised approach of IXS, the main characteristics of existing demographics information models from the main health informatics standards were also investigated by the project team with a view to modelling these common features in a generalised and archetype-able identity model. One consequence of this approach is that the resulting identity reference model is not specific to demographics but could be capable of expressing other entity types that occur in healthcare, that have identifiers and human recognisable traits. The many subtle EHR roles and properties that occur in EN13606 complicate the process of identity exchange and interaction. For maximum flexibility and expressive power, members of the EHR*land* project team have developed an outline of a two level approach to identity management that is based around a generic reference model with strong data typing and which can be constrained by archetypes. A similar but more constrained approach to identity has previously been used by members of the openEHR foundation. The aim of this generalised identity reference model is to facilitate the identity management of multiple identity contexts, the cross-referencing of heterogeneous identity domains and with the support of the two-level modelling approach in Electronic Healthcare Record (EHR) system.

3.7 Access Control

Part four of the EN13606 specification deals with access the the electronic health record. This part of the specification assumes that an agreed access control mechanism is in place and focuses on the correct behaviour of an EHR in different situations. Three principal variations on the access control model have been widely used commercially: the discretionary access control (DAC) in which access is determined by the system rather than the owner and is the basis for access control on UNIX and Linux, mandatory access control (MAC) which is often employed within database management systems, and role-based access control (RBAC) [69] [70]. The most popular access control approach in use today is role-based access control and it also has been underpinned by the national health IT solution in healthcare.

Role-based access control introduces the concept of Role, and it aims to separate the user (the subject of the action) from the privilege (the resource with the operation). As an agent layer between a user and its permissions, the role decouples the relationship between the two of them, and simultaneously the authority will be given to the role rather than directly to the user or group. A common advantage of the RBAC in the user identity management system is that it reduces the amount of administrative work needed to add or detele users due to assigning the different roles for each user.

Access Control: Role Based (with exceptions?)

The access control approach that has been investigated by the EHR*land* follows the EN13606 approach of role based access with exceptions. In this approach, each user of the system is provided with a set of permissible roles which will allow them to access the

record. As part of the care process, users in roles that are associated with care delivery in the current health context of the patient will be provided with access to the EHR of the subject of care.

The role based access control is a proven technology, but the aspect that requires additional investigation is the idea of access control exceptions. Exceptions may apply if the care giver has been explicitly refused access to the record by the patient because they are related to the patient, or live nearby. This introduces the idea of excluding access on be basis of home address and family links which is likely to be problematic but also interesting. As mentioned in the previous chapter, it was controversy around this type of functionality that causes major delays in the French national EHR project and has also been the subject of debate in Canada Health INFOWAY.

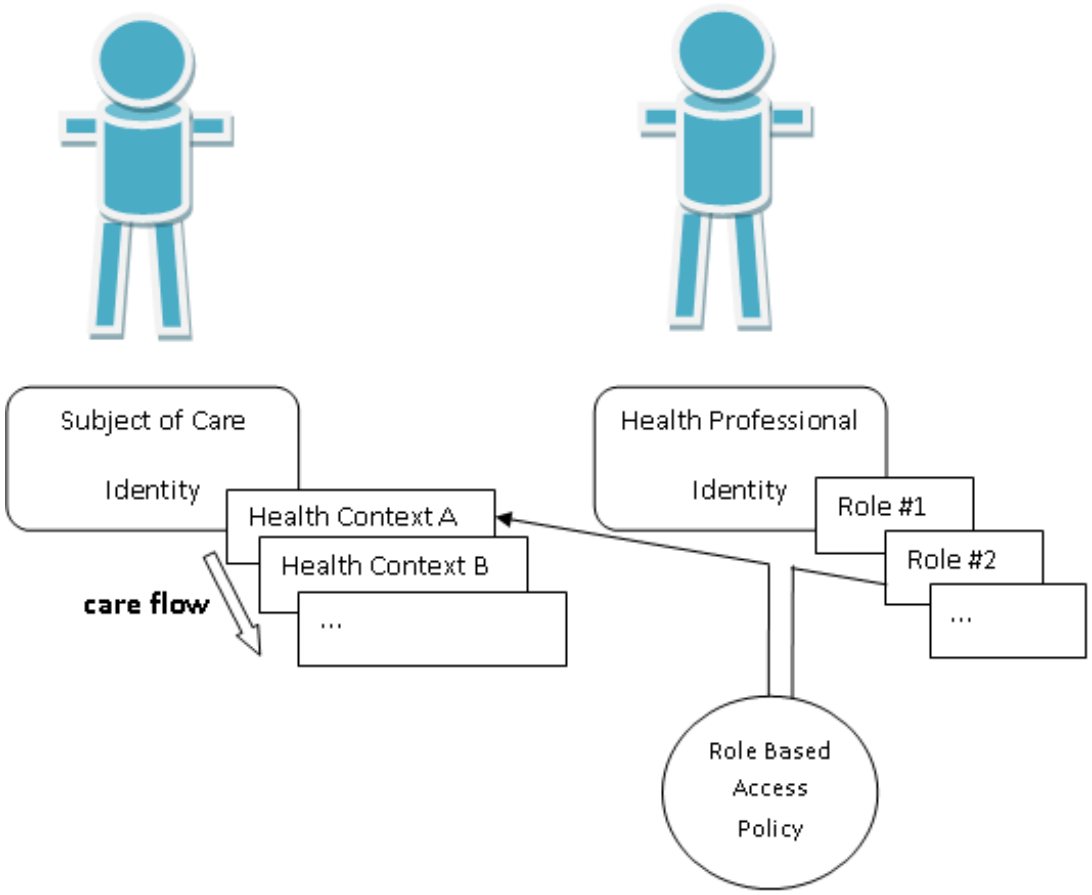

Figure 3.13: Example of the role-based access control for EHR.

Audit Trail Capabilities

The data which is incorporated into an electronic health record is required by ISO EHR requirements to thereafter be subject to audit trail and access control monitoring. The data should never be deleted although multiple versions of data may be retained. Every access of data by a user should also be recorded by the system. In each case, the system is obliged to record the userID, the timestamp and the location. In addition, the time at which information was incorporated into the EHR system community and

becomes available to users will also be recorded, so it will be possible to display the state of the record as it was at the time of a user interaction. To give some context, a short description of access control policy for other national projects is given below. Obviously, none of this will be possible unless there is a single unified identity management scheme across the EHR with globally unique identifiers for resources (EHR providers), users (health professionals) and subjects of care (patients).

Access Control for the NHS Care Record Service

The NHS CfH approach to access control that is employed for the NHS care record service, is called Position Based Access Control (PBAC) [10]. In this approach, access rights are granted to holders of particular positions who are involved in the care of the patient. Access rights are assigned to a health professional as they move into a new care role. These rights are predetermined by the role and are rescinded when the health professional leaves the role. It is intended that this approach simplifies the access control process as it means that access rights do not need to be granted for each individual. Instead, a framework of access rights is established at each care provider site. As individual healthcare providers are assigned a role based CRS account, their access rights are altered to reflect the underlying role. This is clearly similar to role base access control (RBAC) mentioned above. Users are also subject to professional and local codes of conduct in relation to sharing and management of personal health information.

Access Control for Canada Health INFOWAY

A study of 2300 Canadians by EKOS in 2003 concluded that 86% of Canadians are moderately to extremely comfortable with the EHR, but they expect their personal health information to be properly protected with good access control. When asked to offer measures that would make them more comfortable they said. *"...*

1. *the ability to find out who accessed the record and when - 71*
2. *to make it a serious criminal offence for unauthorized access -64*
3. *a clear and accessible privacy policy 61*
4. *their ability to access verify and correct a record 57*
5. *that their doctor supported the EHR - 57*

..."

Reported in [71] An overview of the electronic health record privacy and security conceptual architecture 25pp 2006. [72]

Consequently, in common with the French national project, Canada Health INFOWAY has placed special emphasis on the issue of consent as part of the access control process. The Canadian Standards Authority have developed a number of principles which are applied for this purpose, some of these principles are listed below. *"...*
Principle 1: An organization is responsible for personal information under its control and shall designate an individual or individuals who are accountable for the organizations

compliance with the following principles.
Principle 2: The purposes for which personal information is collected shall be identified by the organization at or before the time the information is collected
Principle 3: The knowledge and consent of the individual are required for the collection use or disclosure of personal information except where appropriate.
Principle 4: The collection of personal information shall be limited to that which is necessary for the purposes identified by the organization. Information shall be collected by fair and lawful means...”

They also designed the system to deliberately separate demographic information from health information using a so called identity protection service. This service uses common identifiers to subsequently join the two parts of the record together when it is required.

In 2006, INFOWAY produced three reports about building secure and privacy-pro tective EHR systems. In the third report of EHR privacy and security requirements, INFOWAY indicated three access control methodologies that are taken for the privilege management. They are role-based access control, workgroup based access control and discretionary access control. [71]

On the basis of the above discussion the RBAC alone is probably not the complete answer for all needs of access control, especially for providing a comprehensive and satisfactory access control solution for shared electronic health record system. The three part ISO PMAC (Privilege Management and Access Control) [73] standard is intended to provide a more inclusive and generalised view of access to health information resources. A number of cooperating access control viewpoints have been described by Blobel [69] from different perspectives for the health domain. Figure 3.14 shows these access control viewpoints and they are summarised below.

Figure 3.14: Different model viewpoints on access control.

The domain viewpoint allows information resources to be grouped into communication domains that share an agreed security policy. Domains can be aggregated into super-domains or broken into sub-domains. These domains could be described according to OMG's (Object Management Group) definition, as having three components, common policies (policy domains), common environments (environment domains) and common technology (technology domains) . The following figure shows the attributes of the security policy domain class which inherits domain class such as domain identifier, domain name, domain authority, domain qualifier.

The policy viewpoint facilitates a range of different policy types. For instance authorization policies contain sets of permitted actions; event-based obligation policies define actions which must be performed when certain conditions are met; refrain policies declare actions the subjects must not perform; delegation policies define which authorizations can be delegated and to whom. A basic security policy model is usually characterized by a list of the attributes. For example, policy identifier, policy name, policy authority, policy domain and operation code.

The role viewpoint allows privileges to be indirectly assigned to users as individuals

are given roles and roles are associated with a set of privileges. This separation allows privileges associated with a role to be updated without needing to modify the role membership. A generic role model can be distinguished in two types which are functional roles and structural roles. It will also corporate with two class types of entity and act.

The document viewpoint, Processes, entity roles, etc. must be documented and signed expressing the particular relations between entities and processes. The combination of processes and relations leads to multiple signatures (e.g. in the case of delegation). A simple document model could have several attributes such as document process, document entity role, document user activity.

The privilege management viewpoint is used by ISO PMAC specification and it allows the system authority to assign the privilege to individual actors or to groups of individual actors which can be a human user, a system or application etc., and playing the closed role to role viewpoint. The general privilege management model consists of three classes, object, privilege asserter and privilege verifier.

The authorisation viewpoint is quite similar as privilege management viewpoint and used by OMG RAD specification and authorization logic is encapsulated within an authorization facility that is external to the application. In order to perform an application-level access control to clinical object, an application requests an authorization decision from such a facility and enforces that decision [74]. The general authorization process has two parts, granting privilege and assigning permission by the security system.

The control viewpoint, illustrates how control is exerted over access to a sensitive object operation [75]. Access control is the process which determines whether a claimant's privileges permit him/her/it to access a service provided by a target component. In this context, access is broader than acquiring some data. It might refer to any service offered by a target component (e.g. deletion, computation, transfer). There are four components in the model: the claimant, the verifier, the target and the control policy.

The delegation viewpoint, a source authority can delegate to certain delegation administrators the privileges to create and manage the identity management for an authorization entity [76]. There are three components of the delegation model: the verifier, the source of authority, and the claimant. The verifier grants an entity known as the source of authority with global privilege within the context a delegation occurs. The claimant asserts its delegated privilege by demonstrating its identity. The source of authority may also process a request from an entity to delegate its privilege by issuing an attribute certificate to another entity.

Chapter 4

EHRLAND EHR ARCHITECTURE

4.1 Overview - ODP Enterprise Viewpoint

This chapter provides a high level description a proposed architecture for a distributed electronic health record system that is based around EN13606. It corresponds to part of the ODP information viewpoint for a national or regional EHR system (other parts of information viewpoint are included in parts one to three of the standard and the class descriptions in the previous chapter of this report.) This design has arisen out of experimentation and extensive discussion over the course of the project. The architecture describes some of the main information services that are required at a national or regional level and those that would need to be merged with the existing relevant ICT resources at each participating site.

4.1.1 Services

National Identity Service

This service provides the functions of identity management that allow certain types of users to register identities, retrieve identities and manage identities for multiple entities within the health domain such as patients, HCPs, organisations and devices. Each domain has its own identities and it correlates these identities (e.g Patient, GP) to establish a standardised information view, which provides a basis for an EHR system. This service employs an approach that is similar to the HSSP Identity Cross-reference Service (IXS) to extend the management of identity to provide cross-referencing query and administrative functions for an identified entity.

National Terminology Service

This service defines a set of interfaces that can be used by various EHR applications to consume terminology resources in a distributed manner. This service exposes interfaces that are intended to suit a loosely coupled application environment. It provides at the national level a unified access point to a set of coding systems. The service is extendable itself however only the considered minimum recommendation of requirement is documented.

National Archetype Service

This service provides access to one or multiple national level Archetype repositories. Its duty includes Archetype searching and retrieval. Any Archetype requester will need to connect to this service to require national legitimate Archetypes.

EHR Provider Finder Service

In the case of a distributed approach to the EHR, this service allows an EHR system (and indirectly the organisation or professional using it) to get IDs of other EHR systems containing clinical data about a particular patient, or containing specific clinical data about this patient. The IDs provided with the request are used by this service to consult the access policies using the national access policies services. This means that the EHR provider finder service will not return the ID of an EHR provider containing data about a patient which access is not allowed by the entities participating in the request.

EHR Provider Service

This service provides EHR extracts containing clinical data (and optionally demographic data) about a particular patient. The clinical content of the extract depends on the request and the access privileges of the requester. The service also provides EHR audit log extracts the content of which also depends on the request and the access privileges of the requester. This service uses the REQUEST_EHR_EXTRACT and REQUEST_EHR_AUDIT_LOG_EXTRACT interfaces described in the part 5 of the CEN EN13606 standard. The EHR provider is composed of further components described below.

Local Access Control Service

On top of national access control policy, which focuses essentially on role-based access control, the EHR provider may wish to enforce addtional policies, based, for example, on the ID of the requester, whether it corresponds to a professional or an entire organisation. The role of a local access control service will specifically be to enforce these locally determined access control policies.

Extract Builder

This component builds an CEN EN13606 extract and asks the composition builder for copies of compositions which constitute an answer to the query received by the EHR provider service. The query can include archetype IDs, free text, terminology codes, record component IDs, which include, of course, composition IDs, on top of the mandatory EHR ID.

Composition Builder

This component instantiates copies of compositions already instantiated by the composition committer. It rebuilds again the structure of record components for the purpose of including it in an extract. Similarly to other components of the EHR provider service,

it is configured by the EHR provider configuration services. Note that this time no interaction is needed with the record identity manager as the IDs of the record components are already created and persisted by the composition committer.

EHR

This component persists data necessary to query and build composition instances complying with EHR structures (archetypes) created with EN13606.

Local Identity Service

This component acts as a service to the composition committer during the committal of new clinical data into the EHR. It is also notified of changes in the local demographics data by the demographic observer. Following changes in local demographics data, it is responsible for interacting with the national identity service and it may also store national IDs obtained from the national service.

Demographic Observer

This component observes changes in the relevant demographics data sources and informs the local identity service. It is configured by the EHR provider configuration tools to interact with the local demographics data sources and the local identity service.

Composition Committer

In CEN EN13606, a composition always corresponds either to an interaction with the EHR, as it is the level at which committal information (at least the committer ID, the EHR ID, and the committal time) can be added. Additionally, it can correspond to the information collected during a particular clinical episode. The rules and constraints regarding the structure and content of clinical episodes may be agreed upon and encoded into archetypes by domain experts. For further information on compositions, see 3.4.

An important point is that this committal is separate, and necessarily posterior, to the initial entry of clinical data in the existing system. The committal of the composition corresponds to a new decision to include data into the EHR of the patient, which is by definition accessible at other points of care, after the requirements of the access control policies, both local and national have been met using the associated services.

The composition which one wants to commit into the EHR needs first to be instantiated. This instantiation corresponds to the creation of new informational entities, mainly instances of record components. Instances of record components are arranged according to a structure which may correspond to an archetype. The job of the composition committer is precisely to instantiate and persist this EN13606 composition structure. It is configured with the EHR provider configuration services to interact with the clinical data observer and the local identification server (to map local entity IDs to national IDs), the record identity manager, and the clinical data sources.

Clinical Observer

This component observes changes in the relevant clinical data sources and sends the new data to the composition committer. It is configured by the EHR provider configuration tools to interact with the local clinical data sources.

Record Identity Manager

This component is responsible for delivering unique IIs with suitable root OIDS and assigning authority names to the composition committer at committal time.

EHR Provider Configuration Tools

The EHR provider configuration tools are a set of tools (which may be integrated in one interface) which are used to configure an EHR Provider. Various data sources and access to services are needed during this configuration process:

1. access to data sources containing clinical data and demographic data: the tool needs access to the local clinical data which will be committed into the patient's EHR; it also needs access to demographic data sources associated with the clinical data, in order to request national IDs from the national identification services for the relevant entities mentioned in the EHR,

2. access to the national identification services in order to send demographic data for the relevant entities the national IDs of which the EHR provider needs,

3. access to national terminology services in order to configure the mapping between local codes and codes from the nationally agreed terminologies,

4. access to national archetype services in order to choose a set of archetypes, if available, to map the local clinical data to, and

5. access to national access policies services if a generic access matrix was agreed at the national level; the local access policies can then further restrict access according to additional criteria. If an EHR provider belongs to a large organisation, multiple local systems may contain clinical and demographic data. Consequently, the configuration process will involve integrating locally clinical and demographic data for each patient. The integration may simply consist in linking data to a unique local patient identifier, if if exists, or directly to the national patient identifier.

Authentication Service

This service plays the role of verifying the EHR users' identities that are cross-referencing on either a national site or a local site. The authentication service grants access that gathers details from the national access control service in relation to a specific user with the associated privileges. That means that the request of EHR clients will only be processed by their own authenticated identity.

National Access Control Service

This service provides the support for the users of the EHR system as well as supporting informed consent and audit trails and not least various forms of access control. It will be definitely under control of security mechanisms and these access control policies will be produced by an access control engine which will be also used for authentication service.

Secure Communication Service

This service is at a different level to the other services mentioned here. It would be required however to realise a large scale EHR system. Basically, it is responsible for securely conveying requests, queries, updates and identity transactions as well as record extracts from EHR providers to clients used by authenticated and authorised users of the EHR.

4.1.2 Clients

Archetype Designer/Viewer

This client application corresponds to the component which can be integrated into an arbitrary EHR environment that requires access to a terminology system. This may not always be a client to a national terminology service whereas a locally cached resource is also applicable. It represents the generic user interface that utilizes the terminology service, remotely or locally.

Terminology Subset Builder/Browser

This component is included in the configuration tool [ref to arch overview diagram] set which allows a locally conducted mapping/migration to have access to the national terminology service. Its primary role is to allow system administrators together with clinical experts to browse and build terminological subsets for a per site use. Specialists of a particular terminology system e.g. SNOMED-CT may be required to complete tasks such as deciding code sets, mapping to local codes etc.

EHR Viewer

This component provides an integrated view of the extracts returned at the requester's site after using the EHR provider finder and EHR provider services.

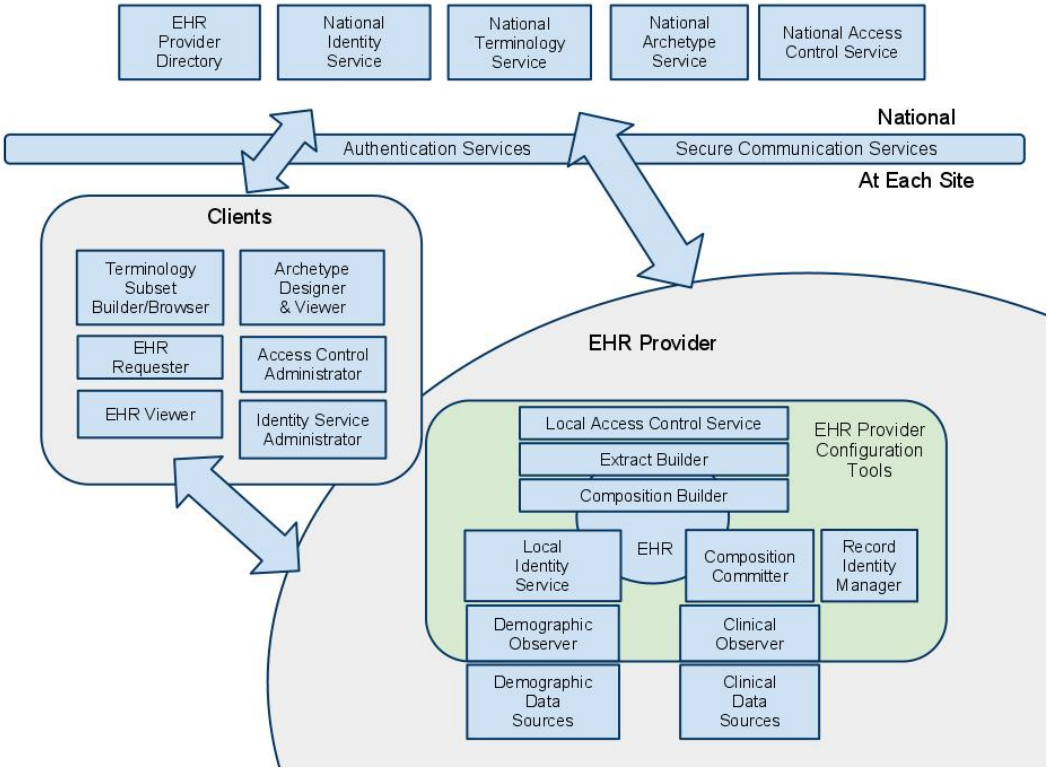

Figure 4.1: Overview of the EHR*land* EHR Architecture.

4.2 ODP Information View Point

In the last section, some of the fundamental concepts behind two-level models were described as well as an overview of some of the main classes used in the standard, in the reference model that is the focus of part one of the standard and in the archetype model in part two of the standard. This section provides a set of use cases and use case descriptions and scenarios associated with implementation of the EN13606 standard.

4.2.1 EHR Provider Use Cases

Overview

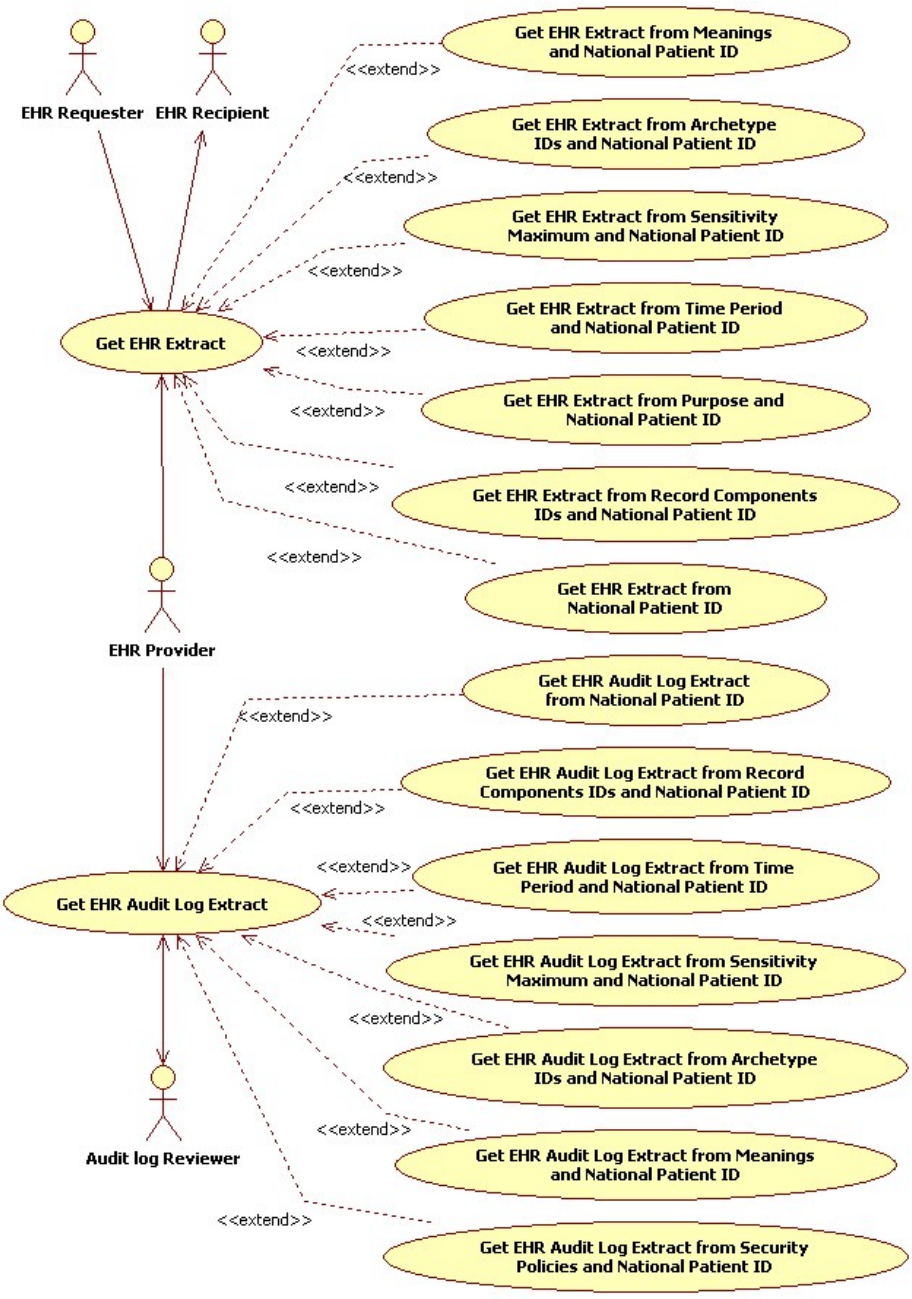

Figure 4.2: Overview of the EHR*land* Provider Use Cases.

The extract service use cases achieve the sending of an EHR extract or an EHR audit log extract from an EHR provider to an EHR recipient or an audit log reviewer, respectively. Description of actors:

- Audit log reviewer: defined in CEN EN13606 (Part 4) as a "healthcare professional,

a patient, a legal representative, or another party with sufficient authorisation to access healthcare information." In this use case, it is a requester and the recipient of an EHR audit log extract.

- EHR requester: defined in CEN EN13606 as an "entity initiating a request for electronic health record communication to take place between an electronic health record provider and an electronic health record recipient".
- EHR provider: defined in CEN EN13606 as an "entity in legitimate possession of electronic health record data and in a position to communicate it to another appropriate entity".
- EHR recipient: defined in CEN EN13606 as an "entity to whom electronic health record data is communicated by an electronic health record provider". In EHR*land*, the EHR recipient and the EHR requester are the same health care agent (HCA). An HCA is defined in CEN EN13606 as a "person, device, or software that performs a role in a health care activity".

Primary Use Case 1: Get EHR Extract

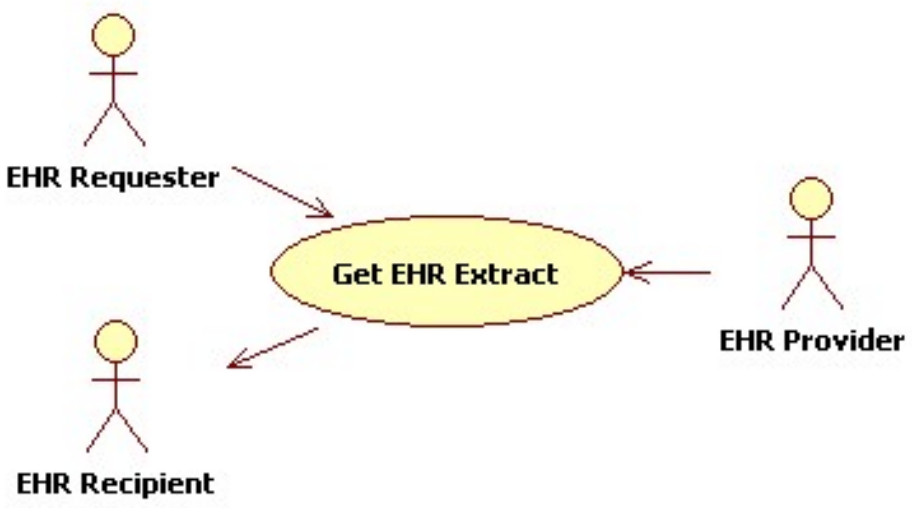

Figure 4.3: Primary Use Case 1: Get EHR Extract.

Summary: the goal of this use case is to retrieve a CEN EN13606 EHR extract from an EHR provider. The main actors are the EHR Requester, the EHR provider, and the EHR recipient. Primary scenario:

1. The EHR requester sends an extract request to the EHR provider. The request contains information about the identification of the subject of care (from whose EHR the extract is requested), identifications of requester and recipient, and the query.

2. The EHR provider authenticates the EHR requester and recipient.

3. The EHR provider checks the access privileges of the EHR requester for the subject of care and the query.

4. The EHR provider decides to send back to the EHR recipient a full extract, a partial extract, or a rejection (no extract at all), depending on the previous step. A full extract fully answers the initial query. A partial extract only answers part of the initial query, for access control reasons, or because the information requested does not exist for this subject of care. If the entire query is outside the parts of the EHR to which the EHR requester has access, if the information requested is temporarily unavailable due, for example, to a technical difficulty, or if the EHR provider has no means of checking the access privileges of the requester, a rejection is sent to the recipient.

Primary Use Case 2: Get EHR Audit Log Extract

Figure 4.4: Primary Use Case 2: Get EHR Audit Log Extract.

Summary: the goal of this use case is to retrieve a CEN EN13606 EHR audit log extract from an EHR provider. The main actors are the audit log reviewer and the EHR provider. Primary scenario:

1. The audit log reviewer sends an audit log extract request to the EHR provider. The request contains information about the identification of the subject of care (from whose EHR the audit log extract is requested), the identification of the audit log reviewer, and the query.

2. The EHR provider authenticates the audit log reviewer.

3. The EHR provider checks the access privileges of the audit log reviewer for the subject of care and the query.

4. The EHR provider decides to send back to the EHR recipient a full extract, a partial extract, or a rejection (no extract at all), depending on the previous step. A full extract fully answers the initial query. A partial extract only answers part of the initial query, for access control reasons, or because the information requested does not exist for this subject of care. If the entire query is outside the parts of the audit log to which the audit log reviewer has access, if the information requested is temporarily unavailable due, for example, to a technical difficulty, or if the EHR provider has no means of checking the access privileges of the audit log reviewer, a rejection is sent to the audit log reviewer.

Extensions of Primary Use Case 1

Get EHR Extract from National Patient ID

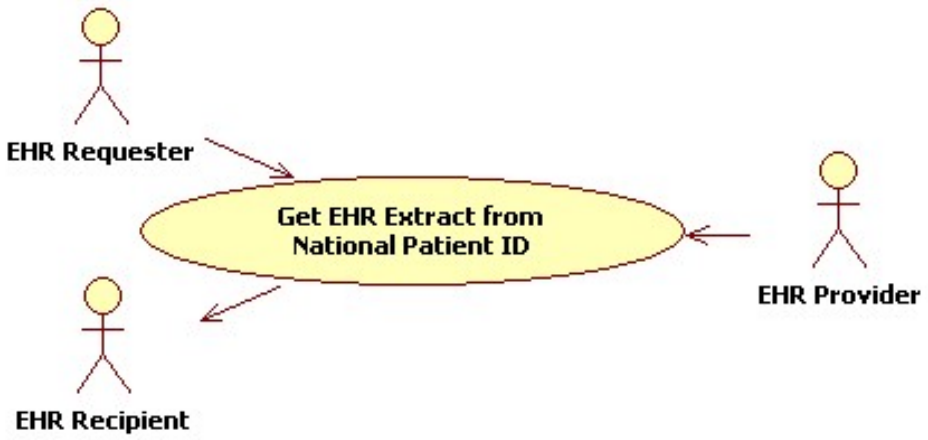

Figure 4.5: Get EHR Extract from National Patient ID.

The request contains information about the identification of the subject of care (from whose EHR the extract is requested), identifications of requester and recipient, and the query. The query is empty as all components about the subject of care are requested.

Get EHR Extract from Record Components IDs and National Patient ID

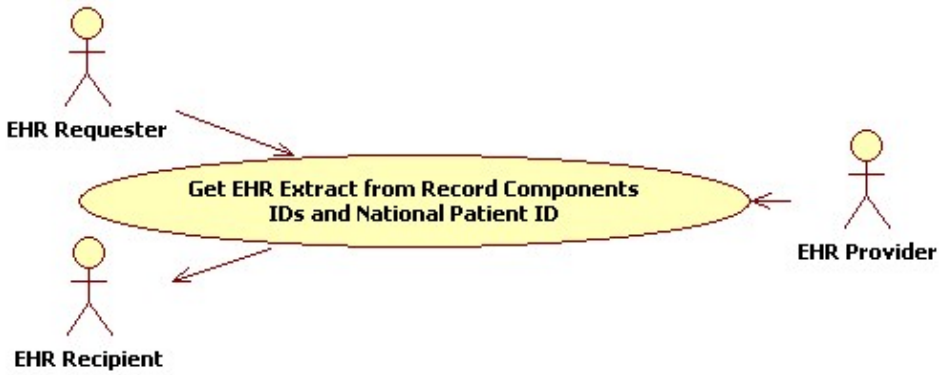

Figure 4.6: Get EHR Extract from Record Components IDs and National Patient ID.

The request contains information about the identification of the subject of care (from whose EHR the extract is requested), identifications of requester and recipient, and the query. The query is a set of record component IDs.

Get EHR Extract from Purpose and National Patient ID

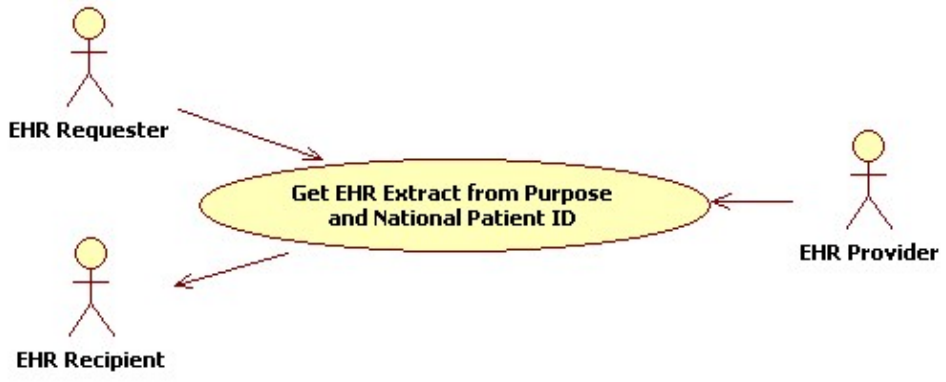

Figure 4.7: Get EHR Extract from Purpose and National Patient ID.

The request contains information about the identification of the subject of care (from whose EHR the extract is requested), identifications of requester and recipient, and the query. The query is a particular purpose, which may be expressed with any standard terminology.

Get EHR Extract from Time Period and National Patient ID

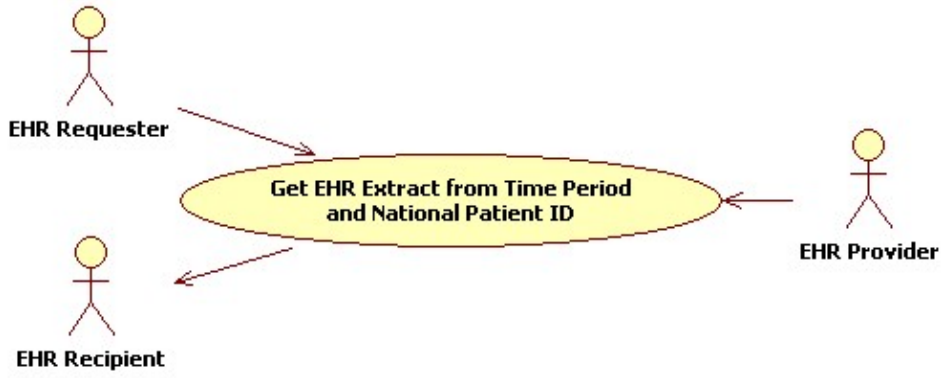

Figure 4.8: Get EHR Extract from Time Period and National Patient ID.

The request contains information about the identification of the subject of care (from whose EHR the extract is requested), identifications of requester and recipient, and the query. The query is a time period, i.e. a time interval.

Get EHR Extract from Sensitivity Maximum and National Patient ID

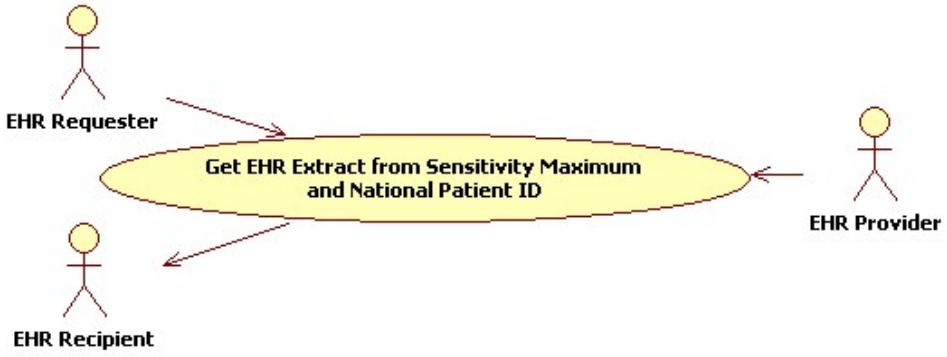

Figure 4.9: Get EHR Extract from Sensitivity Maximum and National Patient ID.

The request contains information about the identification of the subject of care (from whose EHR the extract is requested), identifications of requester and recipient, and the query. The query is a maximum level of sensitivity for the record components to be included in the abstract.

Get EHR Extract from Archetype IDs and National Patient ID

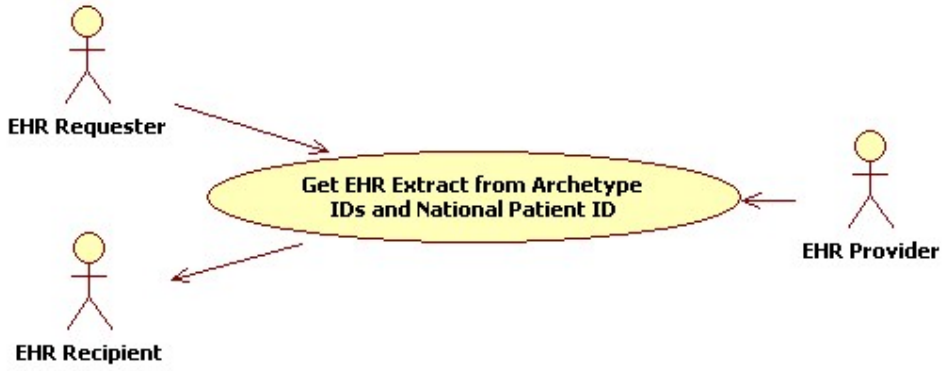

Figure 4.10: Get EHR Extract from Archetype IDs and National Patient ID.

The request contains information about the identification of the subject of care (from whose EHR the extract is requested), identifications of requester and recipient, and the query. The query is a set of archetype IDs corresponding to the record components to be included in the extract.

Get EHR Extract from Meanings and National Patient ID

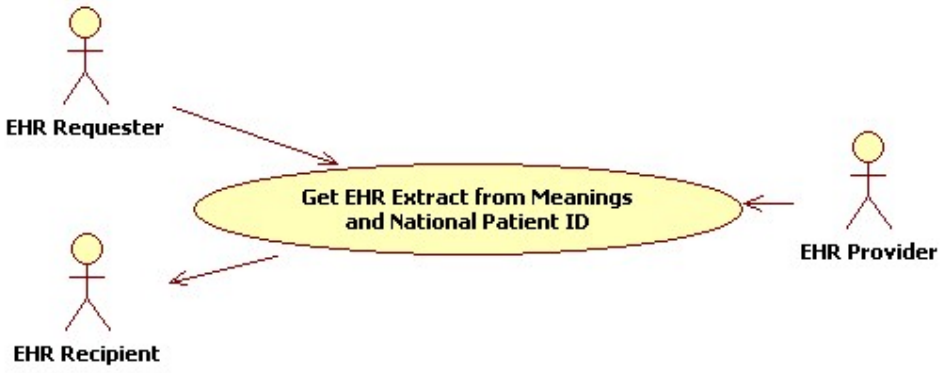

Figure 4.11: Get EHR Extract from Meanings and National Patient ID.

The request contains information about the identification of the subject of care (from whose EHR the extract is requested), identifications of requester and recipient, and the query. The query is a set of meanings corresponding to the record components to be included in the extract.

Extensions of Primary Use Case 2

Get EHR Audit Log Extract from National Patient ID

Figure 4.12: Get EHR Audit Log Extract from National Patient ID.

The request contains information about the identification of the subject of care (from whose EHR the audit log extract is requested), the identification of the audit log reviewer, and the query. The query is empty as audit information about all components for this subject of care is requested.

Get EHR Audit Log Extract from Record Components IDs and National Patient ID

Figure 4.13: Get EHR Audit Log Extract from Record Components IDs and National Patient ID.

The request contains information about the identification of the subject of care (from whose EHR the audit log extract is requested), the identification of the audit log reviewer, and the query. The query is a set of record components IDs the audit information of which is to be included in the extract.

Get EHR Audit Log Extract from Time Period and National Patient ID

Figure 4.14: Get EHR Audit Log Extract from Time Period and National Patient ID.

The request contains information about the identification of the subject of care (from whose EHR the audit log extract is requested), the identification of the audit log reviewer, and the query. The query is an interval of time for the audit log activity to be included in the extract.

Get EHR Audit Log Extract from Sensitivity Maximum and National Patient ID

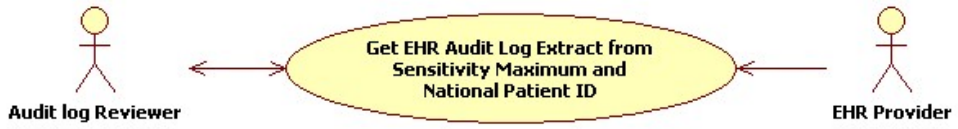

Figure 4.15: Get EHR Audit Log Extract from Sensitivity Maximum and National Patient ID.

The request contains information about the identification of the subject of care (from whose EHR the audit log extract is requested), the identification of the audit log reviewer, and the query. The query is the maximum sensitivity for the record components the audit information of which is to be included in the extract.

Get EHR Audit Log Extract from Archetype IDs and National Patient ID

Figure 4.16: Get EHR Audit Log Extract from Archetype IDs and National Patient ID.

The request contains information about the identification of the subject of care (from whose EHR the audit log extract is requested), the identification of the audit log reviewer, and the query. The query is a set of archetype IDs for the record components the audit information of which is to be included in the extract.

Get EHR Audit Log Extract from Meanings and National Patient ID

Figure 4.17: Get EHR Audit Log Extract from Meanings and National Patient ID.

The request contains information about the identification of the subject of care (from whose EHR the audit log extract is requested), the identification of the audit log reviewer, and the query. The query is a set of meanings for the record components the audit information of which is to be included in the extract.

Get EHR Audit Log Extract from Security Policies and National Patient ID

Figure 4.18: Get EHR Audit Log Extract from Security Policies and National Patient ID.

The request contains information about the identification of the subject of care (from whose EHR the audit log extract is requested), the identification of the audit log reviewer, and the query. The query is a set of security policies which need to be covered in the extract.

4.2.2 Archetype Service Use Cases

Overview

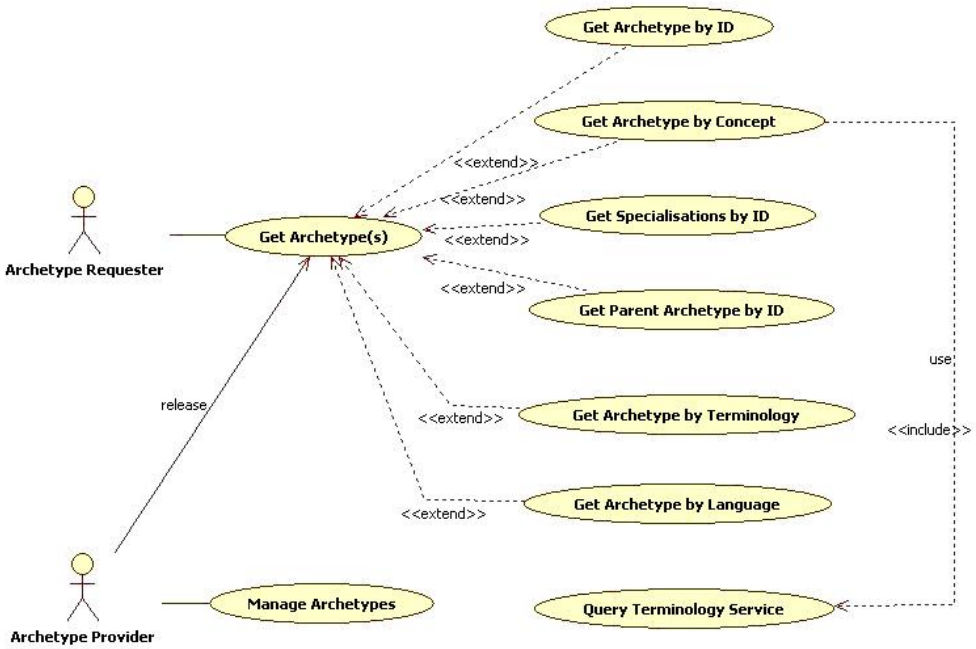

Figure 4.19: Overview of the Archetype Service Use Cases.

Description of actors:

- Archetype Requester: according to CEN EN13606 part 5 is a "requesting service", "in order to request one or more ARCHETYPES (as defined in Part 2 of this

standard)". It is called Archetype Requester here to distinguish it from other EHRcom Requester actors.

- Archetype provider: defined in CEN EN13606 part 5 as "the service expected to provide the ARCHETYPES". It is called Archetype Provider to distinguish it from other EHRcom Provider actors.

Primary use case 1: Get Archetypes

Figure 4.20: Primary use case 1: Get Archetypes.

Summary: the goal of this use case is to retrieve Archetypes from an Archetype repository. The actors are the Archetype Requester, and the Archetype Provider. Primary scenario:

1. The Archetype Requester sends a request to the Archetype provider. The request contains information about the parameters to specify the criteria of the query. The parameters to pass on contain the identification of an Archetype, language or terminology available and a coded medical concept which represents the meaning of the desired Archetype. All parameters are optional; if no criteria are set the request is about to retrieve all the Archetypes available.

2. The Archetype Provider will process the queries received from Archetype Requesters, and send back the correspondent Archetypes accordingly. This process sometimes involves querying the Terminology Service to help find accurate Archetypes.

3. If no parameter specified, by default the Archetype Requester shall get all the Archetypes available in the Archetype repository.

Primary use case 2: Manage Archetypes

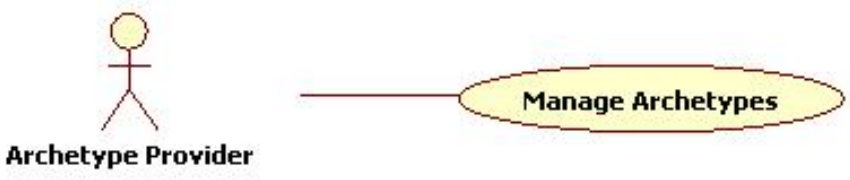

Figure 4.21: Primary use case 2: Manage Archetypes.

Summary: the goal of this use case is to manage Archetypes in an Archetype repository. The actor is the Archetype Provider. Tasks include composing, reviewing, authorising, updating Archetypes etc. Primary scenario: The Archetype Provider is in the position to manage Archetypes. Tasks involve the composing and reviewing Archetypes, organising versions of Archetypes, and publishing after authorising them. These tasks are essential to the EHR community although it is out of the boundary of EHRcom standard.

Primary use case Extensions

Get Archetypes by ID

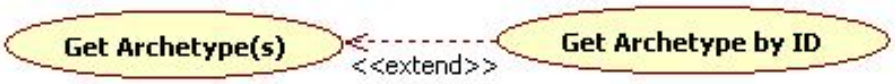

Figure 4.22: Primary use case Extensions: Get Archetypes by ID.

Summary: the Get Archetype(s) use case can be extended to use case Get Archetype by ID. The goal of this use case is to allow the specification of an Archetype ID in the request. Primary scenario: When an Archetype Requester sends a request, it can specify the desired Archetype by providing an Archetype ID. The Archetype Provider then responds with the Archetype that is associated to this ID.

Get Archetypes by Concept

Figure 4.23: Primary use case Extensions: Get Archetypes by Concept.

Summary: the Get Archetype(s) use case can be extended to use case Get Archetype by Concept. The goal of this use case is to allow the specification of a coded medical concept in the request. Primary scenario: When an Archetype Requester sends a request, it can specify the desired Archetype by providing a coded medical concept. The Archetype Provider then responds with the Archetype that is associated to this coded concept. In EHRcom the standard does not constrain the coding scheme of medical concepts. SNOMED-CT, LOINC, MeSH and other medical coding schemes are examples. However it is not limited to standard coding schemes.

Get Specialisations by ID

Figure 4.24: Primary use case Extensions: Get Specialisations by ID.

Summary: the Get Archetype(s) use case can be extended to use case Get Specialisation by ID. The goal of this use case is to get all children Archetypes specialised to which the Archetype ID given by the Archetype Requester. Primary scenario: When an Archetype Requester sends a request, it can ask the Archetype Provider to return all the children Archetypes specialised to an Archetype ID.

Get Parent by ID

Figure 4.25: Primary use case Extensions: Get Parent by ID.

Summary: the Get Archetype(s) use case can be extended to use case Get Parent Archetype by ID. The goal of this use case is to get the parent Archetype of which the Archetype ID given by the Archetype Requester. Primary scenario: When an Archetype Requester sends a request, it can ask the Archetype Provider to return the parent Archetype of a given Archetype ID.

Get Archetypes by Terminology

Figure 4.26: Primary use case Extensions: Get Archetypes by Terminology.

Summary: the Get Archetype(s) use case can be extended to use case Get Archetype by Terminology. The goal of this use case is to get Archetypes which support a terminology with a given name. Primary scenario: When an Archetype Requester sends a request, it can ask the Archetype Provider to return Archetypes that support the terminology associated with the given name (a string value) in their term binding section.

Get Archetypes by Language

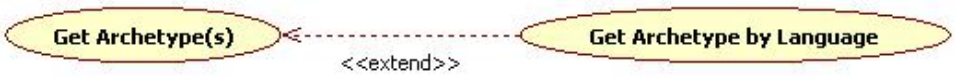

Figure 4.27: Primary use case Extensions: Get Archetypes by Language.

Summary: the Get Archetype(s) use case can be extended to use case Get Archetype by Language. The goal of this use case is to get Archetypes which support the given name of language. Primary scenario: When an Archetype Requester sends a request, it can ask the Archetype Provider to return Archetypes that support the language associated with the given name (a string value).

Use Case Inclusion

Inclusion of Terminology Service

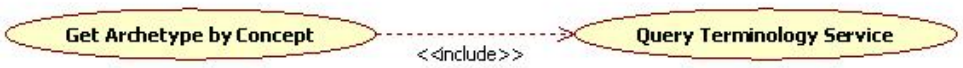

Figure 4.28: Use Case Inclusion: Inclusion of Terminology Service.

Summary: the Get Archetype by Concept use case includes use case Query Terminology Service as a subtask. Primary scenario:

1. When performing a Get Archetype by Concept use case it will further use Query Terminology Service to process the query.

2. The coded medical concept received from the Archetype Requester will be interpreted and sent to the Terminology Service.

3. The Terminology Service will return the detail of the mapping information, e.g a set of Archetype IDs associated with this coded concept.

4. The recommended Archetypes are returned to Archetype Requester for consideration and intervention.

4.2.3 National Identity Service Use Cases

Overview

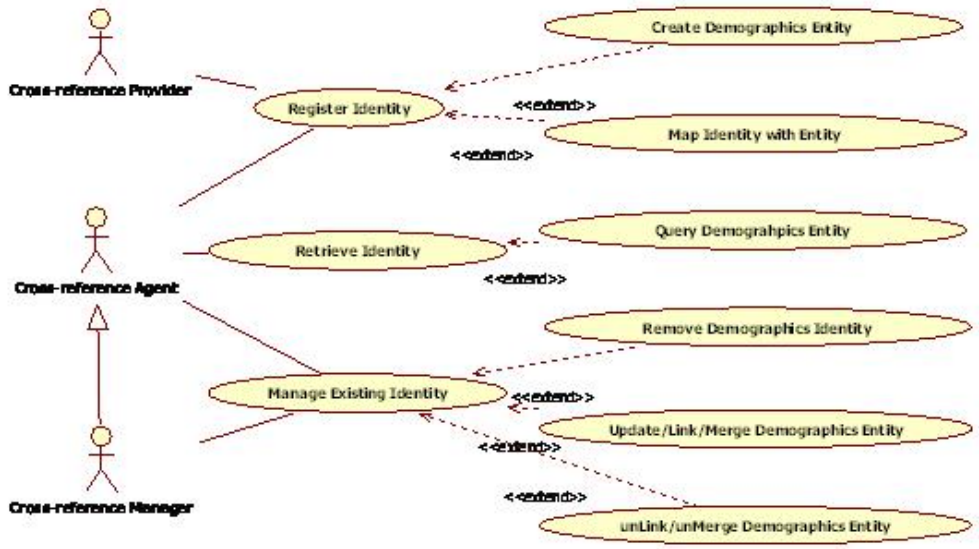

Figure 4.29: Overview of the National Identity Service Use Cases.

The use cases of national identity service can be classified into three tiers by the level of detail. Each use case will be described from the tier of general roles to specific roles. Description of actors:

- Cross-reference Agent: defined in CEN EN13606 as an "Identified_Entity" which contains the sub-classifiers and it may be an organisation, person, or device_or_software. In EHR*land*, cross-reference agent is also defined as the consumer or user of national identity service to perform the operations of register identity, retrieve identity and manage existing identity.

- Cross-reference Provider: is defined in ISO/DTS 27527 as an "Any person or organization that is involved in or associated with the delivery of health services to a client, or caring for client well-being" and it is also defined as national identity service provider in a position to register the identities that is defined in EN13606 demographics package as identified_entity.

- Cross-reference Manager: is the function of the administration of national identity service and it has greater privilege for administrative operation such as remove, link, and update entities.

Primary use case 1: Register Identity

Figure 4.30: Primary use case 1: Register Identity.

Summary: the goal of this use case is to register an identity (CEN EN13606 Identified_Entity) from cross-reference provider. The main actors are the cross-reference agent and the cross-reference provider. Primary scenario:

1. The cross-reference agent sends a request to the cross-reference provider. The request contains the identification information defined in CEN EN13606 demographics reference model. The cross-reference provider will create and store demographics entity and mapping between national identifiers and associated local entity IDs.
2. The cross-reference provider authenticates the cross-reference agent.
3. The cross-reference provider checks the access privileges of the cross-reference agent for the subject of care and the query.
4. The cross-reference provider sends back an acknowledgement message with status response.

Primary use case 2: Manage Existing Identity

Figure 4.31: Primary use case 2: Manage Existing Identity.

Summary: the goal of this use case is to manage existing identity (CEN EN13606 Identified_Entity) from a cross-reference manager. The main actors are the cross-reference agent and the cross-reference manager. Primary scenario:

1. The cross-reference agent sends a request to the cross-reference manager. The request contains the identification information defined in CEN EN13606 demographics reference model with the full or partial traits. The cross-reference manager links, merges and activates the entity and also operates in the reverse. In this use case, the reverse operations will return the corresponding state message for unlinks, unmerges and deactivates.

2. The cross-reference manager authenticates the audit log reviewer.

3. The cross-reference manager checks the access privileges of the cross-reference agent for the administrative operation of national identity service.

4. The cross-reference manager sends back an acknowledgement message with Status response.

Primary use case 3: Retrieve Identity

Figure 4.32: Primary use case 3: Retrieve Identity.

Summary: the goal of this use case is to query (CEN EN13606 Identified_Entity) from a cross-reference provider. The main actors are the cross-reference agent and the cross-reference provider. Primary scenario:

1. The cross-reference agent sends a request to the cross-reference provider. The request contains the full or partial queried traits (identification information) defined in CEN EN13606. The cross-reference provider returns a list of linked identifiers of patient records from all other domains that are linked to the queried information about one particular patient in a specified domain. The cross-reference provider sends a request to national identity repository for retrieving the national IDs that is associated with queried entity.

2. The cross-reference provider authenticates the cross-reference agent.

3. The cross-reference provider checks the access privileges of the cross-reference agent for the subject of care and the query.

4. The cross-reference provider sends back an acknowledgement message with Status response.

Extensions of Primary Use Case 1: Create Demographics Entity

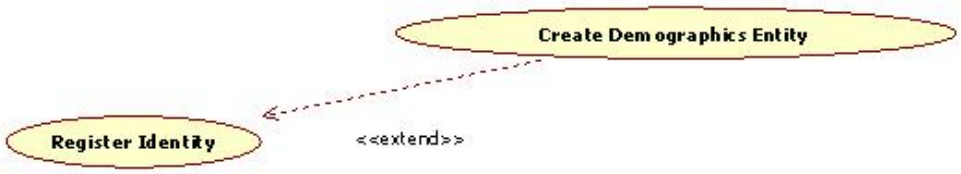

Figure 4.33: Extensions of Primary Use Case 1: Create Demographics Entity.

Primary scenario: The cross-reference agent sends the request to create a new patient entity (CEN EN13606 Identified_Entity) if the patient entity doesn't exist.

Extensions of Primary Use Case 2: Map Identity with Entity

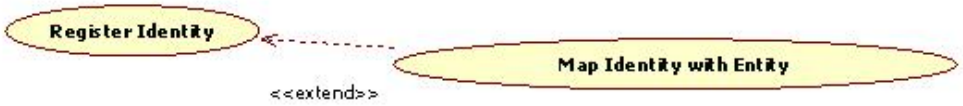

Figure 4.34: Extensions of Primary Use Case 2: Map Identity with Entity.

Primary scenario: The cross-reference agent sends the request to register an identity by providing the given entity/ID pairs for a new patient if the patient entity exists. An ID mapping between national identifiers and local entity will be created in the process of this request.

Extensions of Primary Use Case 3: Remove Demographics Identity

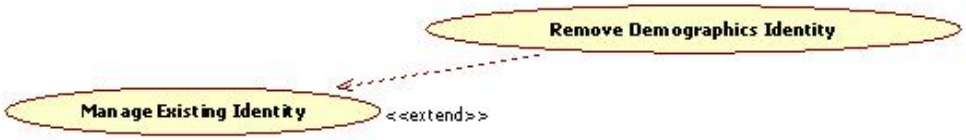

Figure 4.35: Extensions of Primary Use Case 3: Remove Demographics Identity.

Primary scenario: The cross-reference agent sends the request to delete a national entity/local Entity ID pair and its associated traits from the national identity repository and it is done by cross-reference manager.

Extensions of Primary Use Case 4: Update/Link/Merge Demographics Identity

Figure 4.36: Extensions of Primary Use Case 4: Update/Link/Merge Demographics Identity.

Primary scenario:

1. The cross-reference agent sends the request to update an entity with required demographics traits and it is done by cross-reference manager.
2. The cross-reference agent sends the request to create an explicit linking between the source and target entity IDs in the national identity repository.
3. The cross-reference agent sends the request to consolidate two duplicate entities.

Extensions of Primary Use Case 5: unlink/unMerge Demographics Identity

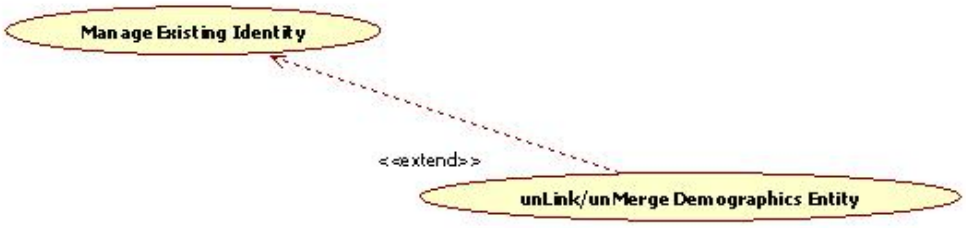

Figure 4.37: Extensions of Primary Use Case 5: unlink/unMerge Demographics Identity.

Primary scenario:

1. The cross-reference agent sends the request to reverse the link demographics entity process.
2. The cross-reference agent sends the request to reverse the merge demographics entity process.

Extensions of Primary Use Case 6: Query Demographics Entity

Figure 4.38: Extensions of Primary Use Case 6: Query Demographics Entity.

Primary scenario:

1. The cross-reference agent sends the request to query a patient identity and cross-reference provider returns the single entity or the multiple entities associated with queried traits.
2. The cross-reference agent sends the request to ask the national identity service to give the national UHI that corresponds to the local ID.
3. The cross-reference agent sends the request to query the national identity service to give the national UHI that corresponds to the traits from the local entity.
4. The cross-reference agent sends the request to query the national identity service to give the full entity that matches a UHI.

4.2.4 National Terminology Service Use Cases

Overview

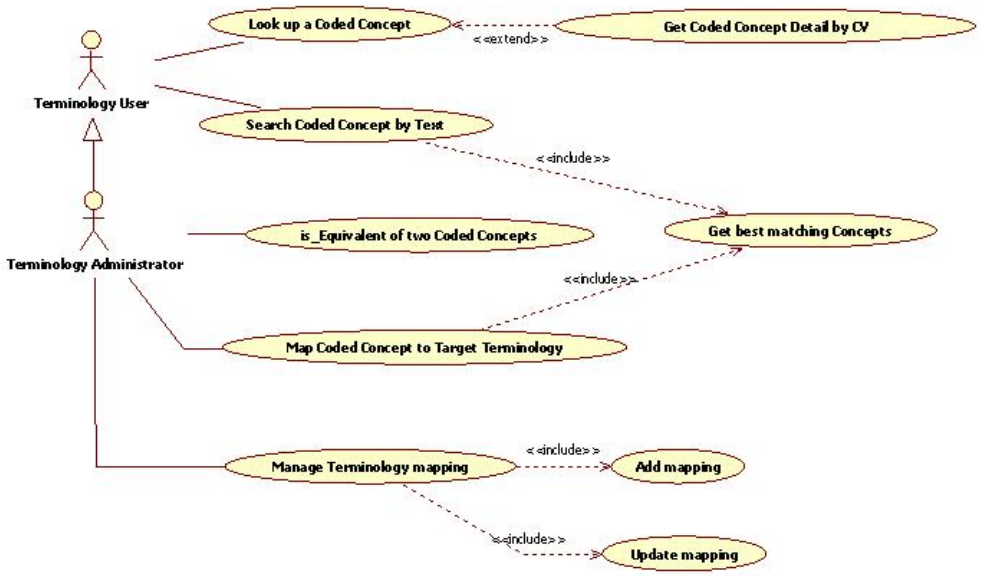

Figure 4.39: Overview of the National Terminology Service Use Cases.

Description of actors:

- Terminology User: is a requesting client or a human user who need to access the terminology service. The basic demand of a Terminology User is to find out a meaning of a coded term or concept and look for a code representing a meaning that needs to be expressed. According to CEN EN13606 there is no explicit definition of a Terminology User. In many use cases of EHRcom it involves the use of a Terminological resource such as a Coded Value. Therefore here Terminology User presents any system or human user who is in need of query a terminology service to get terminological content.

- Terminology Administrator: is a specialisation of Terminology User. It has greater privilege to operate administrative tasks such as organising terminology resources. It is not explicitly defined in CEN EN13606 but in ISO standard 18308 "The foundation for an EHR is a comprehensive reference terminology, whose structure unambiguously represents concepts by using a knowledge-based approach". The Terminology Service can be seen as a service including "data entry; presenting, querying, retrieving, sharing, comparing and integrating information; navigating or browsing, authoring or indexing knowledge". The Terminology Administrator is in charge to carry out administrative tasks such as "presenting, comparing, integrating information, authoring or indexing knowledge"

Primary use case 1: Look up a Coded Concept

Figure 4.40: Primary use case 1: Look up a Coded Concept.

Summary: the goal of this use case is to retrieve Coded Concepts from a Terminology Service. The main actor is the Terminology User. Primary scenario:

1. The Terminology User uses the Look up a Coded Concept to send a Coded Concept to the Terminology Service to look up its meaning. The coding scheme used can be also sent to narrow down the searching scope.

2. The Terminology Service gets the details about this Coded Concept in its resources and gives back the result to the Terminology User in a form it expects; in this case often a human readable form.

Primary use case 2: Search Coded Concept by Text

Figure 4.41: Primary use case 2: Search Coded Concept by Text.

Summary: the goal of this use case is to search Coded Concepts by sending textual description to a Terminology service. The main actor is the Terminology User. Primary scenario:

1. The Terminology User can use the Search Coded Concept by Text use case to perform a search for a Coded Concept by sending a textual description.
2. The Terminology Service processes the search and sends back the result in a form the Terminology User expects. The results can be a Coded Value or a set of them.
3. The Terminology Service will provide additional features to ensure the accuracy of the search by providing options to check correctness.

Primary use case 3: Look up a Coded Concept

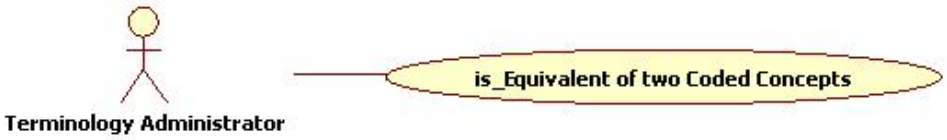

Figure 4.42: Primary use case 3: Look up a Coded Concept.

Summary: the goal of this use case is to compare two Coded Concepts and test equivalency. The two Coded Concepts can be from one terminology or different Terminologies. Primary scenario: A Terminology Administrator can compare two Coded Concepts to testify if they are equivalent. A result with a Boolean expression will be returned.

Primary use case 4: Map Coded Concept to Target Terminology

Figure 4.43: Primary use case 4: Map Coded Concept to Target Terminology.

Summary: the goal of this use case is to map a Coded Concept to a target terminology format. The destination format is not limited to number of standard coding schemes. It could also be an entity, instance or mapping information which holds the equivalent concept that the source holds. Primary scenario: A Coded Concept can be mapped to, according to user specified destination format, other coding schemes. E.g a SNOMED-CT code can be mapped to a HL7 message code or an Archetype ID.

Primary use case 5: Manage Terminology mapping

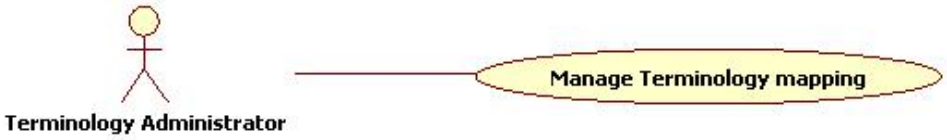

Figure 4.44: Primary use case 5: Manage Terminology mapping.

Summary: the goal of this use case is to allow the Terminology Administrator manage the mapping information. Primary scenario: A Terminology Administrator has the privilege to manage the terminology mapping information. Tasks like create new mappings, validate mappings, update mappings can be carried out. The mapping information represents the relationships between terminological concepts from different terminologies.

Actor specialisation

Figure 4.45: Actor specialisation.

Summary: Terminology Administrator is a specialisation of Terminology User. All use cases that Terminology User has are inherited by Terminology Administrator. Primary scenario: Terminology Administrator can perform all the tasks that a Terminology User can do.

Extension of primary use case 1: Get coded concept detail by CV

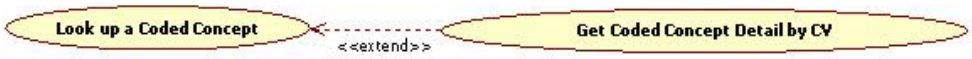

Figure 4.46: Extension of primary use case 1: Get coded concept detail by CV.

Summary: Look up a Coded Concept use case can be extended to Get Coded Concept Detail by CV. Primary scenario: When a Terminology User sends a Code Value which is a class from EHRcom reference model, the service will resolve CV type automatically and return the detail in a human readable format. It can also be seen as an interface to EHRcom service.

Get best matching concepts use case inclusion in primary use case 2

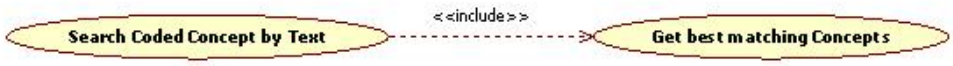

Figure 4.47: Get best matching concepts use case inclusion in primary use case 2.

Summary: Search Coded Concept by Text use case includes a sub use case Get best matching Concepts. Its goal is to collect a set of best matching concepts from the service that correspond to the query. Primary scenario: Text queries are processed and search results are returned. The service will pick best matching concept by ranking the result. The optimised result is then returned to the client.

Get best matching concepts use case inclusion in primary use case 4

Figure 4.48: Get best matching concepts use case inclusion in primary use case 4.

Summary: Map Coded Concept to Target Terminology use case includes the sub use case Get best matching Concepts. Its goal is to collect a set of best matching concepts in one or many coding schemes according to the mapping criteria. Primary scenario: When the

service is processing the request of mapping one concept to a different terminology, it will rank the result to generate a top scored list of matching concepts.

Add mapping inclusion in primary use case 5

Figure 4.49: Add mapping inclusion in primary use case 5.

Summary: Manage Terminology mapping use case includes sub use case Add mapping. Its goal is to create a new mapping of two concepts. They can be from different terminologies. Also a mapping from a Coded Concept to an instance conceptual class such as a class in HL7 or Archetype node ID is allowed. Local coding scheme can be consider as a terminology source too. The mapping will be validated and stored. Primary scenario: A new mapping is created and added to the Terminology Service.

Update mapping inclusion in primary use case 5

Figure 4.50: Update mapping inclusion in primary use case 5.

Summary: Manage Terminology mapping use case includes sub use case Update mapping. Its goal is to update existing mapping information. Primary scenario: Different roles with proper privileges can perform modifying, pending, deleting, and other maintenance tasks.

4.2.5 Access policy service Use cases

Register policy

Figure 4.51: Access policy service Use cases 1: Register policy.

Summary: the goal of this use case is to register an identity (CEN EN13606 Identified_Entity) from cross-reference provider. The main actors are the cross-reference user and the cross-reference provider. Description of actors:

- Cross-reference user: the user of demographics identity service including local service users.
- Cross-reference provider: the provider of demographics identity service and in a position to register and query identified entity.

Primary scenario:

1. The cross-reference user sends a request to the cross-reference provider. The request contains the identification information defined in CEN EN13606 demographics reference model. The cross-reference provider will create and store demographics entity and mapping between identifiers and entity IDs.
2. The cross-reference provider authenticates the cross-reference user.
3. The cross-reference provider checks the access privileges of the cross-reference user for the subject of care and the query.
4. The cross-reference provider sends back an acknowledgement message with EISStatus response.

Manage policy

policy.PNG

Figure 4.52: Access policy service Use cases 1: Manage policy.

Summary: the goal of this use case is to manage existing identity (CEN EN13606 Identified_Entity) from a cross-reference manager. The main actors are the cross-reference user and the cross-reference manager. Description of actors:

- Cross-reference user: the user of demographics identity service including local service user.
- Cross-reference manager: the administrator of demographics identity service.

Primary scenario:

1. The cross-reference user sends a request to the cross-reference manager. The request contains the identification information defined in CEN EN13606 demographics reference model with the full or partial traits. The cross-reference manager links, merges and activates the entity and also operates in the reverse.

2. The cross-reference manager authenticates the audit log reviewer.

3. The cross-reference manager checks the access privileges of the cross-reference user for the administrative operation of demographics identity service.

4. The cross-reference manager sends back an acknowledgement message with EISStatus response.

Retrieve policy

Figure 4.53: Access policy service Use cases 1: Retrieve policy.

Summary: the goal of this use case is to query (CEN EN13606 Identified_Entity) from a cross-reference provider. The main actors are the cross-reference user and the cross-reference provider. Description of actors:

- Cross-reference user: the user of demographics identity service including local service users.

- Cross-reference provider: the provider of demographics identity service and in a position to register and query identified entity.

Primary scenario:

1. The cross-reference user sends a request to the cross-reference provider. The request contains the full or partial queried traits (identification information) defined in CEN EN13606 demographics reference model. The cross-reference provider returns a list of linked identifiers of patient records from all other domains that are linked to the queried information about one particular patient in a specified domain.

2. The cross-reference provider authenticates the cross-reference user.

3. The cross-reference provider checks the access privileges of the cross-reference user for the subject of care and the query.

4. The cross-reference provider sends back an acknowledgement message with EISStatus response.

4.3 Computational View Point

Following the use case overview provided in the previous section, this section provides a computational viewpoint description of a large-scale EHR system.

4.3.1 EHR Provider Interfaces

REQUEST_EHR_EXTRACT interface:

Methods:

Exception thrown by all methods (optional): reason (CS, see Table 4.3)

REQUEST_EHR_AUDIT_LOG_EXTRACT interface:

Methods:

Exception thrown by all methods (optional): reason (CS, see Table 4.3)

Table 4.3: Reasons for exception in Three Interfaces.

Code	Term	Description
REAS01	There is no accessible data that corresponds to the request	Note: The use of this reason does not indicate if data does exist to which the EHRcom_requester does not have authorisation
REAS02	Requested repository is temporarily unavailable	e.g. due to a technical difficulty
REAS03	EHRcom requester's authorisation is not recognised	Note: This is not declaring if the requester is or is not allowed to access the EHR data, but that the EHRcom_provider does not have a means of verifying the requester's privilege

4.3.2 Archetype Services Interface

REQUEST_ARCHETYPES Interface:

Methods:

Exception thrown by all methods (optional): reason (CS, see Table 4.3)

Table 4.1: REQUEST_EHR_EXTRACT Interface.

Name	Parameters	Description	Return Type
getEHRExtract	II subjectOfCare Boolean allVersions Boolean multimediaIncluded	returns EHR extract for given subject of care ID. If allVersions is true, all versions of record components are included, otherwise only the latest versions are included. If multimediaIncluded is true, the multimedia (encapsulated) data are included in the extract, otherwise they are removed.	EHR_EXTRACT
getEHRExtract	II subjectOfCare CV purpose Boolean allVersions Boolean multimediaIncluded	returns EHR extract for given subject of care ID and given purpose expressed in any terminology. If allVersions is true, all versions of record components are included, otherwise only the latest versions are included. If multimediaIncluded is true, the multimedia (encapsulated) data are included in the extract, otherwise they are removed.	EHR_EXTRACT
getEHRExtract	II subjectOfCare Set<II>rc_ids Boolean allVersions Boolean multimediaIncluded	returns EHR extract containing record components with given IDs for subject of care with given ID. Part 5 of EHRcom states that "The resulting EHR_EXTRACT might contain such additional RECORD_COMPONENTS as are required to conform to Part 1 of EHRcom, such as the COMPOSITIONS that contain the requested RECORD_COMPONENTS". If allVersions is true, all versions of record components are included, otherwise only the latest versions are included. If multimediaIncluded is true, the multimedia (encapsulated) data are included in the extract, otherwise they are removed.	EHR_EXTRACT
getEHRExtract	II subjectOfCare IVL<TS>timePeriod Boolean allVersions Boolean multimediaIncluded	returns EHR extract containing record components for subject of care of given ID and covering the given interval of time. Our assumption is that it relates of the AUDIT_INFO.time_committed of RECORD_COMPONENT.feeder_audit or COMPOSITION.committal. If allVersions is true, all versions of record components are included, otherwise only the latest versions are included. If multimediaIncluded is true, the multimedia (encapsulated) data are included in the extract, otherwise they are removed.	EHR_EXTRACT

Name	Parameters	Description	Return Type
getEHRExtract	II subjectOfCare Integer maxSensitivity Boolean allVersions Boolean multimediaIncluded	returns EHR extract containing record components with sensitivity not greater than maximum sensitivity given and for subject of care with given ID. If allVersions is true, all versions of record components are included, otherwise only the latest versions are included. If multimediaIncluded is true, the multimedia (encapsulated) data are included in the extract, otherwise they are removed.	EHR_EXTRACT
getEHRExtract	II subjectOfCare Set<II>archetypeIDs Boolean allVersions Boolean multimediaIncluded	returns EHR extract containing record components for subject of care of given ID and with archetype IDs corresponding to given archetype IDs. Part 5 of EHRcom states that "The resulting EHR_EXTRACT might contain such additional RECORD_COMPONENTS as are required to conform to Part 1 of EHRcom, such as the COMPOSITIONS that contain the requested RECORD_COMPONENTS". If allVersions is true, all versions of record components are included, otherwise only the latest versions are included. If multimediaIncluded is true, the multimedia (encapsulated) data are included in the extract, otherwise they are removed.	EHR_EXTRACT
getEHRExtract	II subjectOfCare Set<CV>meanings Boolean allVersions Boolean multimediaIncluded	returns EHR extract containing record components for subject of care of given ID and with given meanings. Part 5 of EHRcom states that "The resulting EHR_EXTRACT might contain such additional RECORD_COMPONENTS as are required to conform to Part 1 of EHRcom, such as the COMPOSITIONS that contain the requested RECORD_COMPONENTS". If allVersions is true, all versions of record components are included, otherwise only the latest versions are included. If multimediaIncluded is true, the multimedia (encapsulated) data are included in the extract, otherwise they are removed.	EHR_EXTRACT

Table 4.2: REQUEST_EHR_AUDIT_LOG_EXTRACT Interface.

Name	Parameters	Description	Return Type
getEHRAuditLogExtract	II subjectOfCare	returns an EHR audit log extract (as defined in part 4 of EHRcom) for the subject of care with the given ID.	EHR_AUDIT_LOG_EXTRACT
getEHRAuditLogExtract	II subjectOfCare Set<II>rc_ids	returns an EHR audit log extract (as defined in part 4 of EHRcom) for the subject of care with the given ID and the record components with the given IDs.	EHR_AUDIT_LOG_EXTRACT
getEHRAuditLogExtract	II subjectOfCare IVL<TS>time_period	returns an EHR audit log extract (as defined in part 4 of EHRcom) for the subject of care with the given ID and the record components covering the given interval of time.	EHR_AUDIT_LOG_EXTRACT
getEHRAuditLogExtract	II subjectOfCare Integer maxSensitivity	returns an EHR audit log extract (as defined in part 4 of EHRcom) for the subject of care with the given ID and the record components with sensitivity not greater than the given maximum sensitivity.	EHR_AUDIT_LOG_EXTRACT
getEHRAuditLogExtract	II subjectOfCare Set<II>archetypeIDs	returns an EHR audit log extract (as defined in part 4 of EHRcom) for the subject of care with the given ID and the record components with archetype IDs corresponding to given archetype IDs.	EHR_AUDIT_LOG_EXTRACT

Name	Parameters	Description	Return Type
getEHRAuditLogExtract	II subjectOfCare	Set<CV>meanings returns an EHR audit log extract (as defined in part 4 of EHRcom) for the subject of care with the given ID and the record components with given meanings.	EHR_AUDIT_LOG_EXTRACT
getEHRAuditLogExtract	II subjectOfCare Set<CV>usingPolicies	returns an EHR audit log extract (as defined in part 4 of EHRcom) for the subject of care with the given ID and the given security policies.	EHR_AUDIT_LOG_EXTRACT

Table 4.4: REQUEST_ARCHETYPES Interface.

Name	Parameters	Description	Return Type
getArchetypes	Set<II>archetypeIDs	returns a set of archetypes with given ID.	Set<ARCHETYPE>
getArchetypes	CV concept	returns a set of archetypes with root concept corresponding to given concept.	Set<ARCHETYPE>
getSpecialisations	II archetypeID	returns a set of archetypes which are specialisations of archetype with given ID.	Set<ARCHETYPE>
getParent	II archetypeID	returns the archetype which is specialised by archetype with given ID.	ARCHETYPE
getBoundArchetypes	String terminologyID	returns a set of archetypes for which a term binding exists for the terminology with given ID.	Set<ARCHETYPE>
getTrasnlatedArchetype	String terminologyID	returns a set of archetypes for which a language translation exists of the terminology identified by the given ID.	Set<ARCHETYPE>

Name	Parameters	Description	Return Type
getSupportedCodeSystemsIdAndName	None	returns an array of code schemes expressed.	ST[]
getConceptCodeDetail	CV ConceptCode ST display_language_code	Search for detail of a concept by a concept ID/code (Sheng to clarify)	CV
getBestMatchingConceptCode	Text Description OID TargetCodeSystem	Search for best matching ConceptCodes by Description.	CV[]
areEquivalent	CV ConceptCode1 CV ConceptCode2	check if two concepts are equivalent.	BL
mapToCodeSystem	CV SourceConceptCode OID TargetCodeSystem	Map to target Code System.	CV

Table 4.5: Terminology Service Interface.

4.3.3 Terminology Service Interface

Methods:

4.3.4 National Identity Service Interface

REGISTER_IDENTITY Interface:

Methods:

Table 4.6: REGISTER_IDENTITY Interface.

Name	Parameters	Description	Return Type
createDemographics-Entity	String entityId String systemId String traitName Trait trait CS state	creates a local demographics entity by inserting the local system ID with traits.	CV
registerIdentity-WithEntity	II extractId II entityId Trait trait CS state	performs to register an identity by providing a local entity and associated IDs.	CV

RETRIEVE_IDENTITY Interface:

Methods:

Name	Parameters	Description	Return Type
findIdentities-ByTrait	II entityId Trait trait	returns a set of identified entities with identifiers corresponding to the given traits.	Set<Identified_Entity>

Table 4.7: RETRIEVE _IDENTITY Interface.

MANAGE_IDENTITY

Methods:

Table 4.8: MANAGE_IDENTITY.

Name	Parameters	Description	Return Type
removeIdentity	II extractId II entityId String traitName Trait trait	deletes an extract/local Entity ID pair and its associated traits.	CV
updateIdentity-Values	II extractId II entityId String traitName Trait trait	Updates an identity by given trait values from the NIS repository.	CV
linkIdentities	II sourceExtractId II sourceEntityId II targetExtractId II targetEntityId CS reasonCode String traitName Trait trait	creates an explicit linking between the source and target entity IDs in the NIS repository.	CV
unLinkIdentities	II sourceExtractId II sourceEntityId II targetExtractId II targetEntityId CS reasonCode String traitName Trait trait	create an explicit breaking the link between the source and target identity IDs in NIS repository.	CV
mergeIdentities	II sourceExtractId II sourceEntityId II targetExtractId II targetEntityId CS reasonCode String traitName Trait trait	performs explicitly consolidate identities in the NIS repository.	CV
unMerge-Identities	II sourceExtractId II sourceEntityId II targetExtractId II targetEntityId CS reasonCode String traitName Trait trait	performs a reverse operation related to merge identities and the source identity is inactived at the end of this operation.	CV

The interfaces below are modified and referenced by HSSP Identity Cross-Reference Service (IXS), formerly Entity Identification Service (EIS) and Identification Service (IS).

IDENTITY_MANAGEMENT_AND_UPDATE Interface:

Table 4.9: IDENTITY_MANAGEMENT_AND_UPDATE Interface.

Name	Parameters	Description	Return Type
createIdentity-FromEntity	String systemId String sourceId String traitName Trait trait String entityId State state	creates an identity by inserting (based on the internal matching algorithm).	STATUS
createOrUpdate-Identity	String systemId String entityId Trait trait State state	creates or update a identity by providing a local ID (e.g. system ID, hospital ID)	STATUS
updateEntity-Values	String entityId String sourceId UpdateQualifier UpdateQualifier String traitName Trait trait State state	updates the s stored in the NIS for the Entity identified by the supplied Source ID/Entity ID pair.	STATUS
removeIdentity	String entityId String sourceId String traitName Trait trait	deletes a Source ID/Entity ID pair and its associated traits from the NIS repository.	STATUS
getEntityValues	String entityId String sourceId String traitName Trait trait	retrieves the s associated with a Source ID/Entity ID pair.	STATUS

Name	Parameters	Description	Return Type
findIdentities-ByTrait	String entityId String sourceId String EHRId SearchQualifier searchQualifier String traitName Trait trait ResultSet matchin-gResultSet State state	provides the means to per-form a broad search of all records in the NIS whose s match some criteria in the supplied search criteria (such as find all records who match the name "Jones, Bob".	STATUS
listLinked-Identities	String entityId String sourceId SearchQualifier searchQualifier String TraitName Trait trait ResultSet matchin-gResultSet	retrieves all the Source ID/Entity ID pairs that are linked to the supplied Source ID/Entity ID pair.	STATUS
listUnlinked-Identities	String entityId String sourceId SearchQualifier searchQualifier String TraitName String TraitName Trait trait ResultSet matchin-gResultSet	retrieves dupli-cately specified, yet unlinked records in the NIS reposi-tory. It filters the record set to only re-turn matching, but unlinked records.	STATUS
listDomains	List<String>listOf-Domains	lists the domain hierarchy con-figured in the service meta-data repository.	STATUS

IDENTITY_ADMINISTRATION Interface:

Table 4.10: IDENTITY_ADMINISTRATION Interface.

Name	Parameters	Description	Return Type
linkEntities	String sourceEntityId String sourceSouceId String targetEntityId String targetSourceId String reasonCode String traitName Trait trait	creates an explicit linking between the source and target record IDs in the NIS repository.	STATUS
unlinkEntities	String sourceEntityId String sourceSouceId String targetEntityId String targetSourceId String reasonCode String traitName Trait trait	provides the means for explicitly breaking the link between the source and target record IDs in the NIS repository.	STATUS
mergeEntities	String sourceEntityId String sourceSouceId String targetEntityId String targetSourceId String reasonCode String traitName Trait trait	provides the means to explicitly consolidate entity record in the NIS repository.	STATUS
unMerge-Entities	String sourceEntityId String sourceSouceId String targetEntityId String targetSourceId String reasonCode String traitName Trait trait	reverses the merge entities process.	STATUS

Name	Parameters	Description	Return Type
activateEntity	String entityId String sourceId String reasonCode String traitName Trait trait	marks the record as “active” in the EIS repository.	STATUS
deactivateEntity	String entityId String sourceId String reasonCode String traitName Trait trait	marks the record as “inactive” in the NIS repository.	STATUS
getVersionForEntity	String entityTypeName String localEntityId String systemId	returns a version code of specified entity type.	STATUS
setVersionForEntity	String entityTypeName String localEntityId String systemId String versionValue	sets a version code for specified entity type.	STATUS

IDENTITY_TRAIT_MANAGMENT_AND_UPDATE Interface:

Methods:

Table 4.11: IDENTITY_TRAIT_MANAGMENT_AND_UPDATE Interface.

Name	Parameters	Description	Return Type
createTrait	TraitDefinition trait	creates a entity trait definition in the service meta-data repository.	STATUS
findTrait	String TraitName TraitDefinition trait	locates and returns a trait definition from the service meta-data repository.	STATUS
updateTrait	String TraitName TraitDefinition trait	updates a trait definition in the service meta-data repository.	STATUS
listTraits	String entityTypeName List<String>listOfTraits	list the s registered with the system.	STATUS
listConformanceProfiles	Array<ConformanceProfile> listOfConformanceProfiles	returns the list of conformance profile names and versions that this implementation of service supports.	STATUS

Chapter 5

IMPLEMENTATION EXPERIENCES

The previous chapters have described the background to the project from a national and international perspective and provided an overview of the primary focus of the work, the EN13606 standard and the compatible standards. This chapter will provide an overview of some of the key development and experimentation work that was carried out during the course of the EHR*land* project. it was mentioned in earlier chapters that the EHR*land* project team adopted both bottom up and top down perspectives on the EHR problem. The work from the bottom up perspective was carried out within two scenarios.

- Patient referral from a general practice to a Diabetes clinic.
- Shared (nursing) care for older people in the community.

These two scenarios result in different technological focuses. The diabetes scenario, broadly speaking deals with legacy systems and the communication of information that is well understood and for which there is some existing archetype-based support. The shared care scenario on the other hand, is not so well supported by archetypes and there were no legacy systems in place. For this second scenario, the focus was placed on the clinical engagement aspects of the two-level model approach, how to involve interested stake holders and other domain experts.

From the top down perspective i.e. those services that would need to be provided at a national level, members of the project team considered issues to do with identity and identifiers and terminology. The following sections describe some of the experiences of the project team in these disparate aspects of the project work.

5.1 Using EN13606 in the context of Diabetes Referral between general practice and diabetes clinic

The objective of this scenario was to implement an exchange of relevant information between health professionals involved in the detection of Diabetes Metillus type II for a patient. As the project team were using a two-level approach (see Section 3.2), the description of the relevant information to be exchanged was left to the domain experts. Secondly, as health informaticians, the DIT development team focused on the creation of archetype-compatible technologies or adaption of existing ones to integrate the use of archetypes.

5.1.1 Describing Information using Archetypes

Previous chapters have described how Archetypes define data structures for the EHR that have been agreed among communities of domain experts. Before creating new archetypes, a crucial step is to search archetype resources for archetypes which can be reused and possibly adapted (through specialisation). This first step led to the collection of archetypes from two repositories:

- the NHS Connecting for Health / openEHR archetype repository, and
- the openEHR Clinical Knowledge Manager.

The pre-selected archetypes were subsequently shown to experts for approval and filtering. At the end of the selection process, the following archetypes were obtained .

5.1.2 Existing Technologies: the GP side with HealthONE

The HealthONE Model

Integrating EN13606 with (HealthONE), an information that uses a two-level approach

Health Ireland Partners were a partner in the EHR*land* project. Their role was to investigate the relationship between their General Practice EPR application, HealthONE and EN13606 communications. The HealthONE software application is associated with a long history of implementation of standards based patient record structures and thus it is interesting to compare how data is handled in HealthONE in comparison to other software solutions in the Primary Care market in Ireland. Participation of Health Ireland Partners in the study was opportune as it allowed the team to review the capabilities of a standards-based approach solution and question if such a framework is beneficial to the overall information integration goals of the EHRcom standard as implemented in the EHR*land* project.

The traditional approach to data storage in a healthcare environment has typically been driven using standard engineering techniques with tried and tested relational model mapping. While this kind of approach is reasonable and makes sense from a pure software engineering point of view and is very suitable for a myriad of applications and domains, on many levels it is neither sufficient nor flexible enough to cater to the needs of healthcare, especially in relation to the electronic healthcare record.

From a development point of view, the inflexibility of the standard relational model has proven problematic over the years, generally requiring more development man-hours to produce change and output than a corresponding model based on a more object based pattern. If we take the simple example of measuring blood pressure; on first glance it would seem that one needs to simply record two figures, systolic and diastolic pressure. This proves too restrictive however when additional attributes of measurement need to be recorded (sometimes, but not always), such as the state of the patient before and after taking the recording, the position of the patient's body (sitting, prone, standing), the site of measurement (upper arm, leg). It is clear as one looks deeper into the requirements

of clinical data recording that object based flexible models of recording and structuring data are preferable for a multitude of reasons.

Historically, data has been recorded on paper in either a verbose ad-hoc format, or structured (or semi structured) into paper based forms. A tried and tested method of transferring a system from manual to computer has been to take such forms and after analysis, simply provide on-screen representations of same, with corresponding underlying data structures. This approach in many ways is flawed as it assumes the existing methods of data collection are both correct and efficient and does not take into account data or system interoperability. Most software solutions in the Healthcare market in Ireland are form based, and thus inflexible in their ability to change in real-time, according to the needs of the user and indeed the system itself.

HealthONE was designed from the ground up to integrate and promote four core areas; portability, flexibility, clinical detail and security. The architecture for the original design was based on work carried out by CEN Technical Committee 251 in 1995 [44]. The original work and design sought to investigate if the theories proposed by the CEN standard could be implemented in a practical manner. As the architecture developed, concepts and ideas were also incorporated from the "Good European Healthcare Record" [77]. The architecture of HealthONE was based on a merging of standard engineering principals (three tier architecture, with data persistence, business logic and user Interface carefully kept isolated and unlinked) and clinical data management concepts from CEN TC251 and GEHR. Both data storage (persistence), and display (user interface) utilise a granular, hierarchical approach to clinical data, and the separation of business logic allows a "plug in" architecture that allows the system to interoperate easily with health record messages in a large array of formats. For example HL7, ASTM [78] and Dicom [79].

EHRcom (EN 13606) is a standard with a flexible but stable information architecture that enables full or partial electronic records to be communicated between systems. In many respects, this standard builds on earlier research such as CEN TC 251 and GEHR, which of course are the foundations on with HealthONE was built. The similarities between the requirements of EHRcom and the functionality of HealthONE is strong, with clinical data granularity, security and interoperability shared as core objectives.

The structure of a HealthONE electronic record (described below) is based on an object hierarchy that consists of different parts, including audit information (record creation/modification details), security (authorship, role access), ownership (creator, author, institution), patient demographics, and finally clinical parts. The clinical part attempts to ensure coding links with internal HealthONE clinical dictionaries, and beyond this, to standardised taxonomies (ICPC [80], [81], etc). Each part of a record is extremely flexible and allows a tree like structure to be build up by the user on the fly if required. Thus information deemed important for recording by one clinician, but not another, can be captured without restriction or pre-development of the user interface or data persistence layer. This structure maps extremely well to EHRcom and coupled with the plug-in architecture already referred to would allow HealthONE to interoperate on both a query and data extraction level in a manner compliant with the standard. The design of HealthONE is such that any plug-ins required to facilitate interoperability with other systems using the EHRcom standard as a common exchange mechanism can be done independently of the core HealthONE system itself and would appear transparent to the end user.

The HealthONE health care record (HCR)

The HealthONE HCR roughly corresponds to a single practices share of the EHR. It is equivalent of the patient's folder in the GP administration terminology. It contains the following containers for health information. Chapters are composed of Pages which correspond to health transactions. *Pages* can also contain *Items*. HealthONE *Items* are close to EN13606 *Items* and can be organised into ordered lists using *Sequences* or gathered together in a set using an *Aggregate Item* which roughly corresponds to a EN13606 *Cluster*. A brief description of some the main constructs and an example is provided below.

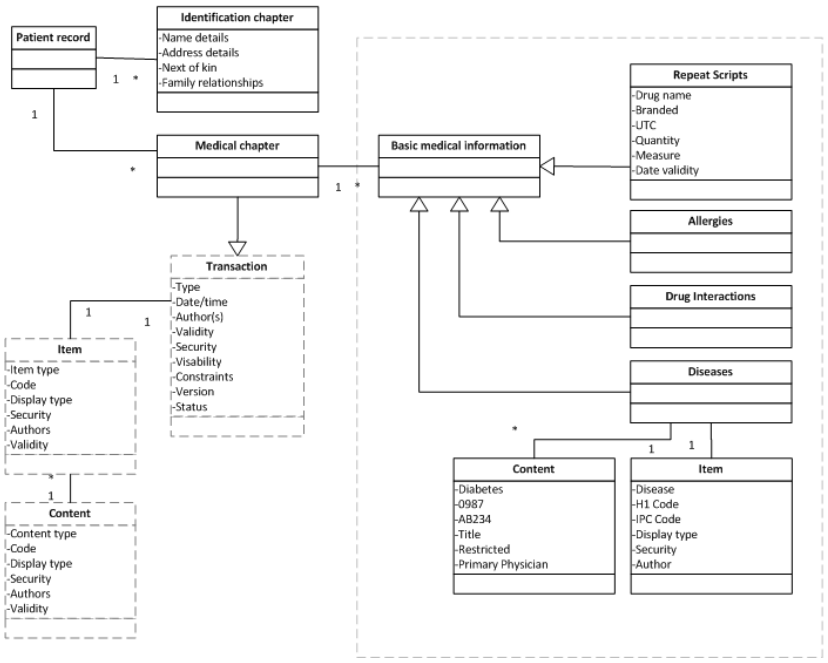

Figure 5.1: HealthONE Information Model

HealthONE Concepts

1. Administrative chapter: The first page of this section of the HCR is a transaction with fixed name attribute value "identification". It is equivalent to persistent compositions in openEHR. It Contains Name. Date of Birth, Sex, Address, Occupation etc. Additional transactions can be added to the administrative chapter but they can only be of type "Administrative transaction". Possible attribute name values are "basic administrative information", "medico-social status", "information related to service", "addressee", "subscription", "additional social data".

2. Medical chapter: The first "page" of this section of the HCR is a transaction with fixed type "Basic medical information" This is roughly equivalent to a persistent composition in openEHR as it contains the "state or situation of the patient". The content in this container is likely to evolve slowly, as new allergies appear for example. Page two of the Medical Chapter and subsequent pages are transactions with the following possible type attribute values:

- "Contact". In this case, possible values for transaction name attributes are "consultation", "visit at home", "drug prescriptions", "obstetrics", "lab", "radiology", "consultation by telephone", "specialized examination", "health check-up", "planning", "expert's report", "payment", "vaccination". Additional names can be added from a longer list in the HealthONE configuration tool.
- The remaining possible type values are: "Institution admission", "Institution discharge", "Department admission", "Department discharge", "Basic medical information", "Summary". They do not use the transaction name attribute. these transactions roughly correspond to event compositions in openEHR, while each page corresponds to a consultation/contact with the patient: probably the equivalent of an event composition in openEHR.

3. Transaction: This is defined as "...the general name given to any page in the Health Care Record", It has the following attributes:

   - Type: mainly "contact" and "basic medical information" for a general practice (the most common types). Other types include "Institution admission", "Institution discharge", "Department admission", "Department discharge", "Summary". item Name: reason only for a "contact" type, it can be a consultation, a visit at home, a lab, a vaccination, a payment, etc This could map to the name attribute of the composition.
   - Responsible: "person responsible for creating or maintaining this transaction". This could map to the composer attribute of EHRcom COMPOSITION.
   - Author: the person who validates the transaction. Could map to attributes of the attestation info for the composition the transaction is mapped to.
   - Date of event: question: it is by default set to the current date and time but can be modified if the transaction refers to a past event.
   - Speciality: "specifies the medical speciality being recorded." Possible values include "general practice", "occupational medicine", "radiology", "lab", "chemical pathology", "histo-pathology", "paedratics", "haematology", "gynaecology", "cardiology", etc... (quite a long list, see software).This information may be included in functional information of the composition.
   - Legal structure: corresponds to the role of the performer. Does it refer to the person responsible? Could be mapped to the functional information of the composition.
   - Comment: "gives the user additional flexibility in tagging transactions. You can insert any free text you like here. Alternatively you can use an associated list of preferred terms that can be defines using the configuration tool." could be an extra free text entry to the content of the composition.
   - Problem: a set of problems the transaction is linked with. The problems seem to describe more persistent and generic aspects of the health of the patient to which transactions are linked. they could be expressed as persistent compositions to which other compositions are linked, or as folders to which other compositions belong.

- Status, Version, Creation, Validation, and Modification attributes:
  - When a transaction is created:
    Status is set to "Current, Temporary".
    Version is set to 0.
    Creation, Author and Date are set.
  - When a transaction is saved (temporarily) without validation: the status does not changed
  - When a transaction is validated:
    Status is set to "Current, Valid".
    Version is set to 1.
    Validation, Author and Date are set.
    Modification, Author and Date are set.
  - Each time the transaction is modified and validated (at this stage you don't seem to be able to save temporarily):
    Version value is incremented.
    Modification, Author and Date are reset.
- Transaction status:

  not saved or validated: as it's not committed to the HCR, it does not make sense to map this to EHRcom. The attribute value is "Current, Temporary".

  saved but not validated: may be mapped to a composition that has no attestation info. The attribute value is still "Current, Temporary".

  saved and validated: may be mapped to a composition that has attestation info. The attribute value is "Current, Valid".

  previously validated but modified and not yet validated: may be mapped to the last version of a composition with no attestation info. The attribute value is still "Current, Valid".

  Transaction types are associated with some items as a default minimal content (e.g. type "Basic medical information" contains by default items "basic medical information", "medical history", "surgical history", "tobacco", "alcohol consumption", "blood group", "problem".

4. Item: a unit of information recorded in a transaction, equivalent to an entry or an element. It has the following properties

   - Item selector: an internal dictionary of item types or names (e.g. subjective symptoms, objective findings). Can be expressed with the name attribute of the a record component. This dictionary may be mapped to SNOMED-CT code or archetype node locations. Question for Allen: is it a type, i.e. it changes the inner structure of the item, or just a name for human readability and querying?
   - To help populating the free text content of the item, HealthONE provides:

     "The Term Dictionary: a complete list of terms known to HealthONE",

     "The Associated List: a list of terms related to the current Item" (e.g., "subjective symptoms" has an associated term list). In turn, the terms chosen

have their own associated list of terms. Terms from sub-lists can be selected without their parent.

"The Permanent List: a list not related to a specific item that expresses degree, intensity, size etc as opposed to a particular complaint." It seems to be organised in a hierarchies or sub-lists (there is a first listof 9 terms, each of which will return more specific terms if selected).

- The use of the dictionary and the lists help the GP be consistent with his/her choice of terms, which is useful for later querying. We need to take that further so that the choices are consistent for the entire community. Note that free text can be entered between the terms selected.
- Some items have very limited list of possible values (e.g. sex), which means there has to be a way to highly contrain items.
- Item value/data type:

  Dates: HealthONE obtains its date format from the Windows Regional Settings.
- Item attributes:

  Name: name of the item.

  Content: value of the item

  Comment: line of free text.

  Severity Index: scales from 0 to 7.

  Display mode: for GUI purposes.

  Responsible: same meaning as for transactions.

  Date of event: same meaning as for transactions.

  Start date and End date.

5. Sequence:

   - A group of items as an ordered list although it is also defined as a "a predetermined set of Items that have been grouped together to suit a particular task."
   - a Sequence selector allows you to use templates containing certain items (e.g. "basic medical information").
   - Could be the equivalent of an entry containing a list of elements or a section containing a list of entries.
   - A sequence "is just a technique to quickly insert items. Once inserted these items can be edited, ignored, deleted, duplicated etc. like any other item that may have been inserted via the item selector, as in the previous session." This definition implies that it is more a GUI-oriented structure, although the fact that items were grouped together shows they form a component.

6. Aggregate item:

   - An item containing other items (which can contain other items).

- Aggregate selector: allows you to select predefined aggregates (e.g. blood pressure).
- Could be the equivalent of record component structures involving an entry and/or one clusters or more.

The HealthONE GUI

An overview of the HealthONE user interface is provided below.

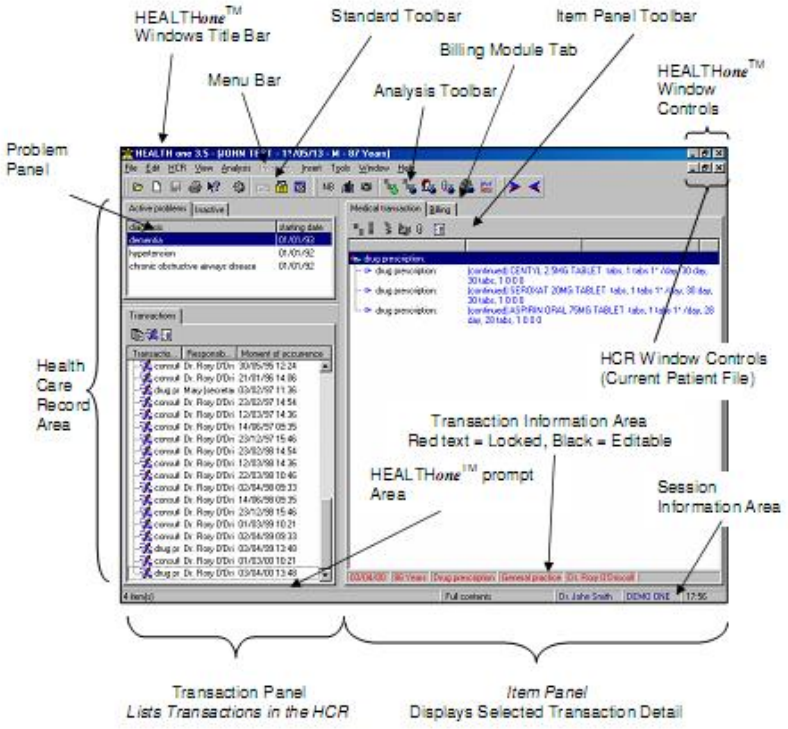

Figure 5.2: An overview of the HealthONE user interface.

The main GUI window is composed of the following graphical elements

- Problem panel.
- Transaction panel: shows the chapter and pages. Transactions are sorted chronologically by default but they can be sorted by the predefined types (e.g. Lab results).
- Item panel: shows content of the pages selected.
- Patient Selector Window:
- Filters (by name, gender, date of birth) allow to shortlist the patients. Columns can be taken out or added, they correspond mostly to the administrative chapter data.
- Analyses: these graphical elements are discussed further below.

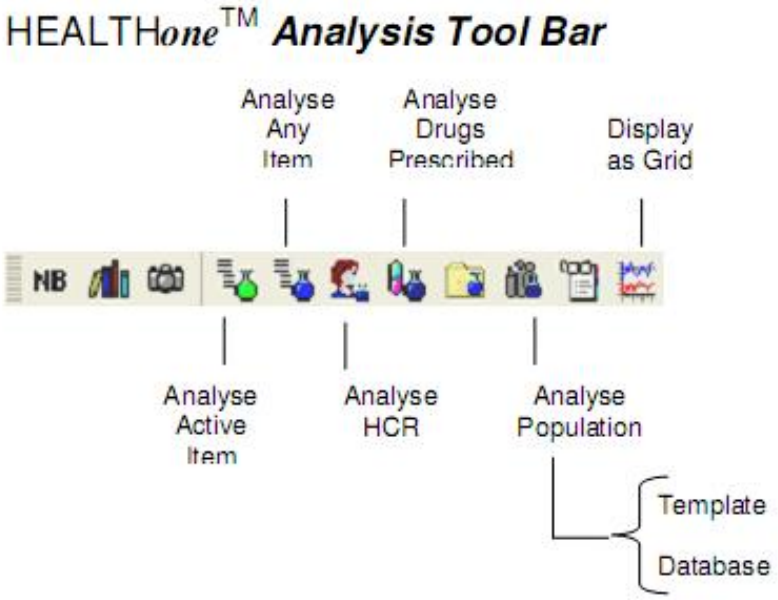

Figure 5.3: The HealthONE Analysis Tool Bar.

- Categories of analysis: the following are the analyses available at the click of a button (see Figure above).
- Individual Patient Analyses:

  Item Analysis:

  - Active Item in a patient's file
  - Any Item in a patient's file

  HCR Analysis: Multiple items in a patient's file. This could be the level at which we produce extracts. By default, there is a list of available HCR analyses like "liver profile" but others can be created by writing an analysis formula (not sure what the script language is).

  - Prescription Analysis: Drugs prescribed for a patient.
  - Grid Analysis: Numerical data, table/graphic representation, i.e. audiometry charts, percentile charts etc. "Grid analyses are based on one of three sources: 1)Predefined Grid Analyses, 2)any Sequence of Items, and

  Any Aggregate Item." The results can be exported to an excel file

- Population Analyses:

  Template: Produce a document that can be viewed, printed/saved.

- Database: Produce results that can be viewed, printed and/or exported. There is a number of pre-set analysis available. The result can be exported to a file, for example a csv file, although other delimiters can be chosen).

When performing the analyses (HCR, population), the SQL queries are visible. Could we interact with HCRs in order to create mappings in SQL for our demonstration? Or could we directly use analyses to encode the mapping to archetyped data?

Adapting HealthONE to EN13606

The HealthONE information entities described above (transactions, items, sequences, aggregates) are generic information content entities which show similarities with CEN EN13606 record components. For example, transactions could be expressed as compositions, items as elements or entries. Also, sequences and aggregates, which are organisational entities (as their main function is to organise other entities), could be expressed as a combinations of sections or clusters (depending on the type of record component they organise).

However, the mapping between models is not simply a mapping at the generic level, or the first level of EN13606. It is a mapping to agreed data structures of record component, the archetypes. Similarly, it is not appropriate to map a HealthONE transaction, as it is still a generic element, but particular semantically enriched transactions. The same can be said about other arrangements of items (i.e. blood pressure measurement) which may be reused in many transactions. HealthONE does offer by default specific transactions (identification, consultation), and item arrangements (blood pressure, SOAP observation), it implies the second level representation of structures of the generic information entities used in HealthONE. These second level structures however are completely customizable and reusable within the application in a similar manner to EN13606.

A known example of second level representation focusing on data entry control is the HealthONE Mediform. It allows the creation with a graphical IDE of a data entry form which may reuse existing structures such as sequences and aggregates. It includes functions using the data entered, to validate or return directly a result. More work is required to compare what can be expressed with Mediform with what can be expressed in an archetype. Nonetheless, based on comparisons and experimentation by the development team in Health Ireland Partners (now part of Helix Health) the Mediform certainly appears to be a strong candidate for configuring HealthONE to capture data which will be expressed later with structure of record components validated by an archetype. In that scenario, GPs would choose specific Mediforms when they want to share data according to specific archetypes. Mediforms offer a method of gathering information that while flexible and configurable, are also capable of being highly consistent where required, thus offering a very simple way of representing EHRcom style data gathering templates/segments visually, yet persisting them in a manner consistent with acceptable structures.

The investigation of HealthONE has shown that due to its legacy of being built on a standards based architecture, it does not represent a significant challenge for integration with EHRcom. However, the same cannot be said for other systems currently on the market which have been designed in a completely different manner. EHRcom strives to provide a highly flexible, fluid model for data extraction and transmission. This investigation has shown that because of the two level nature of HealthONE and its resulting flexibility, integration with the HealthONE system does not give a representative view of integration with other legacy systems currently in the marketplace.

5.1.3 Legacy system integration for EN13606

The second variation on the Diabetes referral scenario focused on EHR exchanges between a general practice and a hospital. The associated technical scenario involved the transmission of patient data collected by a GP to a hospital using an EN13606 record extract based on an EN13606 archetype that has been agreed by both parties. This section describes the steps that would need to be taken on the provider side (the GP) to contribute to the EHR. This was investigated through two different mechanisms. Firstly, for EHR system developers without two-level functionality, who wished to embed legacy system integration capabilities into their existing applications through development of a special purpose software component. Secondly, for legacy system integration using an integration engine which could either preprocess information in "legacy" formats such as HL7 v2.x so it could be imported into an EHR application (i.e. Synthesised record components), or could transform the relevant output of a legacy system from HL7 form to EN13606 form.

5.1.4 Legacy System Integration: Factory Classes for the EHR Extract Provider

Analysis of Constraints and their Scope

The model of part 1 of EN13606 provides a set of core classes: the building blocks of the EHR, the record components, classes of objects contained in record components, and data type classes essentially contained in record components of type ELEMENT. These classes will be instantiated for operations such as data creation or data access. When part 2 of EN13606 is used, the instantiation of a structure of record component follows a receipe of constraints, the archetype, which can be further restricted by local choices made for a specific EHR provider.

However, independently from instructions contained in archetypes, the state of objects at instantiation time may conform to constraints specified in other parts of the standard (part 3 of EHRcom), by the national EHR implementation (e.g. EHR*land*), and by local implementation decisions for the EHR provider (EHR system). In the context of the open source development effort for the EHR, the team examined what type of "factory" classes could help developers implement EHR providers. In particular, team members attempted to answer the following questions:

- What are the generic components of an EHR provider? Can generic interfaces and base classes be provided for developers to reuse when they are developing an EHR provider?
- What is EHRcom-specific EHR*land*-specific, system-specific or patient specific in the EHR provider and the extracts it generates?

The project team then considered the internal state of EHRcom objects (i.e. the fields or attributes of the classes) and distinguished parts of the state which were determined by national or local constraints. Additionally, 2 further sub-levels were distinguished (EN13606 constraints and EHR*land* constraints) for national constraints and 4 sublevels (System-specific, Patient-specific, Template-specific (e.g. HBA1C), and Instance-specific

constraints) for local constraints. Table **??** summarises this analysis with row corresponding the EHRcom classes and their attributes, and columns to the different level/origin of constraints. The results of this analysis are contained in the table of Appendix K.

Java Interfaces

Members of the project team designed Java interfaces and named most of them with the concatenation of the class of the object they build (e.g. "Extract"), and the word "Template". Templates in this section refers to a receipe for the building of a particular object, and by extension the building of EHR structures made of such objects. Figure 5.4 shows a diagram representing the Java interfaces.

The ExtractProvider interface specifies some of the methods mentioned in part 5 of standard EN13606. All methods have at least the subject of care ID as a parameter and return an EHREXTRACT object. Additionally, the methods getExtractByArchetypeId, getExtractByRcId, and getExtractByTimeInterval have a set of archetype IDs, a set of record component IDs, and an interval of time as a parameter, respectively.

The EhrIdFinder interface has a single method which returns an II object, and EHR ID, and has a subject of care ID as a parameter. An implementation of this method will find the EHR ID which correspond to the subject of care ID given. In EHR*land*, subject of care IDs are unique whereas EHR IDs are managed locally in each EHR systems.

The ExtractTemplate interface has a single method getExtract which returns an EHREXTRACT object and takes no argument. This interface is used to initialise an EHREXTRACT object with the default internal state specified at the national or local level.

The IITemplate interface has a single method getII which returns an II object and takes no argument. This interface is used to initialise an II object with the default internal state specified at the national or local level.

The RootCompositionTemplate interface has a single setCompositions method which returns a set of compositions and takes as an argument a set of IIs which refer to compositions located at the top of a record component structure. This method is a receipe for building instatiations of compositions submitted to the EHR from their IDs. The returned compositions contain all the data needed for inclusion in the extract.

The RootCompositionTemplateMapsFactory interface has four methods which all return a Map with keys of type RootCompositionTemplate and values which are sets of IIs. The map gives a pair of record component structure receipes (implementations of RootCompositionTemplate) and the IDs of compositions located at the top of the structure and which content needs to be built according to the associated RootCompositionTemplate. All four methods take an EHR ID as an argument. The getTemplateMap method only takes an EHR ID as an argument. The getTemplateMapByArchetypeId, getTemplateMapByRcId, and getTemplateMapByTimeInterval methods take an additional argument, a set of archetype IDs, a set of record component IDs, and a time interval, respectively.

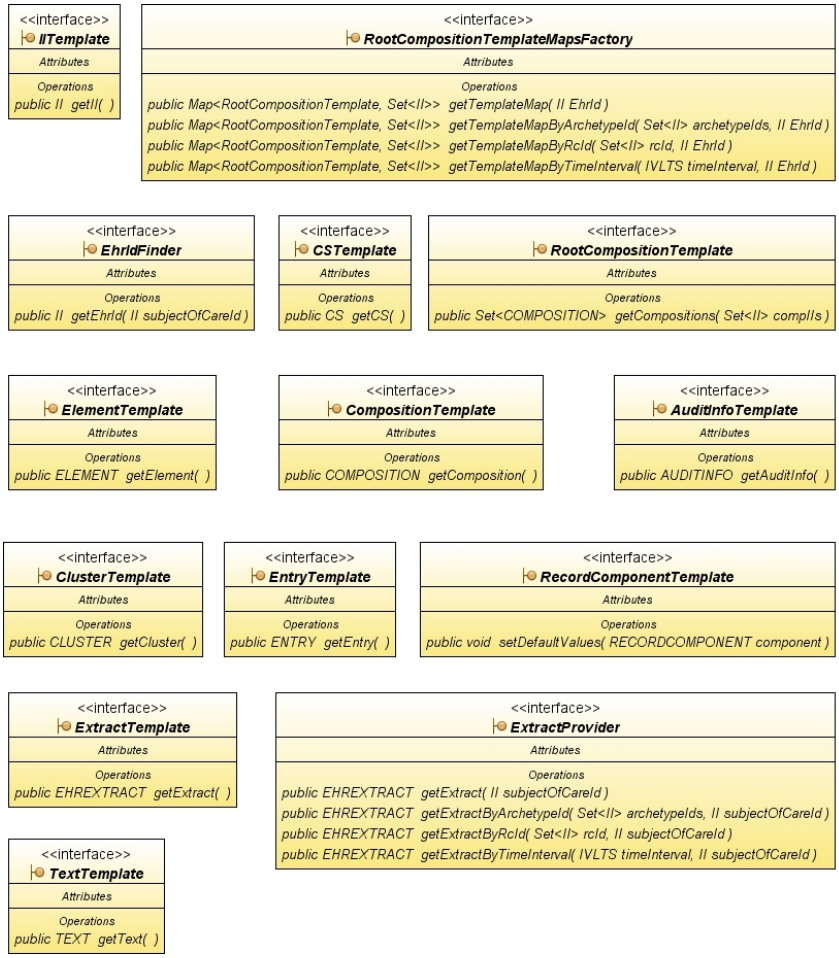

Figure 5.4: UML Diagram of Java Interfaces.

Java Implementations

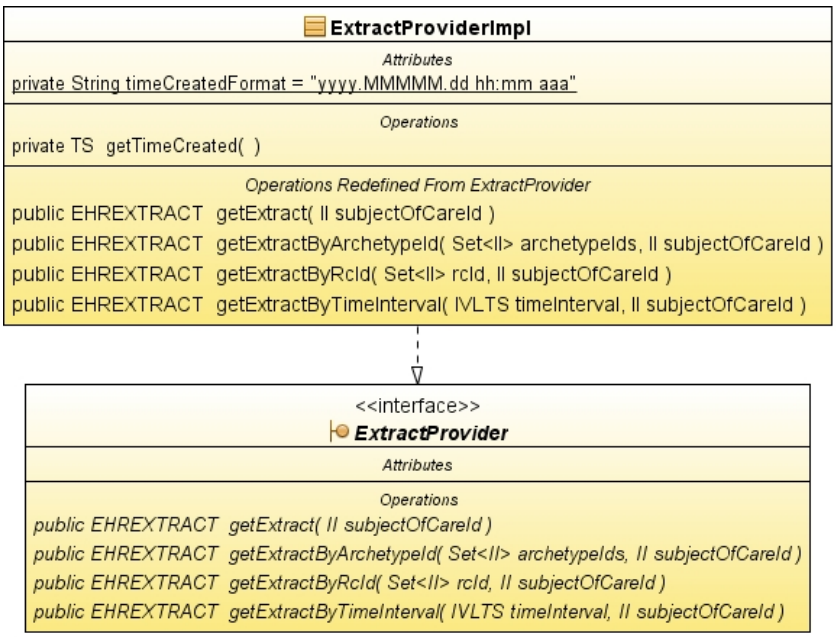

Figure 5.5: Interface of ExtractProviderImpl.

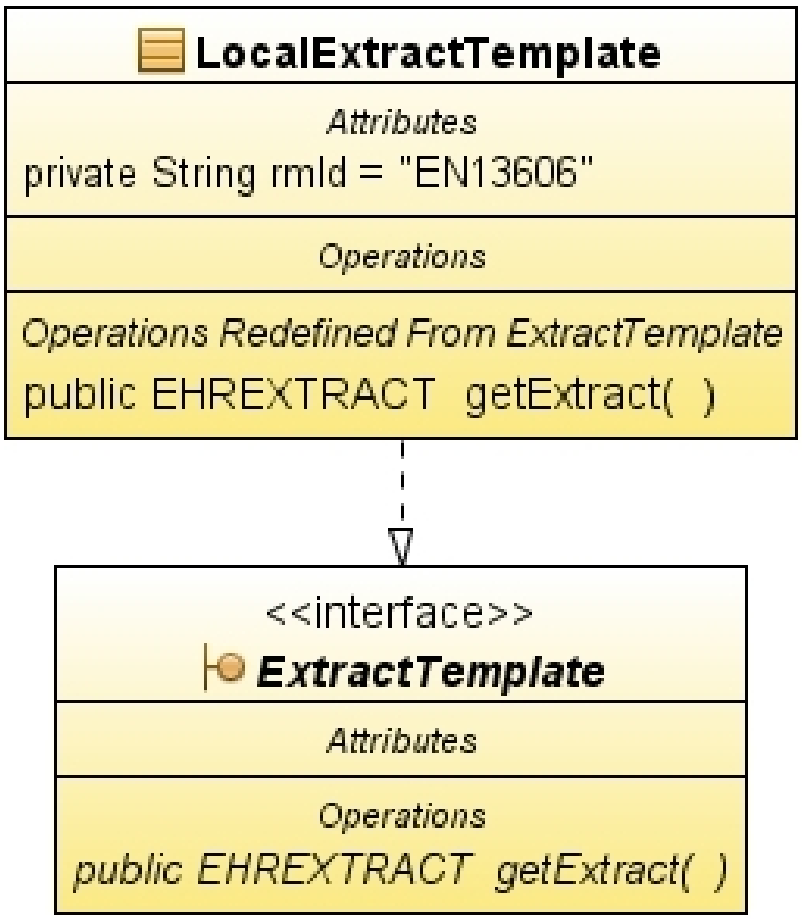

Figure 5.6: Interface of LocalExtractTemplate.

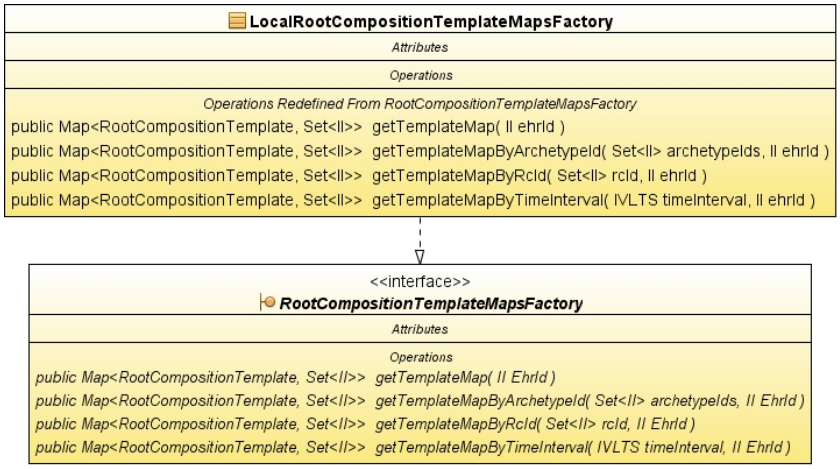

Figure 5.7: Interface of LocalRootCompositionTemplateMapsFactory.

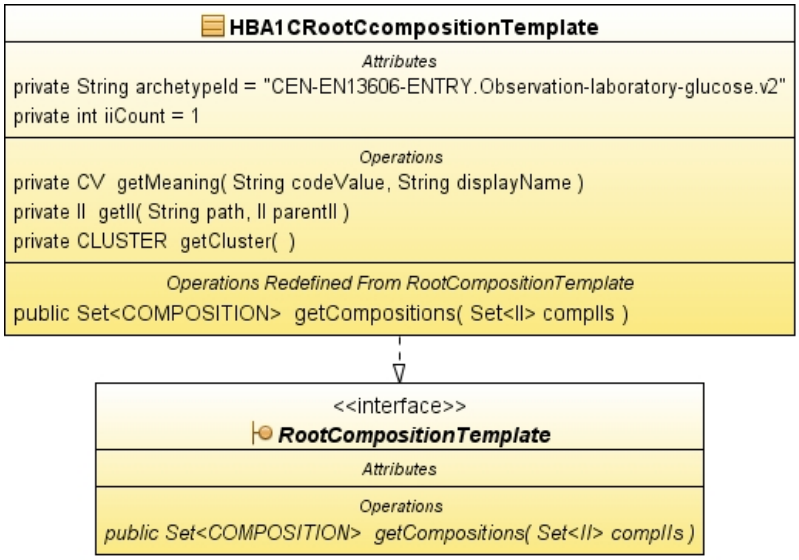

Figure 5.8: Interface of HBA1CRootCcompositionTemplate.

Legacy system integration to two level model based systems comes at a cost. One aspect that needs to be considered is the impact on size and efficiency of data sources that are required to add detailed context and maintain globally unique identifiers. According to experiments conducted by the project team, a two-level retrofit for a system with an annual throughput of 33 million records of laboratory investigations would result in database size of over 500 GB of data per year. In a simple table without identifiers and context would occupy orders of magnitude less space. This is an area that merits further investigation. Heterogeneity of coding, identifiers or schemas can cause implementation difficulties. The transition from the potential ambiguity of legacy systems to the relative order and explicitness of a two-level approach can also be problematic. For example, the project team examined comments accompanying a number of HBa1C measurements. Over 2,700 disctinct comment values were recovered. Removal of slightly different copies

resolved the list down to the following much shorter(!) list of brief comments.

2 hr PP Glucose, Abdominal (Distension/Bloating/swelling), Abdominal (Pain / Discomfort), Abnormal Iron Studies, Abnormal Liver Function Test, Abscesses, Acromegaly, Acute Cholecytis, Admission Bloods, Alcohol Excess, Alcoholic Liver Disease, Ald Cirrhosis, Aleamia, Alzheimers, Anaemia, Arthralgia, Arthritis, Black runny stools, Bleeding prerectum / bleeding from Bowel, Blood Pressure, Blurred Vision, Borderline Diabetic, Bowel obstruction, Breast Cancer, CAD, CD assessment, Chest Pain / Discomfort, Cholesterol Raised, Chrohns Disease, Chronic Diarrhoea, Chronic Renal Faulire, Coeliac, Collapse, Colorectal Cancer, Confusion, CVA, CVD, CVH, CVXB, Cystisis, Cysts on kidney, Deranged lipid profile, DFGS, DFH, Dilated cardiomyopathy, Diplopia, Diverticulum, Dizzyness (acute), Dry Mouth, Dyslipidaemia, Dyspepsia, Dysphagia, E46tw, Elderly, Eosinophilic myocytis, Epigastric Pain, Epiliepsy, ERGTA, Eye infection, Family history diabetes, Fasting bloods, Fasting OGTT, Fasting Risks, Fasting bloods, Fatty Liver, Fertility test, FHX, Fibrosis, Folliculitis, Gaynaecomastia, Glucose intolerance, Goitre, GORD, Gout, Graves, H C282Y, B.S, H/BP, H/O Ischeamic, Haemachromatosis, Haematuria, Haemocrhomotosis, HCV G1 Stage 2, Headache, Heart watch, Hepatitis B, Hiatus Hernia, HONK, HTN, HX, Hypercholesterolaemia, Hyperferritinaemia, Hyperglycaemia, Hyperkalaemia, Hyperlipidaemia, Hyperparathyroidism, Hypertension, Hypertriglyceridaemia, Hypoadrenalism, Hypothoroid, IBD, Infection in toe, Leg cramps, Leg ulcers, Lensslq1, Loose Motions, Low B12 in past, Low ferritin, Lymphoma, Metabolic syndrome, MODM, Muscular Pains, Nash, Nausea, Nausea, Necrotizing Pancreatitis, Neuropathic Ulcer, Neuropathy, New Diabetic, NIDDM, Night sweats, Nocturia, Numbness (hands, legs, arms), Obese / overweight, Oedema, Oesophegal cancer, OGISS, OGTT, On / Off (CRESTOR, clozapine, septrin, deltacortril, epilim,eltroxin, glucophage, isonaizid, istin, keral tabs, lithium, lipostat, omezar, olanzapine,warfarin), On insulin, On Statin, Pagets, Pain abdomen, Pancreatitis, Parkinsons disease, Ployps surveillance, Polydipsia, Polyuria, Poor control, Post (procedures etc), Pre (lots of stuff), Pre-op, Bloods, Previous (lots of stuff), Pruritis, Raised (lots of stuff), Recurrent abcess, blisters, diarrohea, infection miscarriage, UTI, vaginal itch, Renal Disease, Shingles, Short of breath, Sjorgens ,Sleep apnoea, Sore mouth, Steroid induced diabetes mellitus, Stroke, submandibular swellin, Sweating, Swollen (knuckles, ankles), tatt, Tegretol, Thirst, Thyroid, Thyroid Disease, Thyrotoxic, Tiredness, Toe Pains, Type II Diabetes Mellitus, Underactive thyroid, Unwell, Urgent guide, Varicose veins, Vomiting, VTE ,Waldenstroms Macroglobulinaemia, Weight (gain/loss), Work up, Xerostomia, Yellow skin, ZBC, ZXC, ZXVC, ZXVG.

On the other hand, the following much shorter list could be considered as a more focused set of comments to accompany a HBa1C measurement.

New diabetic, Type two Diabetes, Alcoholic disease, Haemochromoatosis, 2hr PP Gluc, Tiredness, Blurred vision, Borderline diabetic, Deranged lipid profile, on insulin, Metabolic syndrome, Poor control.

In wholly archetype-based setting, the shorter list could be suggested to the user, but where the information has already been defined in a legacy environment, there is little opportunity to derive this benefit from the two-level approach. One accompanying issue

is how to map data resulting from the open policy of such a feeder system to the more prescribed archetype-based approach. The problem of mapping from legacy systems has been investigated by Chen, [82] who demonstrated how a legacy EPR system could be incrementally modified to support a two-level approach. This approach requires further investigation however.

5.1.5 Legacy System integration using an Integration Engine

This approach is close to a minimum implementation in the sense that it involves the lightest use of EN13606 tools and services. In order to transmit the patient data to the hospital, a GP's software would need to be modified to comply with the EN13606 standard. This solution is not always feasible for economical and technological reasons; moreover, given that the majority of legacy systems within a general practice or otherwise do not support two-level approach. This presents a problem in the absence of an intermediate two-level mapping module of the type described in the last section. The variety of both patient data and EN13606 archetypes would require a constant upgrading of the GP's software.

In any case, to achieve such a requirement, the existing software would need to

- be modified to extract the relevant data (in any format, proprietary or not)
- convert the data into an EN13606-compliant format following the rules of an agreed archetype
- transmit the data

In order to avoid directly modifying the various software solutions currently deployed at GP practices while adopting a mimimalist approach to two-level model based EHR system, the use of an interface/integration engine (IE) was investigated as part of an EN13606 communications solution. IE software is designed to accept data from a known source, modify the received data, if needed, to accommodate one or more receiving targets and transmit the data. An IE covers all of the requirements for transmitting data from a GP to a hospital using an EN13606 archetype. In order to demonstrate the feasibility of the experiment the Mirth Connect engine from the Mirth Corporation was chosen. It is an open source IE with growing interest from the Health-care community. And it has functionality that explicitly supports HL7v2.x messages.

The business model of the Mirth Corp. relies on income from customer support, training and consultancy. The software is freely downloadable from the internet with no restrictions. The installation is straight forward, requiring the user only to browse through a set of configuration panels (the default values being in the vast majority of cases acceptable).The Mirth Connect engine supports a variety of message standards (e.g. HL7v2.x, HL7V3, XML, ICOM) and communication protocols (TCP/IP, files, database, webservices). It can be easily programmed via javascript and extended via Java classes.

Companion administrator software allows the user to create channels (processes reading from a source data which is subsequently modified to fit a target) and monitor the incoming and outgoing messages. The LinkEHR-ed tool allows the user to create an XQUERY file that maps from a known data structure to an EN13606 patient record extract following the strict rules of an archetype. At the time of writing the tool only

supports the XML data structure.The natural approach was to combine the result of the LinkEHR-ed mapping tool with the Mirth connect engine:- the engine handling the retrieval and transmission of the data and the LinkEHR-ed XQUERY handling the transformation from local XML to EN13606 XML.

In order to proceed, it was necessary to embed the XQUERY with the IE. As previously stated, Mirth Connect is easily extendable/programmable via JavaScript or Java. A simple Java class with a single method was written to accept an XML string as an input; The EN13606 XML was then produced by the Java class which delegated the XQUERY processing to an XQUERY-specialized open-source library (the Saxon library for Java in our example); the sole purpose of the Java class was to call the library and return the produced output.

Using the Mirth Administrator Graphical User Interface, the IE was programmed to accept incoming HL7 v2 messages and transform them into XML messages whose structure was previously defined as part of the LinkEHR-ed mapping procedure. The local XML messages produced by the first channel were then fed to a second channel that handles the EN13606 XML transformation by calling the Java class extension. The generated EN13606 XML could then be transmitted. At this point, one should agree on the transmission protocol with the receiving end (the hospital); As mentioned above, a number of practical options are possible as Mirth supports various communication approaches.

The experiment has demonstrated that it is feasible to produce an EN13606-compliant record extract from a legacy data source (a GP repository) using readily available free software and with limited technological knowledge.

5.1.6 Comments on the validity of this approach

As this experiment being realized in a theoretical environment one can expect additional hurdles when using this approach in a real-life environment:

The first problem is the choice of data that a GP might want to send to the hospital: one could conceive the extension of the GP's software to allow the practitioner to flag the data to be transmitted or to directly produce the HL7 message used as a source for the IE. This would however require a (usually minor?) upgrade to existing GP software. Another approach could be through the use of a second software dedicated to flagging and or producing the HL7 message. If such a software is not developed by the producer of the GP's software, then one must know the repository's data structure in order to produce the HL7 message. This problem also arises if the (original or companion) software only flags the data and leaves the production of the HL7 message to a third party.

A second problem lies in the variety of HL7 messages. It is possible to produce many different HL7 messages to transmit the same data. The integration should be able to understand all of these messages, thus requiring a mapping for what could turn out to be large numbers of messages. If you consider that in general there is a different archetype for each type of recorded health observation, the number of mappings could rapidly multiply.

The use of a local XML message can constitute a third problem: as there can be many types of HL7 messages, the local XML format should be able to accommodate them all. On the other hand, existing work by the GPIT group and the subsequent release of the General Practice Messaging Standard [83] has led to standardization of HL7 messages

that could minimise the number of required mappings for local systems.

A natural approach would be to convert the HL7 v2 message to its XML representation or directly to HL7 v3 (which is an XML format). Unfortunately at the time of writing the version of LinkEHR-ed did not support the dotted notation (for example the <OBX.1>tag). It is expected that a future version of LinkEHR-ed will accommodate such a requirement.

The generation of OIDs and IIs can constitute a fourth problem. These unique IDs are created by concatenating a registry-assigned prefix (for example all patient data relating to a given GP) with a domain-specific identifier. The HL7 message may not necessarily provide the information allowing for the unique identification of the data contained in the message.

The Integration Engine approach allows however for a Java class to be called to generate such an ID "on the fly". This issue will be further discussed.

Despite the above issues and the lack of maturity of the tools, the overall experience of this approach was positive as it was possible to generate an EN13606-compliant record extract using only graphical user interfaces: LinkedEHR guarantees the compliance with the chosen archetypes while Mirth Connect alleviates the problems regarding connection and data transmission between two structures. As the XQUERY integration with the IE was straightforward, requiring only a few lines of java code, one could expect such an integration to be made available right out of the box in a future version of Mirth Connect.

Although the use of Graphical User Interfaces helps in producing the mapping XQUERY, it does not change the fact that the overall mapping process is a lengthy one. However with the right amount of training and an upgraded version of the LinkEHR tool one can expect to dramatically speed up the process; unfortunately it remains a manual process that cannot be completely automated. The wide variety of HL7 messages could make this a daunting task. For the whole scenario to succeed, it is therefore advisable to agree on both the set of HL7 messages to be produced by GPs and the archetypes to be used for producing the record extracts. Only with such an agreement can the time-consuming XQUERY generation task be limited while ensuring a consistent approach to health record data transmission for a wide variety of users.

A detailed "howto" document for this process has been created by members of the project team and it is available on the EHR*land* website.

5.2 Experiences with using EN13606 in Community Nursing Shared Care

5.2.1 clinical directorates

The Irish healthcare / community care environment is currently restructuring with the focus of care moving from large health provider sites towards community based care. Features of this process include the removal of traditional service boundaries, introduction of pathways of care with a stronger focus on shared integrated patient-centred care. This is of particular relevance to the profession of nursing as health care leaders focus more intently on measuring cost efficiency, and based on these results, redesign existing processes to be more effective, particularly from the patient perspective. In the summer of

2009 a national principles-based framework was established to create clinical directorates within Ireland. The primary purpose of creating clinical directorates is to achieve the best clinical outcome and experience for patients with the best available resources [84]. Such developments would suggest that objective data is increasingly becoming the yardstick to inform newly integrated programmes of care, enlighten clinical judgment and decision making and allocate already scant resources to care pathways.

5.2.2 education and training

The anecdotal evidence within Ireland suggests that integrated programmes of care will be difficult to effectively deliver without first laying a strong foundation in the form of education and training [84]. Education can be viewed as an integral part of the restructuring programme. In particular, there is a requirement for action research programmes which educate, train and support nurses on the health informatics theory whilst defining the contextual and clinical requirements for the development of software applications to support shared care. This approach is not solely related to nursing education and training but extends to the entire multidisciplinary team. Although the profession of nursing as one of the largest stakeholder groups involved in the co-ordination of care, this group has been identified as one who will be required to engage as a priority [84]. To do less may have serious ramifications for nurse resourcing and patient safety in future health care service provision [85], [86], [87]). It also may have a direct impact on the successful implementation of ICT in the healthcare domain. The OECD [88] recognise that collecting indicators which offer insight on clinicians readiness to adopt and intention to adopt are useful markers in estimating how successful or not National ICT implementation programmes within the domain of healthcare may or may not be.

5.2.3 Using Two-level Models for Sharing Nursing Information

Chapter of this report gave a broad outline of how Archetypes are designed by health professionals and other domain experts to define the range and type of data that needs to be collected and shared to support a particular aspect of patient care. In order to gain a direct understanding and experience of this process, the project team set out to establish whether information that is gathered according to an archetype could also be useful for reviewing the nursing contribution to patient care effectiveness. In order to test this assertion, a system in the form of a simple database and basic user interface application is required. Key principles guiding this development are that the system is clinically pragmatic, reflects the reality of nursing practice, captures patient-centred outcomes, whilst including the preferred formal language and terms that are relevant and used frequently by the profession [89]. By "cross checking" or mapping the language of nursing into the existing formal reference terminologies, objective data can be identified for inclusion in future EHR. An obvious next step is to where possible embed these candidate terms into the detailed clinical models or archetypes. These archetypes and their associated lists of terms in turn can be subsumed as resources into data entry forms where the coded terms will be at the fingertips of the practitioners on the ground. One of the underlying goals of using this approach is to make coded entry as convenient as possible for practitioners.

5.2.4 Description of Study

This section reports on the process of development and initial outputs of the PARTNERS team in the EHR*land* project who engaged with nurses in an action research study to develop community care nursing archetypes with bound terms to enhance inter-agency communication across the primary acute and continuing care services whilst collecting patient-centred outcomes in a number of clinical settings in the Dublin North area. The work also describes and discusses a technical case study of the design and simulated use of a shared assessment tool for shared community care in Ireland that is based on the ISO CEN standard EN13606. More specifically, we report on the development of the assessment tool using two-level modeling approaches and the outputs of the associated work programme for clinical engagement entitled PARTNERS. In light of the experiences gained, the work also considers the applicability of the CEN/ISO ContSys specification to enhance electronic health records to support shared care.

The nursing domain specialists who participated in the project were keen to collect and store patient-centred outcomes as defined by Doran et al (2003) [90] and involve the patient in the decision making processes relating to their care. Because of the resources implications of the data collection aspects of the project, the project team opted to complete a small pilot study and to evaluate the overall effectiveness on a group of over 65 year olds and on those practitioners who sought to pilot the tool The intention was that this evaluation would focus on whether the PARTNERS assessment form was effective or indeed ineffective, simply stated putting into practice the 3 W's which are if the prototype archetype/s (assessment form) worked for whom and under what circumstances.

5.2.5 Aims and Objectives

The core questions to be answered by the work of the PARTNERS group can be summarised as follows: Do archetypes have the capacity to support the creation and analysis of high quality data that can be shown statistically to be responsive to healthcare interventions across different healthcare interventions?

Is it possible to develop a two-level user-designed patient-centred record and assessment tool across the boundaries of shared care?

Do archetypes have the capacity to support the creation and analysis of high quality data that can be shown statistically to be responsive to healthcare interventions across different settings and in different environments?

The use of two-level models was integral to the work in a number of ways. For example, one of the core ideas of this work was as an educational experience: to involve a multidisciplinary community care team from different parts of the Irish health system in the design of shared assessment tool. The application of the two-level model approach allowed domain experts to participate fully in the design of a set of archetypes to support unified assessment of patients in a community care setting. The participants understood that these archetypes would be closely related to the shape of the associated assessment tool application.

In common with other terminological systems, the 'take up' of standardized reference terminologies and code sets for nursing such as ICNP [91] (International Classification of Nursing Practice) has been slow in Ireland. The use of archetypes also allowed members

of the project team to experiment with binding selected terms to nodes in archetypes. The assessment tool was designed to create data entry forms that were closely related to underlying archetypes. The forms would present lists of bound terms from underlying archetypes to the user. User-selected text with the associated code values could then be stored or communicated. It was hoped by this technique to gain practical experience of how terminologies such as ICNP and C-HOBIC [89] might appear in future e-health applications. The practice of shared care of older people in a community setting in Ireland is challenging. The sheer number of participants in the process and the multidisciplinary nature of the work can also present problems. An effective mechanism for effectively "passing the baton" of patient care across successive patient encounters is required. Another set of challenges relate to the provision of ICT services to support this work. At time of writing Ireland is only beginning to develop national identifiers for health service consumers and health providers and there is currently little mobile ICT support available to health practitioners who work in the community. In addition to the planned focus of a given health encounter, additional health issues may be discovered which require communication referral and follow up.

5.2.6 Description of Two-level Assessment Tool

Figure 5.9 gives an overview of the two-level model based tool for sharing patient centred health information for community nursing. The perimeter of the figure represents the care process while the central part shows elements of the assessment tool itself. The delivery of care in the scenario presented here involves several distinct health provider organisations and organisational units within the Irish health system (e.g. Acute services, Continuing care, Primary care). Each health provider interacts with the assessment tool by submitting an assessment contribution associated with encounters with the health service user. Any healthcare provider participating in community nursing may also request information from the assessment tool (e.g. views, report, discharge summary, e-referral) within the limits defined by the agreed access control policies.

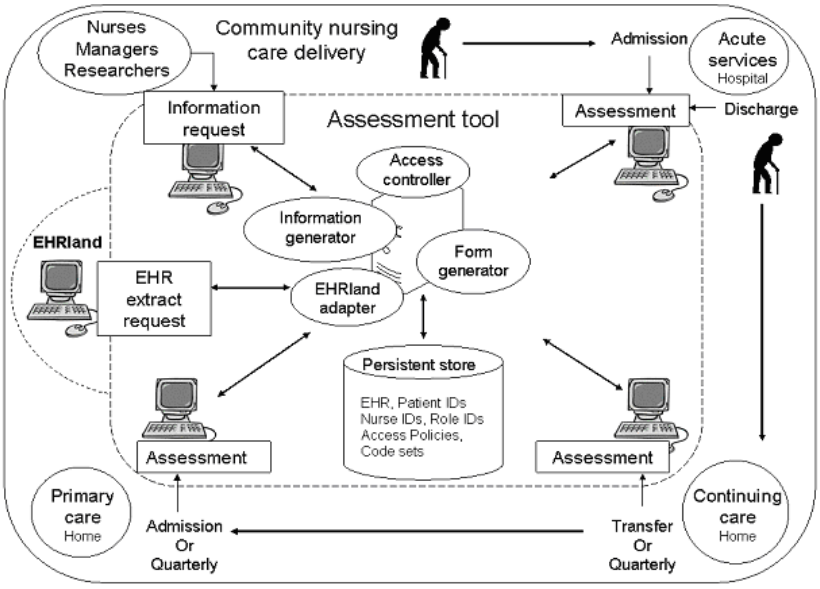

Figure 5.9: Overview of the Two-level Model based Tool.

Key components of a fully functional assessment tool are:

1. An access controller: implements the access control policies depending on service types and roles,

2. A form generator: implements the constraints regarding the information to be entered in the assessment form (e.g. required/optional fields, value intervals, list of string values), which have been

3. agreed by the domain specialists as part of the archetype design process.

4. An information generator: generates an information response depending on service type, role, and query type (e.g. request for view, report, discharge summary),

5. the (EHR*land*) adapter: generates on request, EHR extracts in compliance with the EHRcom standard [92], and with the European standard for health informatics data types [93], and

6. the persistent store: is responsible for the long term storage of data (e.g. EHR, access control policies, code sets).

The current standalone version of the tool is based on Java version 1.6, and uses the Swing toolkit for building the GUI and the iBATIS persistence framework for the persistent store. Also, the tool integrates the Java ADL (Archetype Description Language) parser and the Java implementation of the archetype object model, both available from the openEHR Java implementation. ADL is a formal language for the expression and serialisation of archetypes.

The project team had first hand experience of one of the positive features of the two-level model approach, is its code-free support for archetypes. It allows forms to be generated, simply by adding archetypes to the application without requiring additional

code to be written. The source code for this prototype java implementation is available on the EHR*land* website at www.EHR*land*.ie. In order to try out the tool and the designed archetypes in situ, it was used to collect information from six service providers across the acute primary and continuing care services in an urban setting in Dublin. A summary of the quantitative data collected from the use of the two-level model based patient assessment tool is presented in this section. The data shows the average assessment score and outcome for each measure within the specified episode range. An individual patient was required to have two completed assessments within the same time frame for their information to be included. A more detailed description of the process of this investigation and the associated results, are being compiled into a research paper. An account of the PARTNERS experience as well as multimedia resources on the topic are available on the PARTNERS website at [94]

5.3 Experience of using an extendable identity model to support EN13606

In the previous chapter, the rationale for the approach adopted within this project of purposefully adopting and extending the identity model from the standard has been outlined. The following description outlines the experience of using a two-level information modeling tool in the form of the LinkEHR editor to work with this extendable identity model. The advantage of this tool is that it permits the user to define their own reference model (level one model) in XSD form, which can then be imported into the tool and used as the basis for archetypes (level two model). A screen snapshot of LinkEHR editor menu for importing a reference model is shown in Figure 5.10.

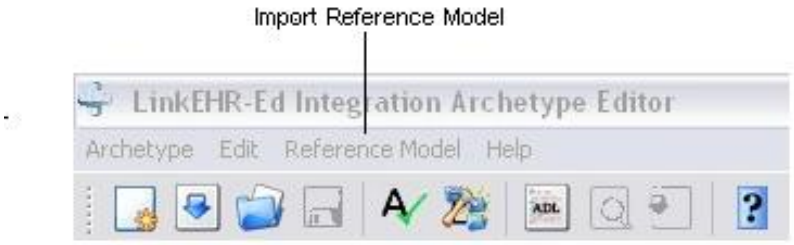

Figure 5.10: The Main Menu of the LinkEHR Archetype Editor.

The LinkEHR editor GUI supports two schema formats of the reference model representation (.XSD, .RM) but this experiment employs the XML schema for representing identity models. The LinkEHR editor requires a set of mandatory settings for creating a new reference model such as Organization name, Reference model name. In the meantime, the types of the represent complex elements need to be selected and added from a XSD file that is including the specified XML representation of reference model by LinkEHR editor. In order to proceed the validation of importing a XML based reference models, we create the first XSD file to represent the structure of model and the second XSD file is to store the complex datatypes which is invoked in the first one, as shown in Figure 5.11.

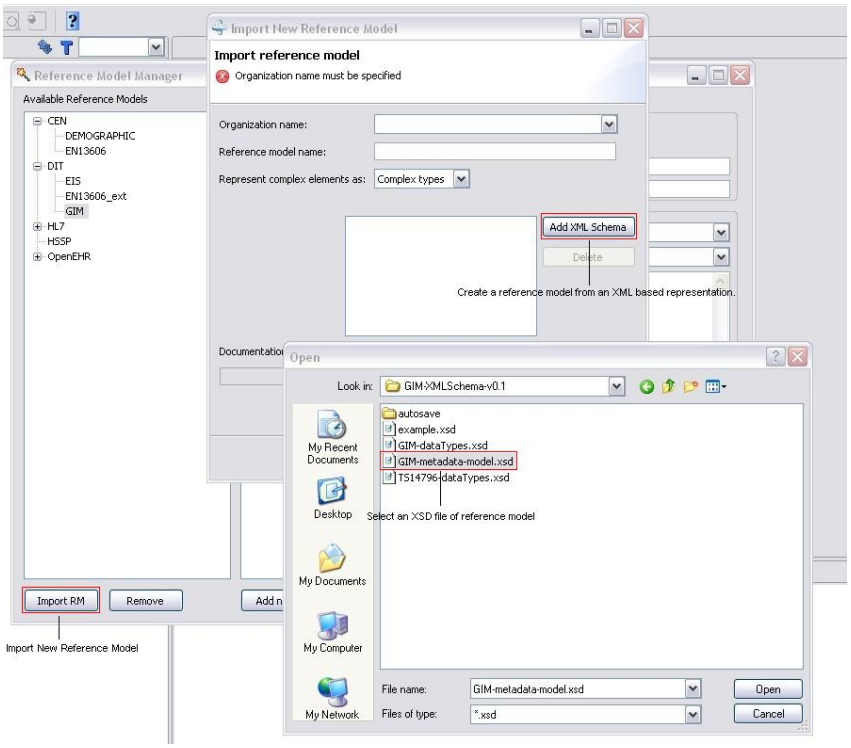

Figure 5.11: Import a New Reference Model to LinkEHR Editor.

After passing the tool's validation procedure for importing the generalised identity reference model, it is a simple matter to create an archetype for example PERSON in this experiment that is based on the EN13606 demographics model. However, the EN13606 demographics model is a static reference model which cannot be archetyped in its current form. Consequently it is not possible to extend the model to permit new types of identified entitity to which traits can be assigned. The experimental reference model developed by the EHR*land* development team, extends the original EN13606 demographics model and adds a flexible placeholder with common features that can be used by an archetype author to express additional types of health identity.

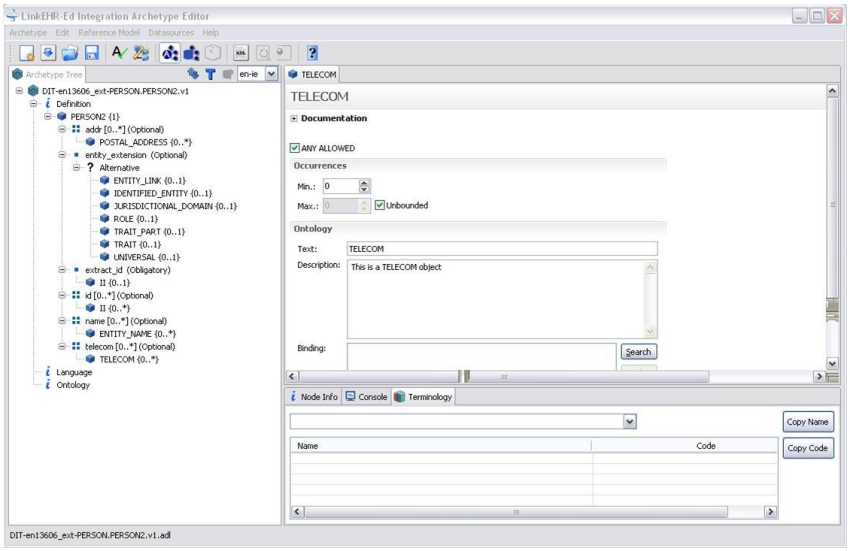

Figure 5.12: Example of an Archetype Created by LinkEHR Editor.

At the end of import process, an example of the PERSON archetype is obtained and displayed as shown Figure 5.12.

It must be noted that although the creation of an archetype-able reference model can be effected very quickly, the design of the model is quite another matter. The project team have attempted to mine existing stable demographic models for their common features. But like the EN13606 clinical information model, an identity information model would need to be strongly validated before it could be used in a working system. nevertheless, the project team are firmly of the opinion that an extendable (by archetypes) model for health entities will enhance the functionality of the two-level model approach to the EHR.

5.4 Experience from implementing a prototype terminology service for SNOMED-CT to support two-level models

In chapter 1 it was noted that in order for archetypes to represent clinical concepts in a way that is commonly understood, they need to be linked to unambiguous concepts in agreed terminologies. This is because although an Archetype contains constraints on a clinical model, it only uses a set of locally defined terms and the information from the underlying reference model in order to define the constraints. Unless bindings to external terminology exist there is no restriction on representation of clinical concepts within archetypes.

To investigate the effort and tasks required to develop a basic terminology service, members of the project team started from the release files of a SNOMED-CT distribution. Each SNOMED-CT release provides three core tables. Their content can be briefly described to consist of SNOMED-CT concepts, descriptions, and relationships. The hierarchies of its concepts are formed mainly by the inheritance relationship between them (i.e. IS_A aka subtype relationship). In order to be able to query this large data

source it has first to be loaded into a database. A normal code resolving-query can be easily handled by a DBMS. However when it came to providing fast full text search on the database, the result was not satisfactory. Text searching will effectively help users of SNOMED-CT to locate and finalise a term that should be used in an Electronic Health Record and where appropriate in any healthcare application. However simplicity, usability and efficiency are important to a terminology service that is provided to end-users. So usability parameters such as the search speed and result relevance ranking need to be optimised.

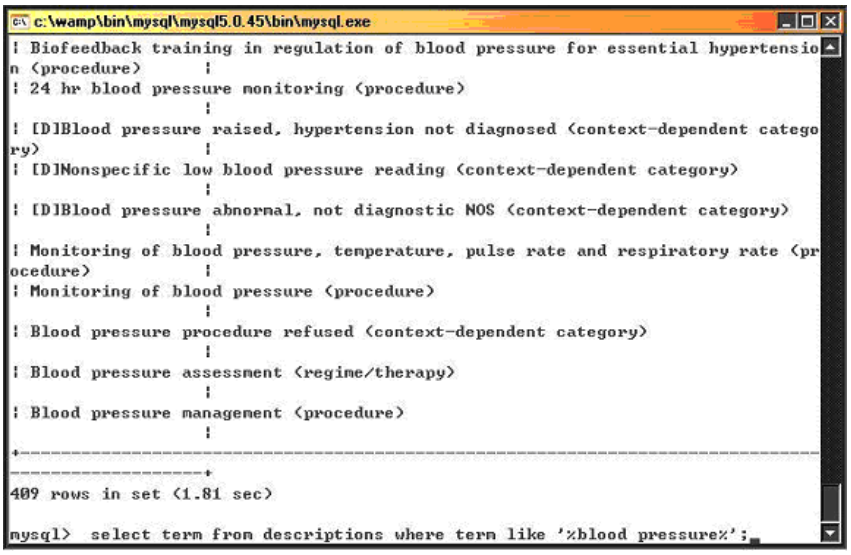

Figure 5.13: SQL query to select concepts contain 'blood pressure' on SNOMED database.

One adaption to improve the usability of the terminology service was to use information retrieval techniques. Lucene [95] is a full text indexing and searching engine using TF-IDF [96] which is a basic but effective term weighing scheme in information retrieval. An index built with Lucene shows great improvement of query time over a more orthodox "relational" query. Also a noticable feature of using an information retrieval based approach is that all the results returned by the query are ranked by their relevance. The scores in figure 2 are factors of relevance which are measured by Lucene.

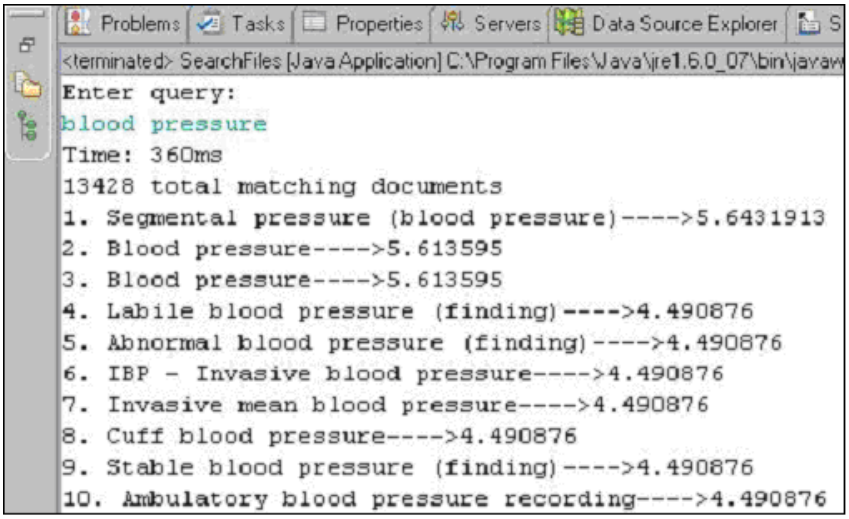

Figure 5.14: The same query was issued with argument Crepeat 100 to run 100 times.

Furthermore, the authors extended the tool to also process "raw" archetypes which are defined by clinical experts and produce the corresponding terms. (We have termed these lists of terms terminological shadows [97]. By using a similar technique, a prototype which parses archetypes and generates suggestions for archetype term bindings was developed. The recommended SNOMED-CT codes are automatically created and stored in an XML mapping file. The core of this system allows the clinical experts to design sharable EHR artefacts, known as Archetypes. The system enables automatic searching and suggestions for SNOMED-CT code bindings, which occur without human intervention. This promotes quality assurance when developing archetypes by embedding codes in an archetype before its release. Tools like this have have potential uses in a wide variety of clinical systems which could benefit from embedded codes. The authors have provided a live demo of this process which is available on the EHR*land* project website [98].

Comments on terminology binding to archetypes

As reported earlier, the algorithm in this system is replaceable. Thus a configurable algorithm can be applied for term binding suggesting adaption to a particular clinical scenario. Future plans for development of the system include possible plug-ins for the LinkEHR [99] archetype editor to support terminology integration at design-time. Also a terminology service tailored for EN13606 will contribute to the outputs of the EHR*land* project.

There are a wide range of search assistive tools available besides Lucene. For example, powerful lexical tools designed specifically for medical text can be obtained freely from NLM [100]. With the aid of domain specific i.e medical text processing toolkit, one likely improvement is the domain relevance in the search for appropriate concepts from SNOMED-CT. In fact, large and sophisticated programs have been written to deliver the task of mapping free text clinical notes to codes. This automatic process utlises Natural Language Processing (NLP) [100] technology and a lot of effort was spent on researching text structure. The difference between these existing tools and the one used in this study is that an integration engine may take the underlying EHR information model into

account, or in this case, archetypes. EHRs are digital entries which comply to the model designed to record clinical data. thus the process of binding codes should be altered from NLP based tools. However issues exist in such processes in relation to assessing the relevance of codes found by an automatic search with minimal human intervention.

A significant result of this study shows that the implemented SNOMED-CT search tool is both faster and more accurate than the conventional database approach. The second part of implementation, archetype integration engine shows the ease of suggesting bindings between SNOMED-CT terms and an expert-designed sharable EHR artefact. A general contribution could be to ensure that codes are embedded in EHR systems before communication happens. The same approach can also be used to map local codes to SNOMED-CT or other terminology.

In order to support a fully working and consistent EHR environment, a set of fundamental services need to be established. This study assessed the necessary foundation technologies for accessing terminology resources. The implementation of a SNOMED-CT based terminology integration engine is both a proof-of-concept prototype of such a service and a step further to merge EHR health information models with medical terminology. An extension of this work could contribute to many clincial scenarios which require terminology binding or code embedding. The process of merging EHR information models and terminology is also promoted by international standardisation organisations.

Chapter 6

CONCLUSION AND RECOMMENDATIONS

6.1 Recommendations

This chapter summarises the main findings of the EHR*land* project. Some resulted either from the mainstream development work of the EHR*land* project that tested out different aspects of the standard and discovery of the associated technical implications. Others came from other supporting investigations.

6.1.1 Appraisal of legacy systems: establishing a baseline for the development of an EHR in Ireland

The process of making clinical data shareable, whether by migrating or mapping them to nationally agreed data descriptions, starts with establishing a clear picture of the heterogeneity of existing data. In order to understand the level of information heterogeneity relating to the EHR, and to gather material for consensus based archetypes, there is a need for a data inventory similar to the one available for public health information. A number of public health organisations are already collecting health information in various different capacities.

- The Health Intelligence Unit of the HSE
- the All-Ireland electronic Health Library. [101]
- Northern Ireland's Population Health Observatory [102]
- the Institute of Public Health in Ireland. [103]
- the Central Statistics Office. [104]
- and StatCentral.ie. [105]
- The Authority is also leading projects in this area

In addition to understanding the schemas used to store information, it is also necessary to understand the scale of the information stored in each site. If information of this type is not available, an inventory process must be started to get a clear idea of the national situation. For an example of how this might work, ProRec Italy has come up with a

process for the inventory of clinical data sets [106]. Each site needs to describe the data it stores, and the descriptions, the clinical data sets, can then be published and compared. Eventually, they're will be in a registry so that data can be located and shared.

There are some existing recommendations/guidelines about the clinical data inventory process. For instance, Rossi Mori et al. (2002) [107] suggest features for the description of clinical information in EPRs. In a 2002 ProREC report, Rossi Mori, (2002), [108] defined elementary units of clinical information (individual items, notifications, documents). These units might correspond to EHRcom record components. There is also meta data categories like pointers, headers, payload, which may correpond to archetypes (note that the author focuses on mapping to levels of HL7 CDA).

Existing methods for establishing interoperability need to be examined (e.g. the NEHTA Interoperability framework [109].

Finally, according to common practice in two-level modelling, another rich source of legacy information that can be gathered to seed the creation of detailed clinical models is paper forms and charts used in everyday operations in hospitals and clinics. These have often been carefully evolved over decades and as such represent a good source of the type of information that is required to be shared at different health provision sites.

RECOMMENDED ACTION - EHR READINESS SURVEYS

- future surveys of acute care, primary care and other sectors should include requests for information which allows estimation of EHR related activity from parameters such as, number of demographic records, number of episodes of care, number of medical samples, number of lab investigations, number of prescriptions, number of medical physics investigations, versions of coding schemes in use, local code sets and nature of content being coded and information system schemas and health message formats. This would help to get an accurate picture of the EHR-readiness of existing e-health infrastructure in Ireland.

Overall Assessment of EN13606

It was mentioned earlier that the project team worked with the LinkEHR tool suite for development of EN13606. This tool suite was as far as we are aware, the first commercial implementation that supports the EN13606 standard. Those of us who have used these tools agree that the two-level modelling paradigm shows great promise and represents a significant step forward in health information.

Templates

It is often stated that clinical data currently distributed over the Irish health system is heterogeneous and lacking in interoperability. This is not a new problem. Nearly two decades ago, in 1991 Rector noted that *"...Many of the difficulties experienced in attempting to generalize existing systems stem from the fact that they have pre-selected and distorted information in order to fit into particular applications, usually clinical research and epidemiology."* [7] The two-level model approach offers the possibility of allowing a community of clinical domain experts to shape the record according to their common need. The use of templates as advocated by the openEHR consortium, also allows multiple

representations of information so long as these representations are based on the same underlying structure using the principal of the maximal data set. Templates are described in the (mainly openEHR) literature in the following way:

- The purpose of templates include data construction, data validation, and also "archetype composition (chaining), reduction in allowed terms, restricting optionality, removing structures defined in the referenced archetypes" (Beale and Heard, 2007). [110] It is not clear from this description how removal of archetype structures is achieved.
- "An openEHR template is an artefact that enables the content defined in archetypes to be used for a particular use case, i.e. business event." (openEHR Templates, 2009). [111]
- "A template may aggregate any number of archetypes, but choose very few data points from each, thus having the effect of defining a small data set from a very large number of data points defined in the original archetypes." (openEHR Templates, 2009) [111]

Templates may be used as part of the definition of a user interface. In another guise, they may act as a form of communication contract that governs the agreed "shape" of an EHR extracts between two individual health provider organisations. Consequently, it is the view of the project team that a template model (possibly inspired by openEHR) is needed at the national level to design and communicate templates. The efforts of the project team in the community health assessment tool have demonstrated that it is possible to have a patient-centred view which nevertheless permits assessment of the health care process and by extension other views. Unfortunately templates are not yet a feature of EN13606. It is the view of the project team that template functionality is required to supplement the existing set of specifications.

RECOMMENDED MODIFICATIONS TO EN13606: TEMPLATES

add template functionality to EN13606 either by adopting ADL1.5 or otherwise.

Object Identifiers (OIDs)

Appendix E is a position paper produced by the project team and submitted to the EN13606 International Interest Group. In that document, another shortcoming of the EN13606 standard is discussed. That is the lack of consideration given to Object Identifiers (OIDs). It could well be argued that OIDs are generally applicable and can be used in many different ways in healthcare and elsewhere. Nevertheless, it is the opinion of the project team that a concerted approach to OID management across national implementations through adherence to a standard is more likely to result in successful cross-border interoperation of EHRs. The position paper document outlines some of the options that would face implementers of an EN13606 based EHR system for Ireland, and suggests appropriate directions. For instance it provides guidance on the establishment of a system of OIDs with an accompanying OID resolution protocol to distinguish identity domains, term sets, contributing information systems, standards and other resources that

are relevant to an EHR system. An ISO TC215 Work Item is currently working on the issue of OID management. Whatever about international agreement, whether the EHR solution is based on EN13606 or HL7 CDA, there will be a need to arrive at an agreed national policy for OID assignment and management.

RECOMMENDED MODIFICATIONS TO EN13606: OIDs

The Standards community needs to provide

- specific guidance on how the ISO work on an OID service and OID management would work with EN13606.
- an implementation guide for EN13606 to recommend particular technical choices with respect to use of OIDs and other types of globally unique identifiers in different situations.

Should EN13606 have a demographics or identity model?

The EN13606 standard, unlike the openEHR demographics model, or the HL7 OMG collaboration on an Identity Cross Referencing Service (IXS) employs a demographics model that is fixed. The openEHR approach reuses features of the openEHR clinical information model to allow demographic entities to be defined and constrained by archetypes. By this mechanism, Brazilian members of the openEHR community have developed archetypes for two highly detailed ISO demographics standards: DTS22220 [61] and DTS25757 [62]. By contrast, it is the opinion of the project team that the approach taken with the fixed demographics model of EN13606 in line with the implied identity model of Hl7 and other approaches is relatively inflexible, and results in additional complexity elsewhere in health information communication. For example, the demographics model allows only a patient to be the subject of an EHR record, when substantial amounts of laboratory information could be more conveniently associated to an identified specimen which in turn could be associated to a patient. As a result, even though lab specimens and results are associated with bar codes, order numbers and specimen IDs in the lab domain, in the record they would need to be associated with the patient. The project team have suggested a flexible identity model that can be archetyped for a range of different purposes.

RECOMMENDED MODIFICATIONS TO EN13606: IDENTITY

- Develop an extendable identity management service that supports the basic functions of registration, query and administration cross the referenced domains.
- Introduce the two-level modelling approach for demographics and health identities, which allows EN13606 to be extended using archetypes.
- Adopt a generalised identity reference model (such as the one proposed by the project team) to support the multiple types of entity within the broad context of EHR referents such as samples, episodes, order.
- Extend use of identifiers with trait sets to categorise and uniquely identify other objects and phenomena in the health process including parts of the human body, samples, diagnostic devices and pharmaceutical products.

Readiness of the standard

It has been stated that the Irish e-health infrastructure needs to be made ready for the introduction of an EHR. It could also be argued that an EN13606-based EHR also needs to be developed to make it ready for Ireland and other countries and regions who could be considered as early adopters of the standard. This is currently happening in at least two large regional / national projects. The two-level model paradigm needs to establish itself, and the tools need time to mature and to become more usable. The work on archetype development which is critical to the success of the two-level model based approach is only beginning. As noted by Corrigan (2010) [27] and Moreno Conde (2010) [26], the pace of archetype development needs to be accelerated. To sustain this work, an international community of experienced two-level model practitioners needs to be established along with a scalable governance mechanism for archetypes. The emergence of the above-mentioned large-scale national projects will undoubtedly accelerate this process at an international level, but Irish domain specialists should also participate in this community effort. Participation will lead to invaluable local expertise. EN13606 and OpenEHR are promising EHR techniques, which are still under development. It will be some years before they are mature enough to be used "off-the-shelf" as the basis for a National EHR system for Ireland.

OTHER RECOMMENDED MEASURES THAT ARE SPECIFIC TO THE EHR

- Develop programmes that give the Irish health informatics community more exposure to the ideas and consequences of the EHR.
- Establish detailed clinical modeling group or another body who can adopt / develop Irish clinical information models for health information in the EHR, perhaps in cooperation with the OpenEHR consortium.
- Develop an archetype governance process for Ireland.
- The EN13606 community should enhance the tools to support inclusive creation and management of archetypes and templates by health informaticians and clinical domain experts.
- There has been discussion at CEN and ISO, of developing a standard specification for archetype knowledge management. This work should be suspended until the medium term. As the number of archetypes grows this will become more useful.

6.1.2 Architectural prerequisites for introduction of an EN13606 based EHR system

The above assessment should not hinder short to medium term moves towards an EHR solution. Both EN13606 and HL7 CDA use OIDs to identify certain information resources. Both approaches rely on use of enterprise-wide (i.e. national or regional) identifiers for patients and health professionals. Both approaches offer opportunities to bind to external clinical terminology. Both involve (if you take the high value CDA version 3) development of detailed clinical models that are an extension of a more generic model. So many of the required underpinning systems and services to support an EN13606 based EHR for Ireland would also be required if the solution was based around HL7 CDA. Based on features in both sets of specifications, large-scale solutions based around both approaches would be made simpler if the required infrastructure was in place. The following recommendations are made in this respect

PREREQUISITES FOR THE EHR

- Develop a registry of national identifiers and accompanying demographic profiles for health service users which are mapped to local identifiers used at health provider organisations.
- Develop a registry of national identifiers and accompanying demographics and professional profile information for health professionals who will contribute to and access the electronic health record.
- Agree and define roles for future Irish EHR users.
- Develop a directory of health provider organisations, health professionals and constituent health care units.
- Develop a national authentication and authorisation service based on the above resources that is resilient at a local level to network failures. This system should also support community based care.
- Develop a national OID registry for distinguishing a wide range of health information resources including health information systems, terminologies and identity domains.
- Adopt and deploy an agreed low-level communications mechanism such as IHE XDS or SOAP which delivers only to authorised users in authorised locations.
- Adopt and make available for general use in existing and future systems, national subsets of terminological systems such as SNOMED-CT, LOINC, ICD10, ICPC and other local code sets such as HIPE.
- Develop a process for improving the quality clinical information that involves adoption, adaption and creation of detailed clinical models for the Irish healthcare system and a community of volunteers to help support this process.

The enablers for a national electronic health record system mentioned in the above recommendations will also enable better, more efficient higher quality communication of health information. In Chapter 2 we presented a summary of the e-health architectural infrastructure and EHR-readiness of seven countries in relation to the above features. It was clear from this summary that many other nations have developed or are developing variants of these basic building blocks. The Health informatics community in Ireland can also prepare for the EHR without committing to it, by developing these information resources. Based on the above reasoning, we recommend the following measures that should be considered to progress e-health nationally but are also important to support the future introduction of an EHR system for Ireland.

RECOMMENDED ACTIONS ON COMPONENTS SUPPORTING AN EHR - IDENTIFIERS

- We endorse the initiative by the Authority on national patient identifiers and demographics profiles
- We endorse the recent exploratory work by the Authority on national identifiers for health provider organisations and national identifiers for individual healthcare providers
- Introduce identifiers to distinguish between local information resources and ID domains (this would correspond to an extension of HIPE coding)
- Introduce an information quality assessment and management programme in preparation for the mapping of local identifiers to national equivalents.
- In the longer term, we propose ontology-based support for more extensive use of nationally recognized identifiers in e-health for medical devices, pharmaceutical products, samples and parts of anatomy.

RECOMMENDED ACTIONS ON COMPONENTS SUPPORTING AN EHR - TERMINOLOGY

- Develop national profiles of selected terminological systems and provide access to tools to allow users to select codes.
- Introduce harmonized national code sets in domains where they can be generated automatically.
- Establish and foster a coding community and form inter-disciplinary terminology expert groups who investigate the local use of codes and provide guidance on mapping local codes to national profiles.

RECOMMENDED ACTIONS ON COMPONENTS SUPPORTING AN EHR - GENERAL ICT INFRASTRUCTURE

- Develop a resource that enables recognition of different types of identifiers (using OIDS, URIs or UUIDs), to support establishement of an EHR and to improve the quality of health messages generally. This measure would for example help systems and users to distinguish a national patient identifier from a local patient identifier or identify the original identity domain of a particular identifier.
- Provide a secure, reliable, flexible and accessible mechanism for transporting health information, with access points at all points of care including community care sites.
- Agree and publish consistent and standardised messages formats for exchanging health information of different types which use strong datatyping, identifiers and coding.
- Develop a service to support authentication and authorisation of users and resulting in consent-based access control with audit trails for sharing of health information.

6.1.3 Archetype Development and Governance in Ireland

No specific recommendations are made in relation to the development and governance of archetypes, but some of the issues highlighted in this section will need to be considered for action by the Authority, by implementers in the health service and by standards bodies.

Archetype development process and participants

It has been mentioned that the pace of archetype creation has thus far been relatively slow. It has also been noted that this archetype development has mostly occurred within the openEHR project in the absence of the imperatives that would be imposed by a full-scale EHR implementation. It is expected that now that large-scale EHR projects such as the National Swedish EHR project, the Minas Gerais project have begun, the pace will quicken. Against this background, it is hard to escape the conclusion that it will not be sufficient for Ireland to rely on an international effort to provide just the archetypes that we need. If Ireland is to implement EN13606 it will be necessary for us to have an Irish community of archetype developers who are developing archetypes according to the national, regional and local needs and priorities. An outline of an approach to archetype development and the roles involved are discussed below.

Irish health professionals engaging in archetype creation and adoption

To be useful, archetype creation must involve interested actors across the health system who are knowledgeable representatives of the key roles involved in using an EHR. It has also been shown from national experiences in other countries that involvement of health professionals is a critical success factor for EHR projects. At a national level in Ireland, it would be in the interest of health organisations and sectors (General practice, acute,

polyclinic, community health, emergency) to provide representatives who will participate in the design of archetypes. Real clinical engagement is more likely to result in an EHR design including archetypes templates, demographics, access control strategies that are fit for purpose and meet the requirements of the stakeholders. In relation to timescales for archetype development, teams must come up with usable archetypes in a matter of months, not years, for them to be accepted and used by communities. If it is too slow, people will look for other non-standard/standard implementations for their current need to communicate data. Therefore, participants must be allocated sufficient time away from their original occupation in order to achieve archetype development in over an appropriate time frame. For this reason, the approaches taken and resulting success or failure of this aspect of the above mentioned national or regional project merits close observation.

Health Informaticians

The openEHR community and at least one commercial implementation of EN13606 are exploring the use of mind maps to provide an intuitive user interface to archetypes for health professionals. Nevertheless, all health domain experts should not be expected to understand all of the technical details of EN13606 in order to agree on archetypes. So where there is a knowledge gap with respect so some aspect of the standard, an additional participant who has full technical EN13606 expertise should follow the discussion between clinicians and encode the agreements using the standard. In this case the EN13606 expert is responsible among other things, for implementing archetype re-usability, i.e. identifying new re-usable archetypes as well as finding existing ones.

General Method

Ideally, the Legacy Data Appraisal described in 6.1.1 would lay down the ground work and provide input material for archetype development participants who would present this information in a uniform way (for instance using mind maps as described above) to describe the data they have and the data they want from other participants. The data then need to be expressed in agreed structures. A service such as the national archetype service described in the architecture chapter would be required, with the help of the health informatician, to search the national archetype repository for existing equivalent structures. At the end of the process a new set of archetypes would be submitted to the national archetype repository.

Binding to Terminologies

Each archetype contains an ontology section (which could more accurately be called a "links to ontology" section) that gives descriptions of the record component constraint structure contained in the definition part. The ontology section of an archetype encodes the semantic agreement, i.e. the agreement on meaning that was achieved by the participants during archetype design. The ontology section allows the archetype creators to apply text labels to the content of the record components to which they correspond. In order to disambiguate the labelling for future users of the archetype who did not participate in the design, labels may be associated to codes (in a process known as term binding) from external terminologies, which themselves encode a semantic agreement.

Archetype identification

The literature proposes the following mechanism for identifying archetypes: "issuing_authority . rom_id . ontological_level . concept[:specialisation] . use_context . version" (Beale and Heard, 2007) [110], where:

1. rom_id stands for the id of the reference model (e.g. "EN13606"),
2. ontological_level stands for a class of the reference model (e.g. "ENTRY"),
3. concept stands for a textual description (no white spaces) of the semantic content of the archetype,
4. use_context corresponds to the stage of the archetype life cycle (e.g. "draft"), and
5. version stands for the version of the archetype.

Examples of archetype identification using this format are:

- "CEN.EN13606.ENTRY.Observation.v1" and
- "CEN.EN13606.ENTRY.Observation:laboratory:hba1c.v2".

However, a similar format with different separators is used by the LinkEHR archetype editor: "issuing_authority - rom_id - ontological_level . concept[- specialisation] . version".

There is also some disagreement about whether it is appropriate to mandate use of uppercase first letters in the naming of archetypes. The situation should be considered and clarified.

Versioning rules

Two level modeling literature provides some principles and directions to organise the versioning of archetypes:

- "The only types of change to archetypes that can be made without changing the version are those which do not invalidate previously created data. Formally, such changes must not 'narrow' constraints expressed in the existing version." principle 14 of (Beale and Heard, 2007) [110]
- "The previous version is deemed to be obsolete. Existing data, created according to the (or in fact any) previous version, must be convertible to the latest version in a well-defined way." (Beale and Heard, 2007) [110]
- "A major consideration for whether a new version should be created is the scale of the knock-on effects on existing data created according to both the original version, but also any specialisations." (Beale and Heard, 2007) [110]

The project team believe that the versioning of archetypes is likely to become a growing problem as the two-level modeling technology matures. But experience of this issue is needed before concrete guidance can be provided on this topic.

Specialisation rules

The following rules need to be followed during the process of archetype specialisation:

- "even standard archetypes allow for optional additions; the motivation to specialise is not to add options, but rather to further specify previously open parts of an archetype, i.e. to reduce the options" (Beale and Heard, 2007) [110]

- Specialisation relationship definitions:

  "An archetype N is a specialisation of an original archetype O if its data also conform to archetype O, i.e. its data can be considered a special case of O. Archetype O is then substitutable for N with respect to the data.

  Accordingly, archetype N may only further constrain the archetype O. If this were not true, data built with N might not conform to O.

  The above relations are recursively true, thus data created using N should conform to any previous parent starting from O back to the special archetype ANY. Each of these archetypes further constrains the previous one in the specialisation chain.

  The identifier is intended to be different." (Beale and Heard, 2007) [110]

- "An archetype is considered a specialisation of another archetype if it mentions that archetype as its parent, and only makes changes to its definition such that its constraints are 'narrower' than those of the parent." (openEHR archetype object model) [112]

As with versioning, specialisation is likely to become increasingly complex and experience with this issue is likely to lead to guidelines on how this should be handled.

Two level modeling tools and other supporting applications and services

At the time of the experiments and implementation that led to this report, the only freely available archetype design tool for the EN13606 reference model is LinkEHR-Ed Archetype Editor. It is open source and available for free download at http://www.linkehr.com/. The editor is developed by the Biomedical Informatics Group (IBIME), which is part of the Institute for Applications of Advanced Information and Communication Technologies (ITACA Institute) and is located at the Technical University of Valencia (UPV), Spain. Note that the archetype editor can be configured to work with other reference models, such as openEHR and HL7, by importing their respective XML schemata.

This situation is already improving at time of writing, with reports of other tools and services under development to support EN13606. National projects have reportedly inspired standards-based development by vendors who wish to take part. Nevertheless, further tooling support is a major factor in the evolution of the archetype development process as it is for the EHR process in general.

6.1.4 Telecom Infrastructure

Decisions on the telecommunication infrastructure needed for the EHR may follow the following method:

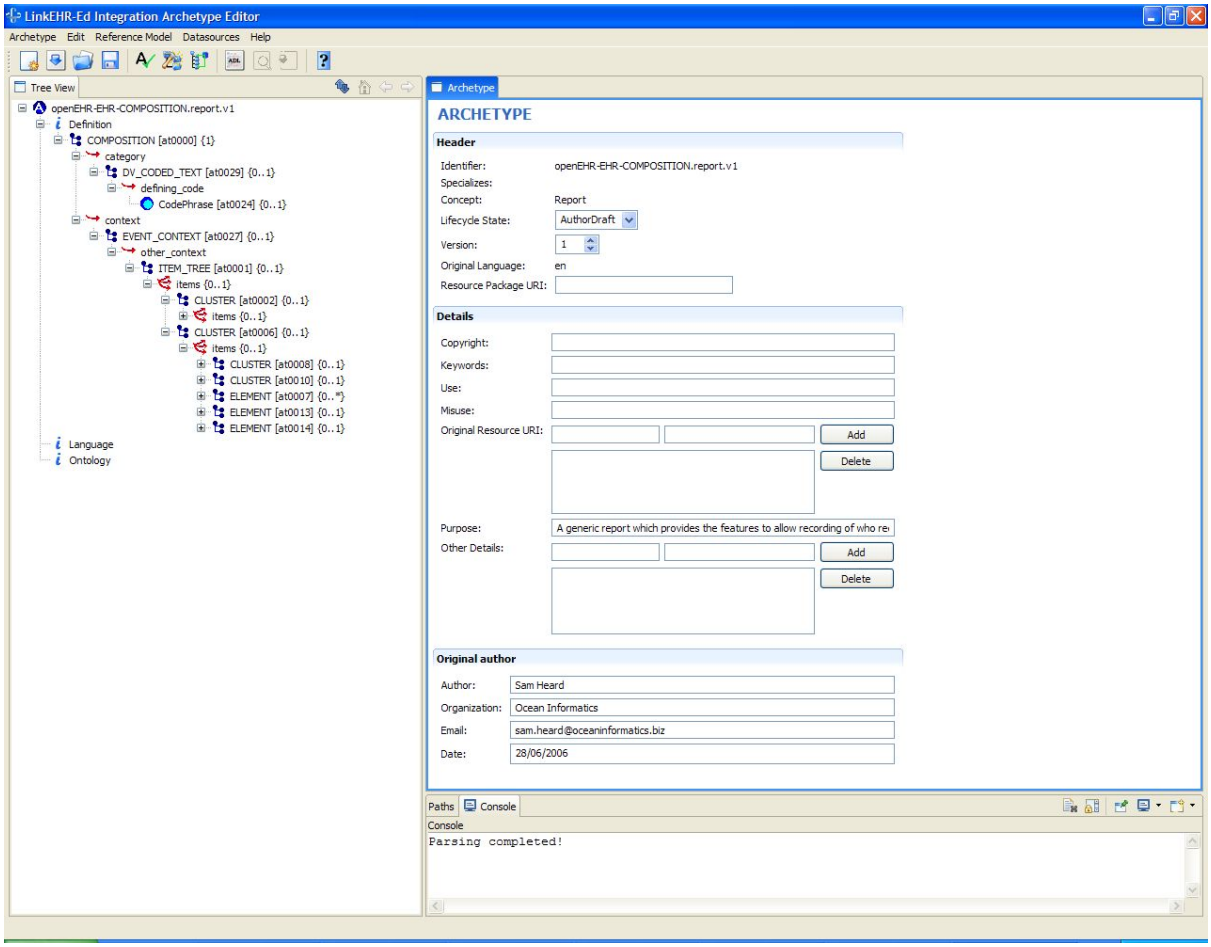

Figure 6.1: LinkEHR editor GUI.

1. the current national telecom infrastructure is assessed;

2. future data traffic need is evaluated following the legacy data appraisal: the appraisal clarifies what can be communicated along with security concerns, estimated bandwidth requirements of different types of EHR communications, predicted level of EHR activity (an extension of the material that we have presented in Chapter 2 on the size of an EHR for Ireland), predicted formats and quality of service and also what will be communicated, i.e. what is relevant at more than one location;

3. the output of steps 1 and 2 will need decisions ranging from the use of the existing infrastructure to the investment in a secure but highly-distributed EHR-dedicated infrastructure.

6.1.5 Data repositories and privacy

Data privacy is of paramount importance within EHR requirements. The French experience as presented in the EHR-Implement Report [2], indicates that there is a need to have a deeper national discussion in Ireland around the sharing of health information and the conditions under which such data should be shared. Therefore, existing data repositories

need to be assessed against these requirements. This could be part of a certification process for health data hosts similar to the one planned in France.

Note that a process could lead to a geographical separation between health organisation and their data, as the data host becomes responsible for the protection of the data from physical and digital attacks.

6.2 A Final comment on standards evaluation

This project was funded under the Health Information and Quality Authority Research funding Scheme 2006. The members of the EHR*land* project team would like to thank the Authority for providing the opportunity to engage with this interesting and challenging standard and to recognise of the vision that led to this research funding scheme. The issue of funding standards-based research and development is one that needs to be addressed at national and international level. In the absence of this support at a national, European and international level, those standards that are developed, are published without testing, a position that is recognised by NSAI as being unsatisfactory.

Bibliography

[1] OpenEHR. What parts of openEHR have Ontological Relevance?. openEHR organisation; 2007. \url{http://www.openehr.org/wiki/display/ontol/Ontologies+Home}.

[2] EHR-Implement. Political and organisational factors influencing large scale implementation of electronic health records:recommendations for a realistic implementation plan about EHR-Implement; 2010. Available from: `http://www.ehr-implement.eu`.

[3] Quantin C, Cohen O, Riandey B, Allaert FA. Unique patient concept: a key choice for European epidemiology. International journal of medical informatics. 2007;76(5-6):419–26. Available from: `http://www.ncbi.nlm.nih.gov/pubmed/17085069`.

[4] Grimson J, Grimson W, Berry D, Stephens G, Felton E, Kalra D, et al. A CORBA-based integration of distributed electronic healthcare records using the synapses approach. 1998;2(3):124–138.

[5] Grimson J, Stephens G, Jung B, Grimson W, Berry D, Pardon S. Sharing health-care records over the internet. 2001;5(3):49–58.

[6] Smith B, Ceusters W. HL7 RIM: An incoherent standard. In: Medical Informatics Europe. vol. 124; 2006. p. 133–138.

[7] Rector AL, Nowlan WA, Kay S. Foundations for an electronic medical record. 1991;30(3):179.

[8] TC215 I. P S, editor. ISO/DTR 20514. Health informatics - electronic health record: definition, scope and context.; 2005.

[9] SemanticHEALTH. SemanticHEALTH Project Deliverable D7.1 Semantic Interoperability Deployment and Research Roadmap. The SemanticHEALTH Consortium; 2008.

[10] NHS CfH. Position based access control (PBAC) - A toolkit for implementing simpler and more secure management o; 2009.

[11] Infoway. Canada Health Infoway;. Available from: `http://www.infoway-inforoute.ca/`.

[12] Office For National Statistics. Population Statistics United Kingdom; 2010. Available from: `http://www.statistics.gov.uk`.

[13] Canada S. Population Statistics Canada;. Available from: `http://www.statcan.gc.ca/`.

[14] WBDI. World Bank Development Indicators 2010; 2010. Available from: `http://data.worldbank.org/sites/default/files/wdi/`.

[15] CSO. Central Statistics Office, Census figures 2006; 2010. Available from: `http://www.cso.ie/statistics/`.

[16] CSO. Central Statistics Office, Population and Migration Estimates ; 2009. Available from: http://www.cso.ie/releasespublications/documents/population/current/popmig.pdf.

[17] DOHC. Primary Care a New Direction. Department of Health and Children; 2001. Available from: http://www.dohc.ie/publications/primary_care_a_new_direction.html.

[18] EuroREC. EuroREC; 2010. Available from: http://www.eurorec.org/.

[19] DOHC. Health Statistics 2008 Section H: Acute Hospital Services Department of Health and Children ; 2008. Available from: http://www.dohc.ie/statistics/.

[20] Thomas Layte, R S. General Practitioner Care in Projecting the impact of demographic change on the demand for an delivery of healthcare in Ireland. ESRI; 2009.

[21] HIQA. REDC - Prepared for the Health Information and Quality Authority. Public Opinion Poll on the Sharing of Health Information; 2008.

[22] gouv fr E. The major milestones in the development of health information systems in France since 2002; 2010.

[23] Brosky J. Voilà! French e-health goes online in 2010; 2010.

[24] CIHI. National Unique Identifier for Health Care Providers Feasibility Study; 2010.

[25] WHO. Dutch EHR plans put on hold; 2010. Available from: http://ehealtheurope.net/comment_and_analysis/608/dutch_ehr_plans_put_on_hold.

[26] Moreno Conde A, D B. Towards best practice in the Archetype Development Process . Dublin: University of Dublin; 2010.

[27] Corrigan D, Berry D. Towards use of OpenEHR Archetypes to support views of Cystic Fibrosis Review Records. Dublin: University of Dublin; 2010.

[28] Rector AL. Clinical terminology: why is it so hard? Methods of information in medicine. 1999;38(4/5):239–252.

[29] Rector AL. Terminology, Codes, and Classifications — Why its hard. In: British Health IT Conferences; 2000. .

[30] Cimino JJ. Desiderata for controlled medical vocabularies in the twenty-first century. Methods of Information in Medicine-Methodik der Information in der Medizin. 1998;37(4):394–403.

[31] IHTSDO. SNOMED Clinical Terms User Guide 2010. Denmark: International Health Terminology Standards Development Organisation; 2010.

[32] Hahn U, Schulz S. Towards a broad-coverage biomedical ontology based on description logics. In: The Pacific Symposium on Biocomputing. vol. 8; 2003. p. 577–588.

[33] Bodenreider O, Smith B, Kumar A, Burgun A. Investigating subsumption in SNOMED CT: An exploration into large description logic-based biomedical terminologies. Artificial intelligence in medicine. 2007;39(3):183–195.

[34] Nelson Stuart J Schopen MSJAN. An Interlingual Database of MeSH Translations. In: 8th International Conference on Medical Librarianship. London, UK; 2000. .

[35] Read Codes, a coded thesaurus of clinical terms. Connecting for Health, NHS; 2010. \url{http://www.connectingforhealth.nhs.uk/systemsandservices/data/uktc/readcodes}.

[36] Beale T, Heard S. An ontology-based model of clinical information. Studies in health technology and informatics. 2007;129(1):760.

[37] Relationship between openEHR Specifications and HL7v3 Standards. openEHR organisation; 2007. \url{http://www.openehr.org/206-OE.html}.

[38] Kilic O, Bicer V, Dogac A. Mapping Archetypes to OWL. Middle East Technical University (METU); 2006.

[39] IHTSDO and openEHR Begin Collaborative Work Programme. openEHR organisation, IHTSDO; 2009. \url{http://http://www.openehr.org/292-OE.html}.

[40] Beeler G W , Huff, S , Rishel, W , Shakir, A-M , Walker, M , Mead, C , Schadow G. HL7 Version 3 - Message Development Framework; 1999.

[41] Flores AE, Win KT. Analyzing the key variables in the adoption process of HL7. Studies in health technology and informatics. 2007 Jan;129(Pt 1):444–8. Available from: `http://www.ncbi.nlm.nih.gov/pubmed/17911756`.

[42] Danko A, Kennedy R, Haskell R, Androwich IM, Button P, Correia CM, et al. Modeling nursing interventions in the act class of HL7 RIM Version 3. Journal of biomedical informatics. 2003;36(4-5):294–303. Available from: `http://www.ncbi.nlm.nih.gov/pubmed/14643725`.

[43] Liaw ST, Sulaiman N, Pearce C, Sims J, Hill K, Grain H, et al. Falls prevention within the Australian general practice data model: methodology, information model, and terminology issues. Journal of the American Medical Informatics Association : JAMIA. 2003;10(5):425–32. Available from: `http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=212779\&tool=pmcentrez\&rendertype=abstract`.

[44] European Committee for Standardization Belgium B. ENV 12265 Health Informatics - Electronic Healthcare Record Architecture; 1995.

[45] CENTC/251. ENV13606: Electronic Health Record Communication. European Standardization of Health Informatics; 1999. Available from: `http://www.centc251.org`.

[46] CEN/TS. CEN/TS 14796: Health Informatics - Data Types; 2004.

[47] CEN/TC 251. (prEN 13606-1) Health informatics - Electronic health record communication - Part 1: Reference model. Exchange Organizational Behaviour Teaching Journal. 2006;p. 1–100.

[48] No Title;. Available from: `www.openEHR.org/knowledge`.

[49] Atala? K. Archetype Based Domain Modeling for Health Information Systems [PhD Thesis]. Middle East Technical University; 2007.

[50] Lundell KH. The Swedish ehealth approach - Symposium on Swedeish ehealth strategy. Center for eHealth in Sweden and the National Board of Health and Welfare; 2010.

[51] Lincoln A Moura. EHR Implementation. In: 15th Annual Conference and Scientific Symposium; 2010. .

[52] ISO TC215. ISO 13606-1:2008 Health informatics – Electronic health record communication – Part 1: Reference model; 2008.

[53] ISO/IEC. ISO/IEC 10746 Information Technology - open distributed processing Parts 1-4;.

[54] TC215. ISO 13606-2:2008 Health informatics – Electronic health record communication – Part 2: Archetype interchange specification; 2008.

[55] TC215. ISO 13606-3:2009 Health informatics – Electronic health record communication – Part 3: Reference archetypes and term lists; 2009.

[56] TC215. ISO TC215 2009 ISO/TS 13606-4:2009 Health informatics – Electronic health record communication – Part 4: Security; 2009.

[57] TC215. ISO 13606-5:2010 Health informatics – Electronic health record communication – Part 5: Interface specification; 2009.

[58] Beale ET, Heard S, Kalra D, Lloyd D. The openEHR Reference Model - EHR Information Model. Health (San Francisco). 2007;.

[59] HIQA. International Review of Unique Health Identifiers for Individuals; 2010.

[60] HL7. HL7 Reference Information Model; 2007. Available from: http://www.hl7.org/Library/data-model/RIM/modelpage_mem.htm.

[61] ISO/TC 215. Health informatics Provider identification. 2007;(30).

[62] ISO/TC 215. Health informatics Identification of subjects of healthcare. 2006;(40).

[63] HSSP. Healthcare Services Specification Project - Identity Cross-Reference Service;. Available from: http://hssp.wikispaces.com/EIS+Normative+Ballot.

[64] OMG. Entity Identification Service (EIS) Specification. Group. 2009;(April).

[65] OMG. Person Identification Service (PIDS) Specification. 2001;(April).

[66] NHS. Personal Demographics Service (PDS) - A guide for general practice; 2008. Available from: http://www.connectingforhealth.nhs.uk/systemsandservices/demographics/pds.

[67] Noumeir R. Integrating the healthcare enterprise process. International Journal of Healthcare Technology and Management. 2008;9(2):167. Available from: http://www.inderscience.com/link.php?id=17371.

[68] IHE. Patient Identifier Cross-Reference (PIX) and Patient Demographic Query (PDQ) HL7 v3 Transaction Updates; 2006. Available from: http://www.ihe.net/Technical_Framework/upload/IHE_ITI_TF_Suppl_PIXPDQ_HL7v3_PC_2006_08_15.pdf.

[69] Blobel B. Authorisation and access control for electronic health record systems. International journal of medical informatics. 2004;73(3):251–7. Available from: http://www.ncbi.nlm.nih.gov/pubmed/15066555.

[70] Ferraiolo D, Kuhn DR, Chandramouli R. Role-based access control. Artech House; 2003. Available from: http://books.google.com/books?hl=en\&lr=\&id=48AeIhQLWckC\&pgis=1.

[71] Health Canada Infoway. An overview of the Electronic Health Record Privacy and Security Conceptual Architecture; 2006.

[72] Infoway. Infoways EHRS Blueprint v2. Health (San Francisco). 2006;.

[73] Blobel B, Nordberg R, Davis JM, Pharow P. Modelling privilege management and access control. International journal of medical informatics. 2006;75(8):597–623. Available from: http://www.ncbi.nlm.nih.gov/pubmed/16199198.

[74] OMG. Resource Access Decision Facility Specification. 2001;(April).

[75] Klein G, Ohyama N. Health informatics - Privilege management and access control - Part 3: Access control management. Access. 2003;.

[76] ISO/TS. Health informatics – Privilege management and access control – Part 1: Overview and policy management. 2006;Available from: http://www.iso.org/iso/catalogue_detail.htm?csnumber=36337.

[77] The GEHR Project; 1998. Available from: http://www.chime.ucl.ac.uk/work-areas/ehrs/GEHR/index.htm.

[78] ASTM. E1238-94: Standard Specification for Transferring Clinical Observations Between Independent Computer Systems. American Society for Testing of Materials; 1994.

[79] Bidgood W D Horii SCPFWVSDE. Understanding and using DICOM the data interchange standard for biomedical imaging. Journal of the American Medical Informatics Association. 1997;4(3):3.

[80] Lamberts H WM. International classification ofprinary health care. Oxford:: Oxford University Press; 1987.

[81] Organization WH. International Statistical Classification of Diseases and Related Health Problems. World Health Organization; 1992.

[82] Rong C, Erik S, Daniel K, Hans A. Archetype-based conversion of EHR content models: pilot experience with a regional EHR system. BMC Medical Informatics and Decision Making. 2009;9:13.

[83] HIQA. General Practice Messaging Standard. Health Information and Quality Authority; 2010.

[84] O'Shea Y. Clinical Directorates in the Irish Health Services: Managing Resources and Patient Safety. Dublin, Ireland: Blackhall Publishing Ltd; 2009. Available from: http://www.amazon.co.uk/Clinical-Directorates-Irish-Health-Services/dp/1842181858.

[85] Aiken, L H , Clarke, J And Sloane DM. Hospital staffing, organisational Support , and quality of care: cross -national findings. International Journal for Quality and Healthcare. 2002;p. 14pp5–13.

[86] Mac Neela P, Scott PA, Treacy MP, Hyde A. Nursing minimum data sets: a conceptual analysis and review. Nursing inquiry. 2006 Mar;13(1):44–51. Available from: http://www.ncbi.nlm.nih.gov/pubmed/16494666.

[87] Needleman J, Buerhaus P, Mattke S, Stewart M, Zelevinsky K. Nurse-staffing levels and the quality of care in hospitals. The New England journal of medicine. 2002 May;346(22):1715–22. Available from: http://www.ncbi.nlm.nih.gov/pubmed/12037152.

[88] Organisation for Economic Co-operation and Development. Improving Health sector Efficiency. OECD Publishing; 2010. Available from: http://www.oecd-ilibrary.org/social-issues-migration-health/improving-health-sector-efficiency_9789264084612-en.

[89] Hannah KJ, White PA, Nagle LM, Pringle DM. Standardizing nursing information in Canada for inclusion in electronic health records: C-HOBIC. Journal of the American Medical Informatics Association : JAMIA;16(4):524–30. Available from: http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=2705256\&tool=pmcentrez\&rendertype=abstract.

[90] Doran D, Almost J. Nursing sensitive outcomes: the state of the science. Toronto Canada: Jones & Bartlett Learning; 2003. Available from: http://books.google.com/books?id=CxPP9jaT-TIC\&pgis=1.

[91] International Classification of Nursing Practice version 1.1;. Available from: http://icnp.clinicaltemplates.org/icnp/.

[92] European Committee for Standardization Belgium B. EN13606 Health informatics - Electronic health record communication-Part 1: Reference model.;.

[93] European Committee For Standardization Belgium B. TS 14796. Health informatics Data types: Technical Specification. 1994;.

[94] Group P. No Title; 2010. Available from: http://www.partnersct.com.

[95] McCandless M, Hatcher E, Gospodnetic O. Lucene in Action, Second Edition: Covers Apache Lucene 3.0. Manning Publications; 2010. Available from: http://www.amazon.com/Lucene-Action-Second-Covers-Apache/dp/1933988177.

[96] Baeza-Yates R, Ribeiro-Neto B. Modern Information Retrieval. Addison Wesley; 1999. Available from: http://www.amazon.com/Modern-Information-Retrieval-Ricardo-Baeza-Yates/dp/020139829X.

[97] Yu, S; B , Damon; Bisbal J. An Investigation of Semantic Links to Archetypes in an External Clinical Terminology through the Construction of Terminological Shadows . In: IADIS International Conference e-Health; 2010. .

[98] EHRland. A technological assessment of the five-part EN13606 standard; 2010. Available from: www.ehrland.ie.

[99] Maldonado J, A Moner D, Tomas D, Angulo C, Robles M, Fernandez JT. Framework for Clinical Data Standardization Based on Archetypes. STUDIES IN HEALTH TECHNOLOGY AND INFORMATICS. 2007;129:454–458. Available from: http://books.google.com/books?hl=en\&lr=\&id=dEXxG4XyvKwC\&pgis=1.

[100] Allen C Browne Alexa T McCray SS. The SPECIALIST Lexicon;.

[101] IEHL. All Ireland Electronic Health Library;. Available from: http://www.aiehl.org/.

[102] INISPHO. Ireland and Northern Ireland Population Health Observatory;. Available from: http://www.inispho.org/.

[103] IPH. Institute of Public Health ;. Available from: http://www.publichealth.ie/.

[104] CSO. Central Statistics Office;. Available from: www.cso.ie.

[105] StatCentral. StatCentral;. Available from: http://www.statcentral.ie/.

[106] ProREC. Inventory of clinical data sets. ProREC Italy;. Available from: http://www.prorec.it/registry.htm.

[107] Rossi Mori A, Consorti F, Ricci FL. Sharing clinical information. principles and task-oriented solutions. Studies in health technology and informatics. 2002 Jan;87:102–14. Available from: http://www.ncbi.nlm.nih.gov/pubmed/15458046.

[108] Mori R. Systematic sharing of clinical information - from local EPRs to EHR services; 2002.

[109] NEHTA. NEHTA Interoperability Framework. NEHTA;. Available from: http://www.nehta.gov.au/connecting-australia/ehealth-interoperability.

[110] Beale T, Heard S. Archetype Definitions and Principles. Ocean Informatics / openEHR foundation; 2007.

[111] McNichol I, Leslie H. Introduction to openEHR Archetypes and Templates. Ocean Informatics / openEHR foundation; 2009.

[112] Beale T. openEHR Archetype Object Model. Ocean Informatics / openEHR foundation; 2007.

Appendix A

Title

An investigation of semantic links to archetypes in an external clinical terminology through the construction of terminological "Shadows"

Authors

Yu, S., Berry, D. and Bisbal, J.

Abstract

The two-level model based specifications for electronic health record communication EHRcom (ISO 13606) and openEHR both support the embedding of terminological references in Archetypes. This terminological binding can be created manually by a health terminology expert during Archetype design, and the binding is assessed during Archetype evaluation. There has also been some recent work on using lexical queries to generate term sets to represent concepts in Archetypes. This work created an information construct which we call a Terminological Shadow that links Archetype nodes to sets of candidate concepts from a terminology system. The coding scheme used for this work is SNOMED-CT. The proposed Shadows can be used to facilitate the mapping between an Archetype information model and terminological systems. A framework, which also acts as an analysis tool, has been created to construct Shadows from Archetypes. The work also demonstrates how the framework can be used to evaluate different searching algorithms by comparing the search results to the existing bound SNOMED codes.

Publication or Conference

Presented at *IADIS e-health Conference*, Freiburg Germany, 2010

Appendix B

Title

An EHRcom-compliant assessment tool for community nursing in Ireland

Authors

Camous, F., Duignan, F. and Henry, P.

Abstract

Community nursing in Ireland refers to the delivery of healthcare to patients at several locations by nurses with different specialties. To ensure continuity of care, community nurses need to access patient-centered information collected during health assessments as the patient moves through the system. The comparison of assessments at different stages of the care process produces patient-centred healthcare evaluation measures called outcomes. The outcomes give a better visibility of the impact the care delivered by each service has on the patients health. However, successful information communication and comparison necessitates a high level of interoperability with the use of agreed standards, data types,and code sets. In this paper we describe the presentation of a patient assessment tool compliant with European standards (CEN EN13606, TS14796), and using terminologies describing patient outcomes (C-HOBIC) and nursing practices (ICNP). The tool is developed within the PARTNERS (Participatory Action Research project To develop Nursing Electronic ResourceS) project, a part of the EHRland (EHR for Ireland) project. The demonstration includes the capture of data from assessment forms, and the generation of data views specific to the interests of health service providers and the patient. Section 1 presents the assessment tool and Section 2 describes the demonstration.

Publication or Conference

Presented at *IADIS International Conference e-Health Conference*, Algarve Portugal 2009

Appendix C

Title

An analysis framework for electronic health record systems

Authors

Bisbal, J. and Berry, D.

Abstract

Background: The timely provision of complete and up-to-date patient data to clinicians has for decades been one of the most pressing objectives to be fulfilled by information technology in the healthcare domain. The so-called Electronic Health Record (EHR), which provides a unified view of all relevant clinical data, has received much attention in this context from both research and industry. This situation has given rise to a large number of research projects and commercial products that aim to address this challenge. Different projects and initiatives have attempted to address this challenge from various points of view, which are not easily comparable.

Publication or Conference

Methods of Information in Medicine 2010 (Vol. 49): Issue 6 2010

Appendix D

Title

Archetype alignment: a two-level driven semantic matching approach to interoperability in the clinical domain

Authors

Bisbal, J. and Berry, D.

Abstract

Semantic interoperability between electronic health record systems and other information systems in the health domain implies agreement about the structure and the meaning of the information that is communicated. There are still a number of similar but different EHR system approaches. Some of the newer approaches adopt the two-layer model approach where a generic reference model is constrained by archetypes into valid clinical concepts which can be exchanged. The meaning of the concepts that are represented by an archetype can be conveyed by embedding codes from a commonly recognised terminology at appropriate points in the archetype. However, as the number of archetypes multiply it will become necessary to match archetypes from different sources to facilitate interoperability. This paper describes an approach that supports semantic interoperability between heterogeneous two-level health information systems by identifying similarities between archetypes. The approach identifies relationships between ontological terms which have been embedded in pairs of archetypes as a means of matching these terms. The matched terms can then in turn be used to identify similarities between archetypes. The limited contextual scope of an archetype simplifies this matching process.

Publication or Conference

Proceedings of the International Conference on Health Informatics, HEALTHINF 2009

Appendix E

Title

Use Of OIDs And IIs in EN13606

Authors

Berry, D., Ven, J., Freriks, G. and Moner, D.

Publication or Conference

DIT technical paper

Appendix F

Title

EHRland XML Adapter (And Boundary DB)

Authors

Kuba Chrzanowski.

Appendix G

Title

Terminology enhanced EHR: integration of archetypes and terminology, an implementation experience

Authors

Yu, S. and Berry, D.

Abstract

The integration of terminology and EHR information models is an important step in the journey towards semantic interoperability. Archetypes and two-level models for EHRs provide a mechanism that not only applies constraints on clinical content but also ensures effective terminology binding. However the lack of a standardised mechanism to bind terminology to the EHR and the difficulty of systematically coding clinical content, has led to a number of possible implementation choices.

This study presents a review of the problems that may occur when working with modern terminology systems and discusses some related state of art technologies. The paper aims to share the experience of prototyping a minimum terminology integration service. A set of tools utilising medical text processing and a customised SNOMED-CT data source are the output of prototyping that enables quick processing of archetypes and automatic link suggestions to SNOMED-CT. The elaboration of prototypes of this sort can be used as components of an integration engine.

Publication or Conference

Presented at *the 15th Annual HISI Conference and Scientific Symposium*, 17th- 18th November 2010 in the Stillorgan, Dublin.

Appendix H

Title

EHRcom-compliance for EHR exchange in Ireland: requirements for an architecture

Authors

Camous, F., Chen, X., Yu, S., Berry, D and Grimson, W.

Abstract

Abstract. The Electronic Health Record (EHR) contains information about the health of a patient in a computable form. The implementation of the EHR within national health systems is largely motivated by the improvement of patient care by measures such as the reduction of data entry errors, the ease of data exchange, a better-informed care delivery nationwide, and cost control. Such an implementation is challenged by a lack of semantic inter-operability between current health information systems, and by health-specific issues such as privacy and access control, given the sensitive nature of the information contained in the EHRs. These challenges have recently been addressed by a collaboration of standards organisations (ISO, CEN), research groups, and open source initiatives such as openEHR. In particular, CEN standard EHRCom uses a two-layered model approach that separates the information system implementation from the evolving domain knowledge. This paper presents an EHRCom-compliant architecture for the implementation of the EHR in Ireland. The architecture is compared with the state-of-the-art and tackles several requirements for EHR implementation in the Irish context. Specifically, initial solutions for adapting legacy information systems, identity resolution, semantic inter-operability, and access control are described. This work is part of the EHRland project, which is funded by the Health Information and Quality Authority (HIQA).

Publication or Conference

Presented at *the 13th Annual HISI Conference and Scientific Symposium*, 17th- 18th November 2009 in the Stillorgan, Dublin.

Appendix I

Title

Identity management to support access control in e-health systems

Authors

Chen, X., Berry, D. and Grimson, W.

Abstract

The related and often challenging topics of identity management and access control form an essential foundation for e-health infrastructure. Several approaches and supporting specifications for electronic healthcare record system (EHR-S) communication have been proposed by research projects and standards development organizations in recent years. For instance, part four of the CEN TC251 EN13606 EHRcom standard and the HL7 Role Based Access Control Draft Standard for Trial Use have helped to specify the nature of access control behaviour in relation to EHR communication within and between healthcare organisations. Access control services are a core component not only of the integrated care EHR-S but also for other information systems in the e-health domain. To underpin functionality of this type in a distributed environment, it is necessary to provide access to scalable, secure and uniform ID domains for users and patients.

This paper considers the use of part four of the EHRcom standard in the context of the availability (or lack thereof) of national identification systems for patients and for users of an integrated care EHR-S. This work begins with a brief summary of the state-of-the-art in identity management and access control in the health domain and a description of approaches that could lead to a secure and interoperable identification mechanism. To address the identification problem, the authors describe well known EHR access control viewpoints that are compatible with the CEN standard for EHR communication, EN13606 and describe how an identification service can support this functionality.

Publication or Conference

Presented at *4th European Conference of the International Federation for Medical and Biological Engineering*, 23 - 27 November 2008, Antwerp, Belgium.

Appendix J

Title

Tutorial on using MirthConnect with XQUERY output of LinkEHR to transform Hl7v2 messages into EHRcom-compatible XML messages

Authors

Sebastien Pardon

Description

This document describes how a developer can take an XQUERY file produced by LinkEHR and use it as a the basis of a HL7 to EN13606 message converter using the open source integration engine, MirthConnect. The tutorial shows how the combination can be used to transform a simple HL7 lab message into an equivalent EN13606 message.

Publication or Conference

Available at `http://www.ehrland.ie/resource/MirthConnect-howto.pdf`, July 2010.

Appendix K

Reference model objects	Attributes	National constraints		Local constraints			
		EN13606 constraints	EHRland constraints	System-specific	Patient-specific	Template-specific (HBA1C)	Instance-specific
EHR extract &	ehr_id.II.assigningAuthorityName.String			same as for EHR system			
	ehr_id.II.extension.String				MRN		
	ehr_id.II.validTime.IVLtextless TStextgreater				TBD		
	ehr_id.II.OID.oid.String			EHR system OID			
	ehr_system.II.assigningAuthorityName.String		TBD				
	ehr_system.II.extension.String		null string				
	ehr_system.II.validTime.IVLtextless TStextgreater			received from assigning authority			
	ehr_system.II.OID.oid.String			received from assigning authority			
	rm_id.String		"EN13606"				
	subject_of_care.II.assigningAuthorityName.String		TBD				
	subject_of_care.II.extension.String				received from assigning authority		
	subject_of_care.II.validTime.IVLtextless TStextgreater				received from assigning authority		
	subject_of_care.II.OID.oid.String		TBD				
	time_created.TS.time						generated on extract creation
	all_compositions.Settextless COMPOSITIONtextgreater						populated according to request

Table. Distinguished Parts of the State by National Constraint or Local Constraint

Reference model objects	Attributes	National constraints		Local constraints			
		EN13606 constraints	EHRland constraints	System-specific	Patient-specific	Template-specific (HBA1C)	Instance-specific
Record component	name.TEXT					originalText.String value depends on location in template (see table below)	
	meaning.CV.codeValue.String					depends on location in archetype (see d table below)	
	meaning.CV.codingScheme.OID.oid					TBD (archetype OID)	
	meaning.CV.codingSchemeName.String					archetype name	
	meaning.CV.codingSchemeVersion.String					archetype version	
	meaning.CV.displayName.String					text value of archetype node in ontotlogy or given by archetype constraint (see dedicated table)	
	rc_id.II			=LocalRcIITemplate.getII()			
	synthesised.Boolean					depends on location in template	
	archetype_id.String					only if located in archetype: "CEN-EN13606-ENTRY.Observation-laboratory-hba1c.v2" + path	
Composition	committal.AUDIT_INFO.committer.II			=LocalCommitterIITemplate.getII()			
	committal.AUDIT_INFO.ehr_system.II			=EhrSystemIITemplate.getII()			
	committal.AUDIT_INFO.time_committed.TS.time.String						determined at committal time
	content.Settextless CONTENTtextgreater					one element: the root ENTRY of the archetype	
Entry	uncertainty_expressed.Boolean			"false"			
	subject_of_information.RELATED_PARTY.relationship.TEXT					originalText.String="self"	
	items.Settextless ITEMtextgreater					Only one CLUSTER with constraints associated with path "/items[at0011]"	

Table. Distinguished Parts of the State by National Constraint or Local Constraint

Reference model objects	Attributes	National constraints		Local constraints			
		EN13606 constraints	EHRland constraints	System-specific	Patient-specific	Template-specific (HBA1C)	Instance-specific
Item	obs_time.IVLtextless TStextgreater.low.TS.time.String						single value for locations "/items[at0011]" and "/items[at0011]/items[at0020]"
	obs_time.IVLtextless TStextgreater.lowClosed.Boolean					always true	
	item_category.CS					codeValue.String="IC01". just for archetype location "/items[at0011]/items[at0020]" and "/items[at0011]/items[at0020]/items[at0004]"	
Cluster	structure_type.CS	MANDATORY, see structure_type.CS				codeValue.String="STRC01" for all CLUSTERs in archetype	
	parts.Settextless ITEMtextgreater					depends on location in template	
Element	value.DATA_VALUE					DATA_VALUE subtype depends on template location	
RTO	numerator.PQ.value.Real					only one location in template (HBA1C element)	single datasource
	denominator.PQ.value.Real					only one location in template (HBA1C element), always =100	
TEXT	charset.CS		see charset.CS				
	language.CS		see language.CS				
	originalText.String						any text
language.CS	codeValue.String		"en"				
	codingScheme.OID.oid.String		"777.777.777.777"				
	codingSchemeName.String	"ISO 639:1988 (E/F)"					
	codingSchemeVersion.String		"1"				
charset.CS	codeValue.String		"ISO/IEC 8859"				
	codingScheme.OID.oid.String		"888.888.888.888"				
	codingSchemeName.String	"IANA RFC 2978"					
	codingSchemeVersion.String		"1"				

Table. Distinguished Parts of the State by National Constraint or Local Constraint

	Attributes	National constraints		Local constraints			
		EN13606 constraints	EHRland constraints	System-specific	Patient-specific	Template-specific (HBA1C)	Instance-specific
Reference model objects	obs_time.IVLtextless TStextgreater.lowClosed.Boolean					always true	
	item_category.CS					codeValue.String="IC01". just for archetype location "/items[at0011]/items[at0020]" and "/items[at0011]/items[at0020]/items[at0004]"	
structure_type.CS	codeValue.String						"STRC01" or "STRC02"
	codingScheme.OID.oid.String		"999.999.999.999"				
	codingSchemeName.String	"CEN/TC251/EN13606-3:STRUCTURE_TYPE"					
	codingSchemeVersion.String		"1"				
item_category.CS	codeValue.String						"IC0[1-9]"
	codingScheme.OID.oid.String		"101.101.101.101"				
	codingSchemeName.String	"CEN/TC251/EN13606-3:ITEM_CATEGORY"					
	codingSchemeVersion.String		"1"				

Table. Distinguished Parts of the State by National Constraint or Local Constraint

The first column gives the name of relevant reference model objects for which it is intended to create factory classes integrating constraints specified at different levels (EN13606, EHR*land*, local system). Some objects are given a context as the constraints only apply to them in specific contexts: structure_type.CS corresponds to a CS object assigned the structure_type attribute of a cluster object; this distinction is useful as constraints are specified in EN13606 for a CS object only when it is assigned to the structure_type attribute of a cluster object.

The second column lists paths which point to values specified at some level by constraints. Paths are used as the constrained values are not always directly assigned to the attributes of the object given in column one. For example, there are no constraints at one particular level (national, local) to specify how to instantiate an II object assigned to the ehr_id attribute of an EHR_extract object. However, an EHR system will be given an OID, and the actual value of this OID will be stored at the location pointed by the path "ehr_id.II.OID.oid.String". Note that we could also have presented this constraint in a new row, as a constraint for an II object in the ehr_id context, namely ehr_id.II, similarly to the structure_type.CS row mentioned in the previous paragraph.

The third column in the table, "EN13606 constraints", corresponds to constraints which are given by the standard. For example, the structure and type of a cluster component must be specified using a CS data type. Furthermore, the coding scheme name for the structure type of a cluster (assigned to structure_type.CS.codingSchemeName.String) must be "CEN/TC251/EN13606-3:STRUCTURE_TYPE". The code value for the structure type (assigned to structure_type.CS.codeValue.String) is limited to two possible values: "STRC01" or "STRC02".

The fourth column, "EHR*land* constraints", corresponds to constraints which were determined over the course of the EHR*land* project, some of which can be considered as recommendations for the implementation of EN13606. It is especially the case for the management of IIs in EHR*land*. For example, the team decided on a hierarchical way to organise IIs and their root OIDs in the following fashion:

1. the II of an EHR system has no extension, only a root OID,
2. any EHR managed by the EHR system will have the same root OID, but will be distinguished by the assignment of an extension, and
3. any record component belonging to an EHR will have an rc_id.II (II object assigned to the rc_id attribute) sharing the same root OID, which value is a concatenation of the EHR root and the EHR extension, and a distintive extension, determined locally.

This is why the value pointed to by the path "ehr_system.II.extension.String" is null and is specified as an EHR*land* constraint.

The fifth column, "System-specific", corresponds to constraints specified locally, or specified nationally but only applied locally. For example, the root OID value of the II of the EHR system (an attribute of the EHR extract object) is only used for a specific EHR system, but the value is generated by a national authority.

The sixth column, "Patient-specific", correspond to patient-specific constraints, essentially relating to the II identifying the EHR in the EHR extract. Note that in the case of the II of the subject of care, the constraint, while being obviously patient-specific, is not really a local constraint but a national/EHR*land* constraint. Indeed, in EHR*land*'s interpretation of EN13606, the subject of care IIs share the same OID root and are distinguished nationally by their extension.

The seventh column, "Template-specific (HBA1C)", corresponds to constraints decided locally, including national archetypes or not, which indicates how a particular composition, here a composition containing an HBA1C observation, must be structured for inclusion in an EHR archetype. For example, the name of a record component which is part of an HBA1C record component structure, and which value is pointed to by path "name.TEXT.originalText.String", depends on its location in the template as indicated in Table 1.

Possible values for RECORD_COMPONENT.name.TEXT.originalText.String are showed in Table 1.

Table 1: Possible Values for RECORD_COMPONENT.

Template location	value
Root composition	"HBA1C Composition"
path: "/"	"HBA1C Observation"
path: "/items[at0011]"	"Data"
path: "/items[at0011]/parts[at0020]"	"Point event"
path: "/items[at0011]/parts[at0020]/-parts[at0004]"	"Event data"
path: "/items[at0011]/parts[at0020]/-parts[at0004]/parts[at0.0.6]"	"HbA1c"

Finally, the eight column, "Instance-specific", corresponds to constraints applied to instances of reference model objects. It does not mean that the constraints are specified for each instance, but that a choice is made for each instance within a constraint which may be specified nationally. For example, for the reference model object "item_category.CS", the standard gives us a list of possible values for the attribute "codeValue.String". However, only when we instantiate a cluster object are we able to determine the value of that attribute.