Towards use of OpenEHR Archetypes to support views of Cystic Fibrosis Review Records

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Declaration

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

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Summary

Developing software poses a number of significant challenges. One of the most fundamental is how to accurately represent domain information required by a clinical computer system. This is particularly problematic with traditionally designed computer systems due to the constantly dynamic state of clinical knowledge.

The OpenEHR approach to designing systems using 2-level information models has been proposed as providing such a dynamic solution to knowledge representation. The claims for OpenEHR have been investigated as part of this study by practically applying the OpenEHR data modelling approach to data that is represented as part of the Cystic Fibrosis Registry of Ireland using OpenEHR concepts of archetypes and templates. This study aimed to assess whether OpenEHR was able to provide the required dynamic views of data to satisfy a number of Cystic Fibrosis multi-disciplinary team members.

The practical outputs of this study included an archetype development methodology and a template development methodology addressing key deficiencies identified in the existing literature. In addition a practical new archetype relating to spirometry measurements was positively reviewed and incorporated into development efforts being carried out by the OpenEHR foundation.

OpenEHR was found to be sufficiently descriptive to achieve the primary goals of the study and addresses key problems inherent in developing clinical systems. Its strongest point and greatest potential is in its ability to re-use existing archetype designs to rapidly prototype and develop new systems, and to change as knowledge is updated.

OpenEHR still needs to mature in a number of key areas. Despite significant progress, archetype and template development standards, data governance mechanisms and graphic representation of archetype data need to develop further.

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Abbreviations

ADL – Archetype Definition Language

AEG – Archetype Editorial Group

AM – Archetype Model

ANSI –American National Standards Institute

BMI – Body Mass Index

CEN - Comité Européean de Normalisation

CDA – Clinical Document Architecture

CFTR - Cystic Fibrosis Transmembrane Conductance Regulator

CKM – Clinical Knowledge Manager

CF – Cystic Fibrosis

EHR – Electronic Health Record

EHRCom - Electronic Healthcare Record Communication

FEF - Forced Expiratory Flow

FEV – Forced Expiratory Volume

FVC - Forced Vital Capacity

GEHR – The Good European Health Record / The Good Electronic Health Record

GP – General Practitioner

GUI – Graphical User Interface

HL7 –Health Level 7

ICT – Information Communication Technology

ISO – International Standards Organisation

IT – Information Technology

JPEG – Joint Photographic Experts Group

NHS – National Health Service

ODMA - OpenEHR Data Modelling Approach

PMI – Patient Master Index

RM – Reference Model

SM – Services Model

SVN - Subversion

SNOMED CT - Systematized Nomenclature of Medicine Clinical Terms

XML – Extensible Markup Language

1. Introduction

Developing software systems has never been an easy task. This is despite continual evolution of software design over a period of fifty years and continued research into how to develop better quality software (Mens et al., 2005).

Any computer system must somehow represent the knowledge it uses in a computable format that the system can interpret and use. This knowledge defines the logic that is to be applied to generate the useful information that a computer system generates as information from it. In essence this computer knowledge defines the inherent usefulness and scope of any given computer-based system.

Representing the Knowledge Domain in Software

Knowledge is domain-specific in that a financial system will use knowledge from the finance domain (e.g. a tax calculation), a manufacturing system will use knowledge from the manufacturing domain (e.g. how to calculate dimensions to cut a sheet of wood) and a clinical system will use knowledge from the clinical domain (e.g. what blood pressure reading constitutes high blood pressure).

Typically most computer systems will be constructed from at least three or more distinct architectural 'layers' within which domain knowledge may be represented (Sunblad et al., 2000) (Knight et al., 2002). These are:

- a Graphical User Interface (GUI) layer which is the interface displayed to the user so they can meaningfully interact with the system

- an information layer which typically applies the domain knowledge and logic about how to interpret and perform calculations on certain recorded facts (e.g. blood pressure) to generate information (e.g. blood pressure is high)

- a data layer which is typically a database that holds the persistent information that is recorded and held on an on-going basis by the system e.g. an electronic health record

The second layer typically will hold most of the knowledge about how to apply domain knowledge within the system. However in many cases, particularly in older systems, examples can be found where domain knowledge is embedded in any of the three layers.

Two major questions posed by Beale et al. (2008) need to be asked in relation to representing the knowledge that a computer system needs and how it impacts on that system:

- when domain knowledge changes, who is responsible for updating this knowledge in a computer system and how easily can those changes be incorporated into the system?

- what happens when our understanding of relevant domain knowledge changes outside of a particular computer system?

The answer to these questions is problematic for the majority of commercial computer systems in use today. When domain knowledge changes it is typically the job of an Information Technology (IT) specialist to liaise with the domain experts e.g. doctors or nurses for a clinical system (Beale et al., 2008).

They interpret their knowledge and re-code it as part of the different architectural layers in the system. This can result in potentially serious mistakes if their interpretation is incorrect resulting in the dreaded 'bug fix' or 'service patch' to address it (Bennett et al., 2000).

Even if the interpretation is correct, the new knowledge is implemented in the system layers and a new release of the software needs to be made and distributed to the users of that system. This is done through a process called 'program compilation' as part of a 'servicing stage' (Bennett et al., 2000) which essentially packages the different layers together. They are represented as a single program called an executable (for example

Excel.exe). This usually involves considerable expense and time spent primarily on testing the new release of the software before being provided generally to the users.

The two major problems with representing domain knowledge in computer systems as described by Beale (2002) can therefore be summarised as:

- domain experts are not responsible for updating the domain knowledge in computer systems

- changes to domain knowledge are not dynamically incorporated and represented in the system resulting in rigid, inflexible views of data that need to be rebuilt when clinical knowledge changes

Representing Clinical Multi Disciplinary Team data

The problems we have seen in representing the knowledge domain in computer systems are greatly exacerbated when the domain being represented is in the clinical domain. The main reasons for this as discussed by Garde et al. (2007) are:

- IT experts are not clinicians: The clinical knowledge domain is an inherently complex one where experts have studied for many years to acquire their expertise in very specific areas e.g. a cardiologist. It is unreasonable to expect an IT expert to become a clinical expert in order to develop clinical systems

- the rate of change of the clinical knowledge domain: The creation or revision of clinical knowledge through research means that the clinical domain is constantly in flux and subject to rapid change

Inherent in the above statements is the conclusion that if clinical systems are to be of use at any given time, they must have the facility to change rapidly to reflect changes in clinical knowledge at that point in time.

Furthermore, to ensure system accuracy it is highly desirable that this knowledge should be able to be updated by the domain experts themselves rather than IT staff (Leslie et al., 2009).

It is clear that there is a direct contradiction when these requirements are viewed in conjunction with the limitations we detailed previously for representing domain knowledge in traditionally built computer systems.

A further clinical complication arises from the fact that best practice dictates that for many illnesses an approach known as 'multi-disciplinary team care' be adhered to, whereby patients are cared for by a team of specialists who collaboratively care for that patient rather than just one single clinician (Kerem et al., 2005).

This requires that a single set of data, such as a particular patient electronic health record, be presented using dynamic views of data that can be tailored to the requirements of each multi-disciplinary team member as clinical knowledge changes. We can conclude that current conventional software models are not suited to provide such a dynamically updating system.

OpenEHR – A Silver Bullet?

One potential solution that has been put forward by Beale et al. (2008) for addressing the problems previously detailed is called the OpenEHR architecture and has been proposed by an organisation known as the OpenEHR Foundation (OpenEHR Foundation 2006).

This uses an architectural software approach known as two-level information modelling which fundamentally changes the way we represent domain knowledge and who is responsible for updating it (Beale et al., 2008). OpenEHR is targeted specifically at representing knowledge in the clinical domain.

Target Clinical Domain for Study

It was decided to apply OpenEHR against a real world clinical problem domain to assess its suitability to address the issues previously highlighted. The chosen domain

was patient records for care of Cystic Fibrosis patients and will be detailed fully in section 2.2.

Existing Research

A literature review was carried out to establish what existing work has been done in applying the OpenEHR architecture to a practical clinical case study. This aimed to identify topics relating to use of OpenEHR that could be developed further to provide additional practical knowledge.

The following limitations were identified in the existing literature:

- no concrete example provided a 'how-to' complete practical walkthrough of implementing OpenEHR in a specific clinical case

- the OpenEHR 'archetype' concept (as detailed by Beale et al., 2007 and discussed in detail in section 2.3.3) is the fundamental building block in an OpenEHR system. A lack of detailed information exists on archetype design standards and methodologies

- the OpenEHR 'template' concept (as detailed by Beal et al. 2007 and discussed in detail in section 2.3.3) is the fundamental building block of data views in an OpenEHR system. A lack of detailed information exists on template design standards and methodologies

- no published archetypes currently exist that were specifically developed relating to the clinical area of Cystic Fibrosis

Statement of Thesis Goals

The primary goal of this case study is to assess the suitability of using the OpenEHR software architecture for providing dynamic views of patient data to support multi-disciplinary team care.

A practical OpenEHR software based prototype will be used to develop working OpenEHR archetypes and templates applied to a specified subset of Cystic Fibrosis patient records.

A secondary goal of this study is to develop the existing knowledge-base relating to the OpenEHR architecture specifically in relation to limitations identified in the existing literature.

Outline of Dissertation

Chapter 2 comprises a literature review of the state of the art and latest research on OpenEHR based systems.

Chapter 3 describes the research methodology and outlines the research approach adopted for this thesis and the research processes used.

Chapter 4 outlines the detail of the research primarily in describing the steps carried out to develop OpenEHR archetypes and templates for this case study.

Chapter 5 comprises an evaluation and discussion of the work done as part of this study.

Chapter 6 formally states the conclusions from this study.

2. Literature Review

2.1 Purpose of the Literature Review

Creswell (2009) states that the literature review 'provides insight into the ways in which the researcher can limit the scope to a needed area of inquiry'. With this in mind, a number of key requirements were identified to give focus to the review and narrow its scope to only the relevant literature that would further the specific goals of this study. These requirements along with the research goals that they aim to address are summarised in table 2.1.

Table 2-1: Requirements for Literature Review

No.	Literature Research Requirement	Research Goals
1	To **obtain a clinical overview** of what Cystic Fibrosis is and the major clinical effects it has on the human body.	To enable clear understanding of the clinical terminology and data that is collected as part of a Cystic Fibrosis patient record which will assist in the goal of creating clinically complete OpenEHR archetypes.
2	To **identify the key clinical concepts** typically captured as part of the periodic review carried out for Cystic Fibrosis patients according to currently documented best practice treatment guidelines.	To define the clinical concepts that will drive the design and content of the OpenEHR archetypes that will be used to model the Cystic Fibrosis data.

3	To **determine the key members of a multi-disciplinary team** for treatment of Cystic Fibrosis according to currently documented best practice treatment guidelines.	To identify the key multi-disciplinary team views of Cystic Fibrosis data that are required to be defined to drive the design and content of the required OpenEHR templates.
4	To understand the role and **usage of archetypes and templates** as part of the OpenEHR approach to EHR implementation.	To identify how to design and construct OpenEHR archetypes and templates using currently available design tools.
5	To identify current best practice **guidelines for designing and implementing OpenEHR archetypes** and templates.	To define the core design methodology to be used to construct and implement OpenEHR archetypes and templates.
6	**Identify key literature studies** where the OpenEHR approach has been applied in a practical clinical problem.	To assess the current maturity of OpenEHR as a technology. To identify any existing OpenEHR archetype and template design methodologies currently available that can be used for this study.

The definition of these goals focussed the review by identifying three main areas of literature research that needed to be carried out and are summarised as follows:

- research of Cystic Fibrosis clinical documents detailing current clinical understanding of the illness and best practice treatment guidelines for it

- research of OpenEHR technical documents which detail the design goals and architecture of the OpenEHR approach and specifically the role of archetypes and templates within it

- research of existing academic papers on practical clinical implementations of the OpenEHR approach for comparative purposes and to define a clear methodology for the practical work to be done as part of this study

The literature review will therefore be divided into two main sections. One will focus on summarising the relevant clinical literature available regarding Cystic Fibrosis. This will serve as the clinical domain for the practical application of the OpenEHR approach for this study.

A second section will look at the theory and technical details behind the OpenEHR approach. This will be framed in the context of any existing academic studies where it has been applied in a practical clinical setting.

2.2 Cystic Fibrosis Review

2.2.1 What is Cystic Fibrosis?

Cystic Fibrosis is a genetically inherited illness that cannot be contracted but may be passed from parents to their children. It is passed in the form of a faulty or defective gene which does not function in a clinically normal way. The gene in question was identified in 1989 and is known as the Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) gene and is found on chromosome 7 (Davies et al., 2007).

This gene plays a key role in producing mucus secretions for lubricating numerous organs such as the lungs and the pancreas. In a person with Cystic Fibrosis the mucus that is produced is not properly diluted by water. This results in particularly thick and sticky mucus that clogs and severely interferes with the clinical functions of a number of organ systems in the human body (Cystic Fibrosis Association of Ireland, 2010).

Each parent has a pair of CFTR genes of which they each pass one to their children. There are therefore four potential scenarios shown in figure 2.2 representing a 1 in 4 chance of a child developing Cystic Fibrosis where both father and mother are Cystic Fibrosis carriers:

- should you inherit two healthy CFTR genes (one from each parent) then you are free from Cystic Fibrosis

- should you inherit one faulty CFTR gene and one healthy CFTR gene from either combination of father and mother then you are said to be a 'carrier' of Cystic Fibrosis. You do not actually develop any Cystic Fibrosis symptoms but may pass the faulty gene to your own offspring

- should you inherit two faulty CFTR genes (one from each parent) then you have Cystic Fibrosis and develop the symptoms associated with it

(CF Association of Ireland, 2010)

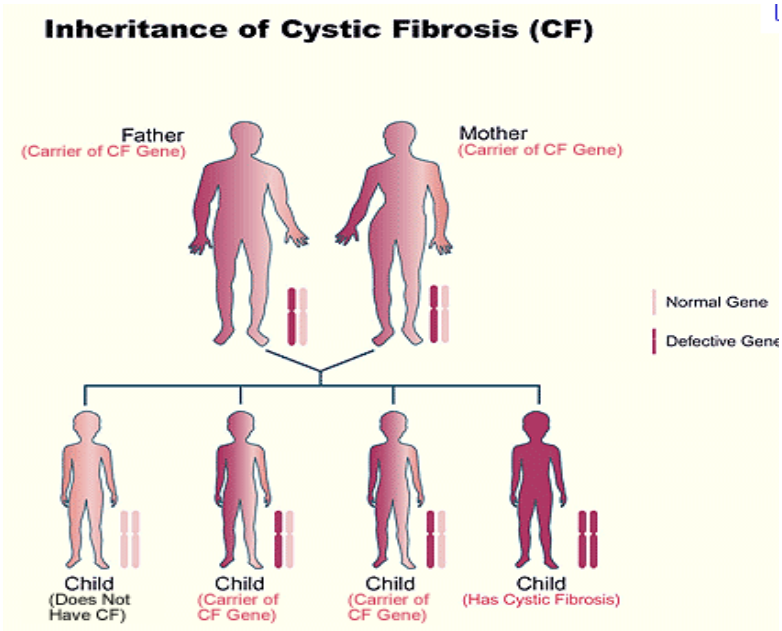


Figure 2-1: Inheritance of Cystic Fibrosis – (Adam Medical Images 2010)

2.2.2 Primary Clinical Effects of Cystic Fibrosis – (Davies et al., 2007)

The CFTR gene is found in numerous organs and systems in the body. The effects of Cystic Fibrosis are therefore extremely debilitating as it is in effect a multi-organ system disease. The primary effected systems are shown in table 2.2.

Table 2-2: Clinical Effects of Cystic Fibrosis

Organ/System	CF Effects
Lungs	Mucus builds up and clogs the lungs resulting in pulmonary damage leading to reoccurring lung infections and respiratory failure. Pulmonary failure is the primary cause of mortality for Cystic Fibrosis patients.
Pancreas	Mucus build up prevents proper release of enzymes preventing normal nutritional absorption of proteins and fats which results in malnutrition.
Gastrointestinal System	Mucus build up resulting in conditions such as vomiting, anorexia and constipation.
Sexual Organs	Usually results in infertility in men due to mucus build up obstructing the sperm canal. May cause reduced fertility in women.
Endocrine System	Mucus builds up resulting in reduced insulin production leading to CF related diabetes.
Bones / Muscles	Poor nutrition can result in osteoporosis and poor muscle tone.

2.2.3 Multi-Disciplinary Team Requirements for Effective CF Care

CF is an illness that affects a large number of anatomical systems. As a result of this, a general approach to treating CF is not feasible. Consensus among medical professionals has advocated the formation of dedicated CF teams of specialists based in dedicated CF treatment centres that treat the multiple effects of CF (Kerem et al., 2005). This is done on both an individual anatomical basis but also collectively and collaboratively with a view to providing the best possible care for a CF patient as a whole.

From a patient perspective, the following summary from Corrigan (2009) details the key individuals that will typically be part of the treatment team:

2.2.3.1 Physiotherapist

This team member is responsible for assessing pulmonary function and formulating individualised physiotherapy regimens for CF patients. They optimise lung function by instruction in preventative airway clearance techniques to remove mucus from air passageways, and correct use of inhalation devices and physical exercise. They provide education and assistance to patients and their family to optimise adherence to the designated regimen.

2.2.3.2 Dietician/Nutritionist

This team member is responsible for assessing dietary function and formulating individualised nutritional management regimens for CF patients to optimise nutritional intake with the assistance of nutritional and enzyme replacement therapy. They provide education and assistance to patients and their family to optimise adherence to nutritional and enzyme treatment drugs.

2.2.3.3 Psychologist/Social Worker

The following quote from Davies et al. (2007) details the need for a psychologist and social worker in CF care: 'Cystic Fibrosis clearly poses a huge burden to patients and families in terms of the life-shortening nature of the disease, the time consuming treatments prescribed, and the ongoing morbidity'. The role of the psychologist and social worker is to assist with management of these issues particularly at key points in the life of a CF patient such as diagnosis, transition of care and adolescence.

2.2.3.4 Pharmacist

A pharmacist plays a key role in CF treatment due to the complex medication regimens that CF patients must adhere to. Because of the multi-system nature of CF, a patient may potentially be on any combination of a large numbers of inhaled drugs, intravenous antibiotics and oral drugs at the same time. It is therefore crucial that a pharmacist with CF knowledge be part of the team to calculate optimal dosage of prescribed drugs and to monitor, advise and alter as necessary any regimens where drug interactions occur

2.2.3.5 Clinical Microbiologist

Bacterial lung infections such as Pseudomonas Aeruginosa are one of the primary contributors to mortality and morbidity in CF patients. These infections are typically different from similar infections found outside of CF patients. A clinical microbiologist with CF bacteriology knowledge is therefore crucial in identifying, treating and preventing these infections.

2.2.4 Outpatient Care – The Periodic Review

Best practice clinical guidelines (Kerem et al., 2005) state that CF patients will attend outpatient clinics for a detailed annual review and a less rigorous periodic review every 1 to 6 months depending on general health and CF severity levels.

The items typically covered as part of any periodic review are summarised in table 2.3. (from CF Registry of Ireland documents in Appendix A).

Table 2-3: Cystic Fibrosis Periodic Review items

Assessment Component	Details
Demographic Data	Name, Address, Sex.
Physical Examination	Physical examination recording critical CF related physical measurements such as body-mass index, height, weight and head/mid-arm circumference (for infants).
Pulmonary Function Tests	Record of spirometry test results.
Medication Review	Complete review of current medication regimen with changes made if necessary and communicated to associated general practitioner (GP).
Sputum Culture Swab Test	Results of test to identify if bacteria or fungi are infecting lungs giving a positive or negative result. Further analysis required by microbiologist to ascertain the specific cause.

2.2.5 CF in Ireland

Cystic Fibrosis is a particularly significant illness for Irish people. Ireland has the highest incidence rate of CF in the world with approximately 1 in 1,461 people affected and approximately 1 in 19 people being 'carriers' of the faulty CFTR gene that causes the illness (HSE, 2009). Despite this many deficiencies have been

highlighted in the approach to treatment here in key studies such as the Pollock report (Pollock 2005).

2.3 OpenEHR Review

2.3.1 The OpenEHR Foundation

The OpenEHR foundation describes itself as 'an international, on-line community whose aim is to promote and facilitate progress towards electronic healthcare records of high quality, to support the needs of patients and clinicians everywhere' (OpenEHR Foundation 2010).

The origins of OpenEHR can be found in the desire to build upon the achievements of two milestone European based projects in health informatics that were crucial in the development of the OpenEHR standard for creating electronic health records.

The two projects were The Good European Health Record (GEHR) (Ingram 1995) which ran from 1992 to 1994 and the Synapses project (Hurlen et al., 1998) which ran from 1995 to 1998. These projects promoted the core idea of a complete electronic health record as opposed to the alternative view of electronic communication of pieces of health information in the form of individual messages.

A number of the individuals who were involved on these key projects subsequently identified a need to allow disparate groups to work as part of a collaborative umbrella organisation that would take ownership of the emerging standards and promote them more effectively.

The component groups that belong to the foundation come from Europe, the USA and Australia. From this idea the OpenEHR foundation was created in 1999. The standards it put forward were refined and developed as part of a proposed OpenEHR platform first published in February 2006 (OpenEHR Foundation 2010).

2.3.2 What is the OpenEHR Platform?

The OpenEHR health computing platform (Beale et al., 2008) provides a complete open source software infrastructure for implementing a comprehensive EHR in a clinical knowledge domain.

The architecture is structured to provide generic building blocks in the form of information models that allow construction of the specific clinical information to be recorded in any particular EHR. In addition a set of core software services are provided to organise and manage this information and make it available to users in a secure, version controlled and traceable environment.

The core software specifications upon which the platform is built can be broken into three main models, the relationship between which is illustrated in figure 2.3.

The three specifications are:

- the Reference Model (RM) (Beale et al., 2008) provides the core informational generic building blocks upon which information is represented in an OpenEHR based system. These building blocks represent generic information concepts and do not specify real world clinical knowledge. The RM is an abstract model from which actual instances of information are created i.e. actual computerised data

- the Archetype Model (AM) (Beale et al., 2008) allows the description and creation of specific instances of it in the form of archetypes and templates which represent specific clinical knowledge to be captured in an OpenEHR based system. This is separate from the RM

- the Services Model (SM) (Beale et al., 2008) provides basic supporting services for EHRs in the healthcare environment such as version control, security and auditing, clinical terminology interfacing (such as to SNOMED (Spackman et al., 1997)) and demographic information interfacing to allow patient identification

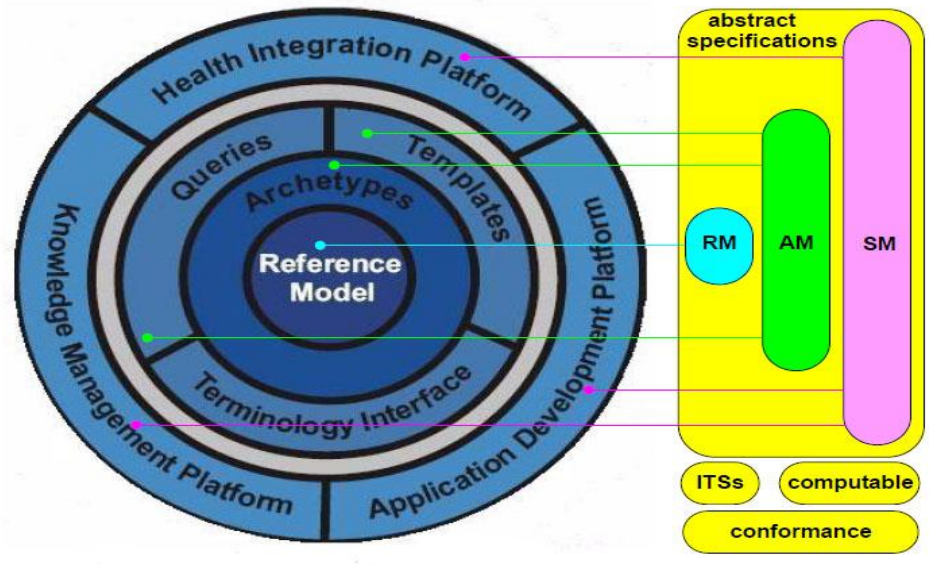


Figure 2-2: The OpenEHR Health Computing Platform –(Beale et al., 2008)

The Importance of 2-Level Modelling

A key concept that is built into this architecture and stressed by Beale et al. is the separation of computer 'information' from real-world clinical 'knowledge' by use of a paradigm known as 2-level modelling.

The first level of modelling is the 'information' layer that is implemented in the reference model, and the second level of modelling is the 'knowledge' layer implemented in the archetype model.

The RM consists of generic information system building blocks upon which the actual information system objects are entirely built. The clinical knowledge is implemented using the AM and is completely separate and not implemented at all in the actual information system software itself.

The aim of 2-level modelling is to de-couple the real-world clinical information from the actual information system to allow it to dynamically change to meet new clinical requirements without the need for costly redesign of the underlying information system.

This is achieved by separating the knowledge layer and only incorporating the knowledge into the system dynamically at program run-time rather than compiling the software and hard-wiring a specific snapshot of clinical knowledge into that specific software release version.

Another key corollary of this approach is that because the knowledge layer is now separate and dynamic, it can be maintained separately by empowering knowledge domain experts rather than regular IT staff. In the context of a clinical domain, it is envisaged that the knowledge domain experts creating the knowledge in the system will be the clinicians themselves.

2.3.3 The Role of OpenEHR Archetypes and Templates

An Informal Definition

The key mechanisms by which clinical knowledge is represented in an OpenEHR system are called archetypes and templates (concepts that were briefly introduced in section 1 and discussed in detail by Beale et al. (2007)).

Archetypes can be thought of as representing discreet clinical concepts e.g. 'blood pressure'. Templates can be thought of as grouping a number of related archetypes together to represent the whole views or compositions that are captured as part of the health record in the system.

For example a 'vital signs' template may use a 'blood pressure' archetype and a 'pulmonary function' archetype along with additional related archetypes. Templates usually correspond closely to forms or screen designs for data capture in the system. In this case the 'vital signs' template may model an emergency department paper-based admission form.

Beale (2007) describes how the template drives the creation of the graphical user interface in the system which is then used to create and edit a well-defined chunk of information in the system. This chunk of information is known as a composition (in this case 'vital signs') and will be stored along with other additional template-based compositions (e.g. 'demographic details') to form the complete EHR for a patient as a collection of compositions.

Formal Definitions

A formal definition of an archetype is provided by Garde et al.(2007) where it is stated that a single archetype 'represents one clinical or other domain specific concept by constraining instances of the OpenEHR information models to express a valid structure, valid data types and values'.

The information model referred to in this definition is the reference model (RM). Archetypes can therefore be thought of as being constructed from the generic

building blocks of the RM and constraining them to produce specific well-defined clinical concept representations.

Beale et al. (2007) formally defines a template as 'a directly locally usable definition which composes archetypes into larger structures corresponding to a screen form, document, report or message'.

Creating Archetypes and Templates

Special editing tools are available to create and maintain archetypes and templates. Ocean Informatics is a key OpenEHR services provider and partner in the OpenEHR Foundation (Ocean Informatics 2010).

They provide both an archetype editor (figure 2.4) and a template editor (figure 2.5) for this purpose. The archetype editor is used by the domain knowledge specialists (clinicians) to create and maintain the knowledge to be represented in the system.

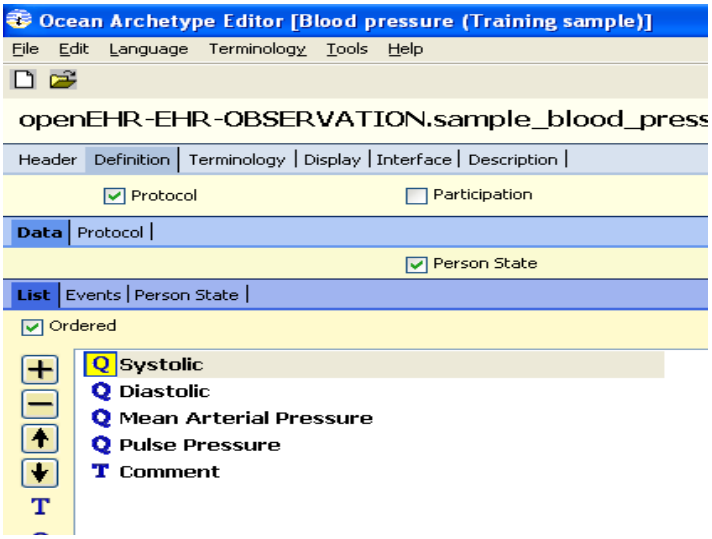


Figure 2-3: Example of archetype definition in an archetype editor

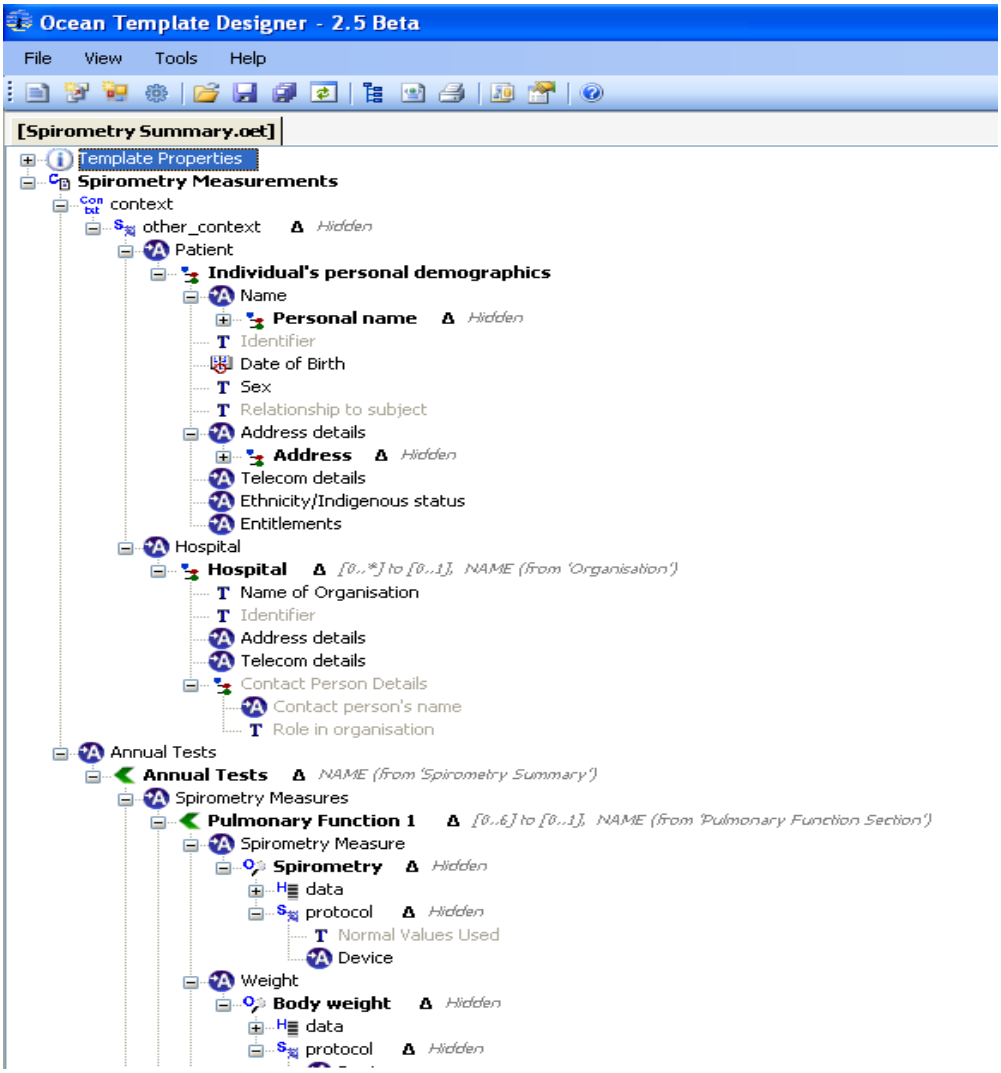
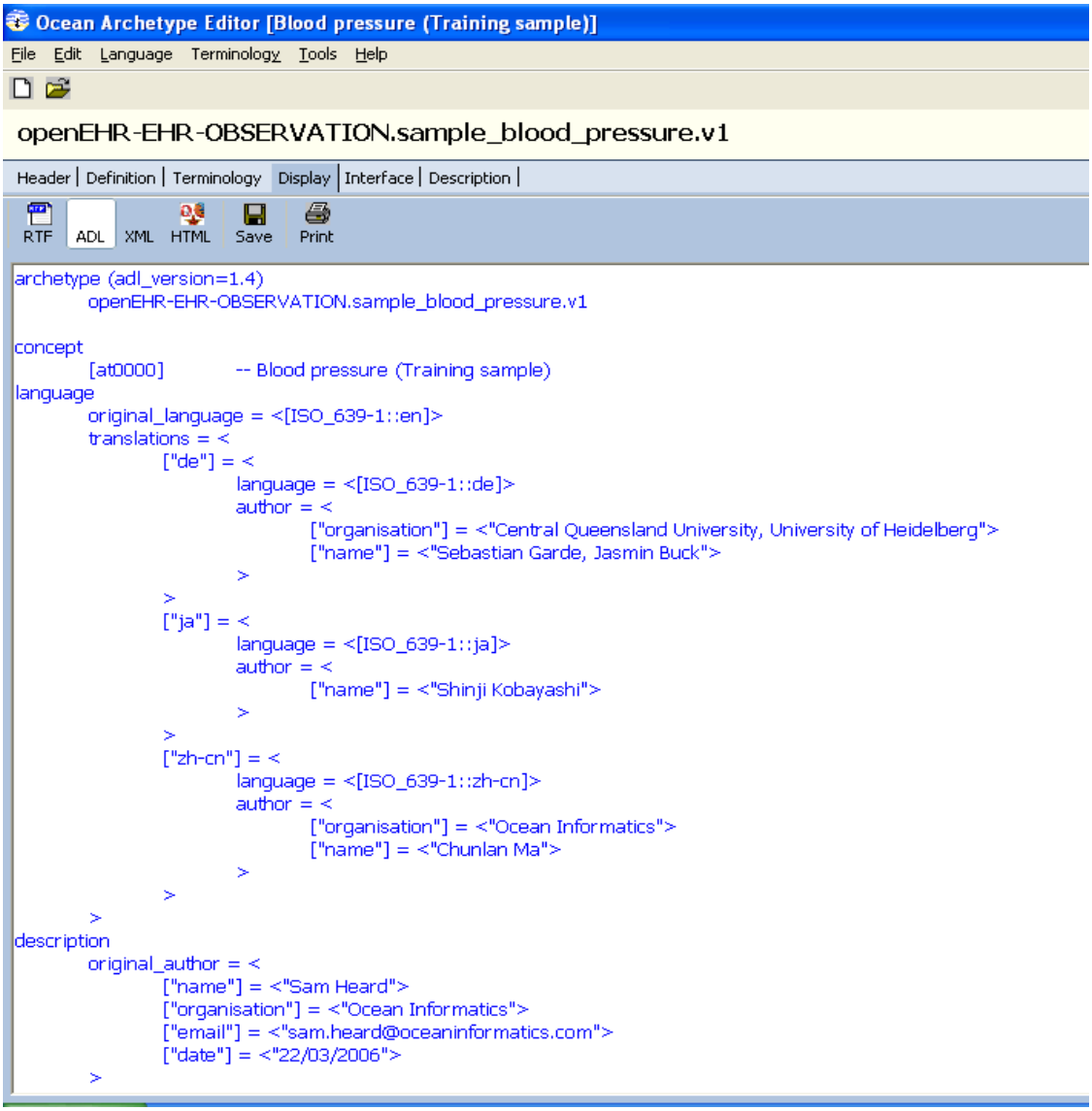


Figure 2-4: The Ocean Informatics template designer

A core principle of building OpenEHR archetypes is that they are all built and represented using the same language to support system interoperability which is a fundamental goal of OpenEHR (Beale et al., 2008). This language is called Archetype Definition Language (ADL) (Beale et al., 2007) as shown in figure 2.6. Exchanges of data can then take place with other systems that are built using OpenEHR.



Archetypes are collectively held in an archetype library and templates in their own template library. Incorporating archetypes and templates into our understanding of the information models, we now get an OpenEHR system architecture as shown in figure 2.7. Archetypes and templates are created separately from the main system and are incorporated into it at runtime.

The archetypes are maintained by the domain specialist (the clinician). The role of traditional IT staff is focussed on the development of the actual system based on the generic building blocks of the RM. The specifics of the knowledge held in the system are completely separate and not in the IT developer domain.

Editing tools also allow archetypes to incorporate links or bindings to external clinical terminologies such as SNOMED which may be held in a separate terminology data store. This allows consistent use of clinical terminology to be applied to any developed archetypes and removes ambiguity in relation to use of clinical terms.

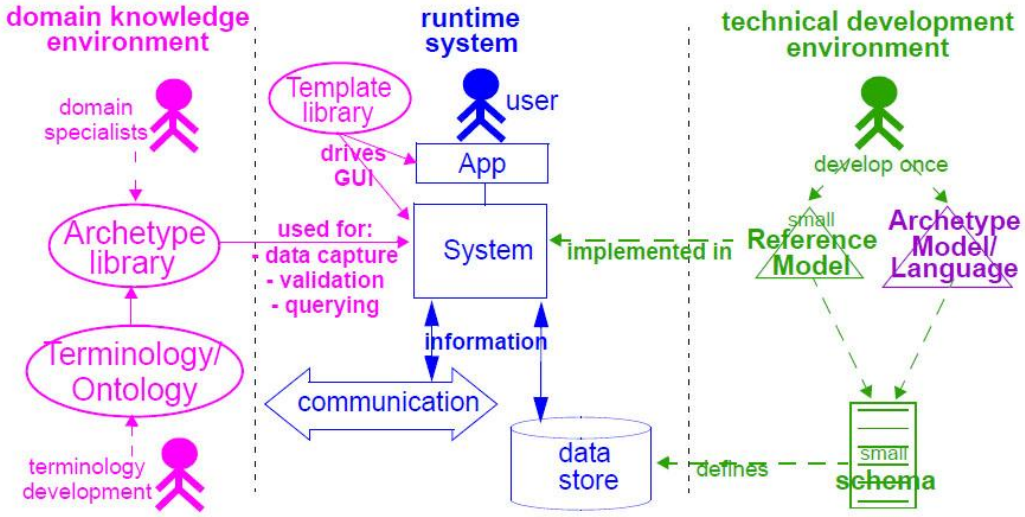


Figure 2-6: OpenEHR System Architecture – (Beale et al., 2008)

Classes of Archetypes

Archetypes are broadly classed into two main types:

- Demographic – archetypes holding demographic information for patients e.g. name, address, sex, date of birth

- Clinical – archetypes that model our understanding of the clinical process

(Beale et al., 2008)

The clinical process as viewed from an OpenEHR point of view can identify a number of different classes of clinical archetype which represent distinct steps in the clinical care process as shown in the figure 2.8.

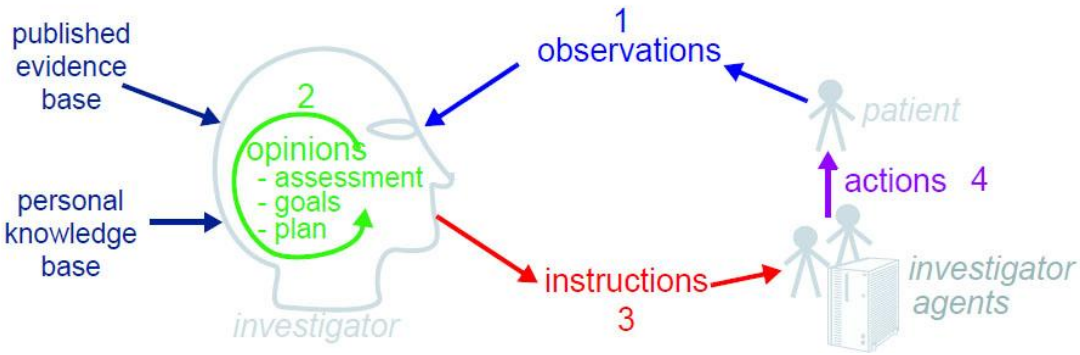


Figure 2-7: The OpenEHR Clinical Care Process – (Beale et al., 2008)

This model defines an iterative care cycle consisting of:

- observation of the patient usually in the form of clinical tests
- leading to evaluation of the clinical problem by the clinician who forms a clinical opinion
- leading to detailed clinical instructions of care given to clinical agents or staff
- leading to actions carried out by clinical agents based on the instructions
- which may lead back through the iterative cycle again

On this basis the core classes of archetypes that can be defined in the OpenEHR model are defined as OBSERVATION, EVALUATION, INSTRUCTION and ACTION archetypes. In addition there may be a requirement for administrative entries so a final type is defined as ADMIN_ENTRY. By defining archetypes of these types we can describe the full cycle of clinical care for a patient.

The Composition

Archetypes formed from basic OpenEHR data types can be aggregated together in what is known as a composition to describe a clinical document or view of a collection of clinical data. It allows the data to be structured and ordered using section headings to create our fully formed compositions as shown in figure 2.9.

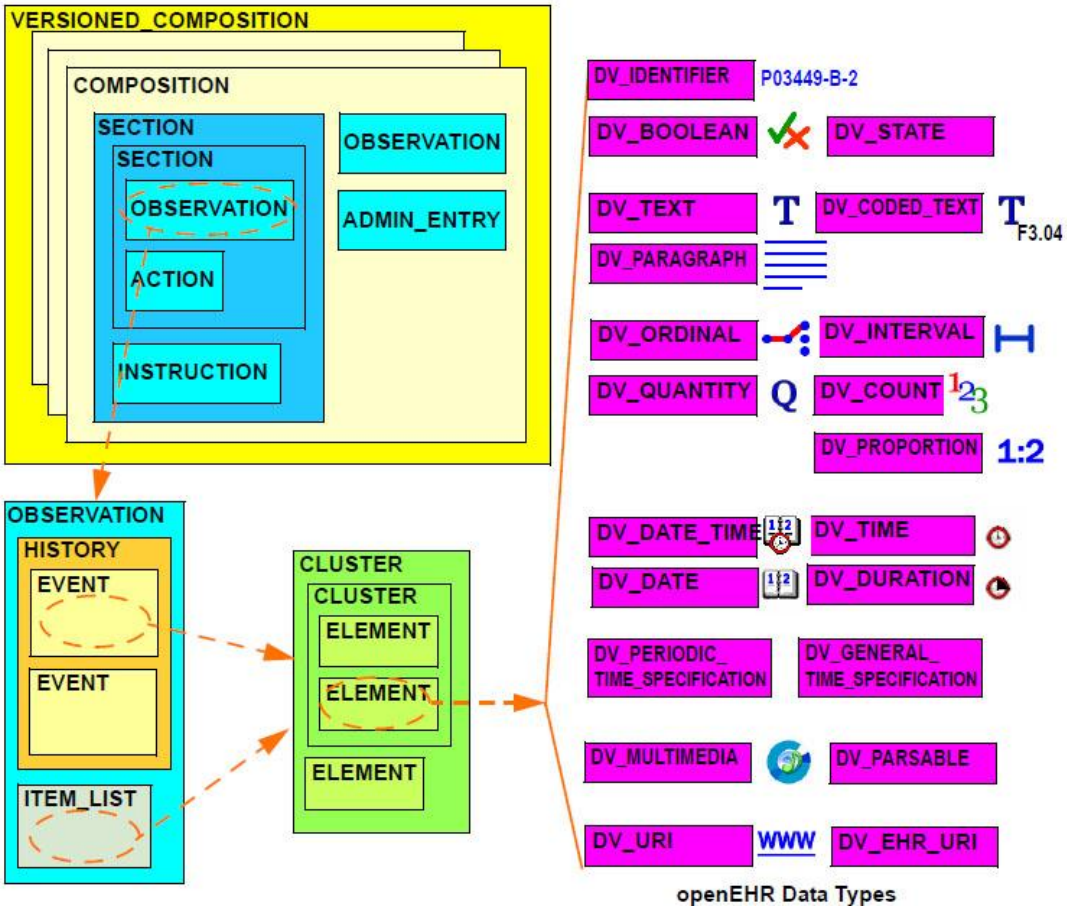


Figure 2-8: The Full EHR Composition – (Beale et al., 2008)

The OpenEHR Health Record

Compositions form the main content of the entire health record for a patient in an OpenEHR system. By combining them with some additional strucutres to allow for patient identification, stucturing compositions, auditing and security we get a fully formed EHR as in figure 2.10.

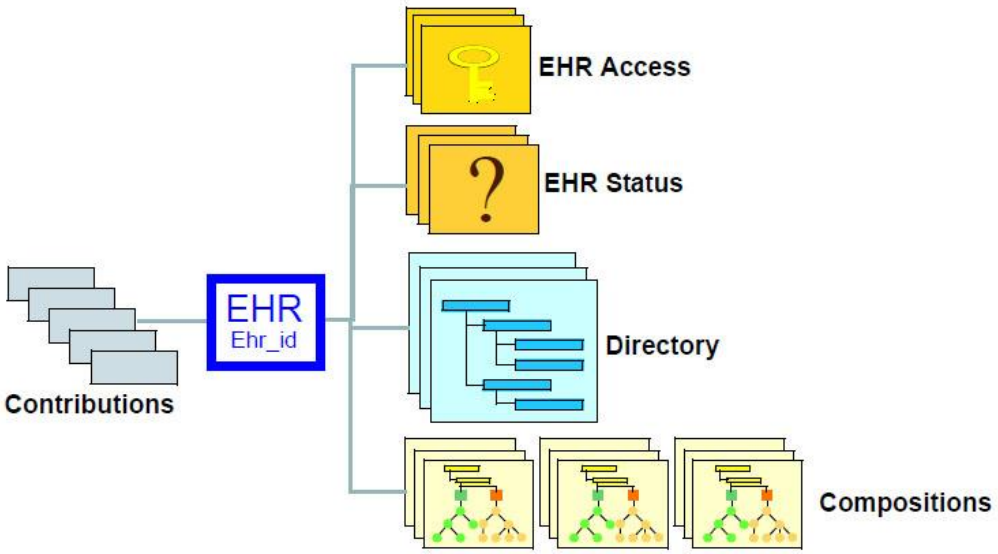


Figure 2-9 : The Full EHR – (Beale et al., 2008)

The additional items that complete the record are:

- EHR_ID – A unique identification number that references a patient master index store which is separately held from the main EHR store for security purposes and to allow for anonymised data

- EHR_ACCESS – This holds security information defining who has authorisation to access this record

- EHR_STATUS – A record of the current status of the record i.e. current editing status

- Directory – Determines the hierarchical structure of associated compositions associated with the EHR

- Compositions – The chunks of the actual clinical and administrative data held as part of the EHR

- Contributions – An audit trail of all changes made to the record which are associated with version numbers to enable full version control

The Complete OpenEHR Architecture

The fully functional OpenEHR architecture as shown in figure 2.11 will contain:

- EHR repository – the collection of all EHR data for all patients

- an archetype and template library to hold the system definitions of clinical knowledge

- a clinical terminology repository which links to the archetypes to ensure consistent clinical terms are used

- a demographic repository which defines all the demographic entities held in the system

- a separate patient master index (which may be accessed through the demographic repository) to which the EHR records are linked identifying the patient details relating to any particular EHR

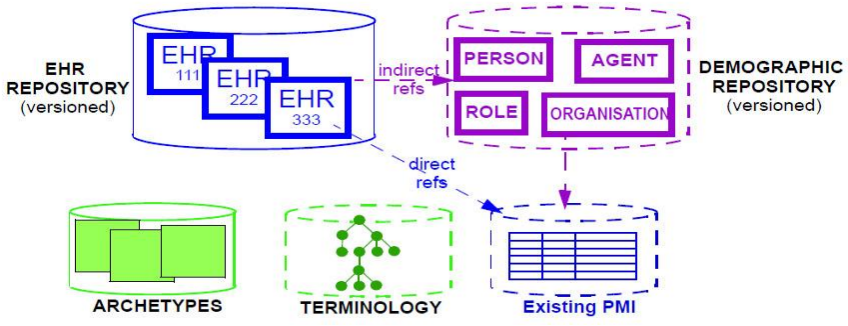


Figure 2-10: The Full OpenEHR Architecture – (Beale et al., 2008)

2.3.4 The Relationship of OpenEHR to other EHR Standards

The Standards Organisations

In order to develop different ICT systems that are able to communicate with each other and share data, it is necessary that standards are agreed on the technical details of how this is achieved. It is therefore necessary to have recognised standards bodies that define and agree what constitutes 'a standard'.

One such standards body in Europe is the Comité Européean de Normalisation, better known as CEN. For the purposes of this document we will define a standard as per their definition which states that 'a standard is a document, designed for common and repeated use, to be used as a rule, guideline or definition. It is both consensus-built and approved by a recognised body'. (CEN, 2010)

There are a number of standards bodies currently in operation covering a wide range of industrial and technological fields. However, there are three main recognised bodies internationally (figure 2.12), particularly in the area of health and ICT.

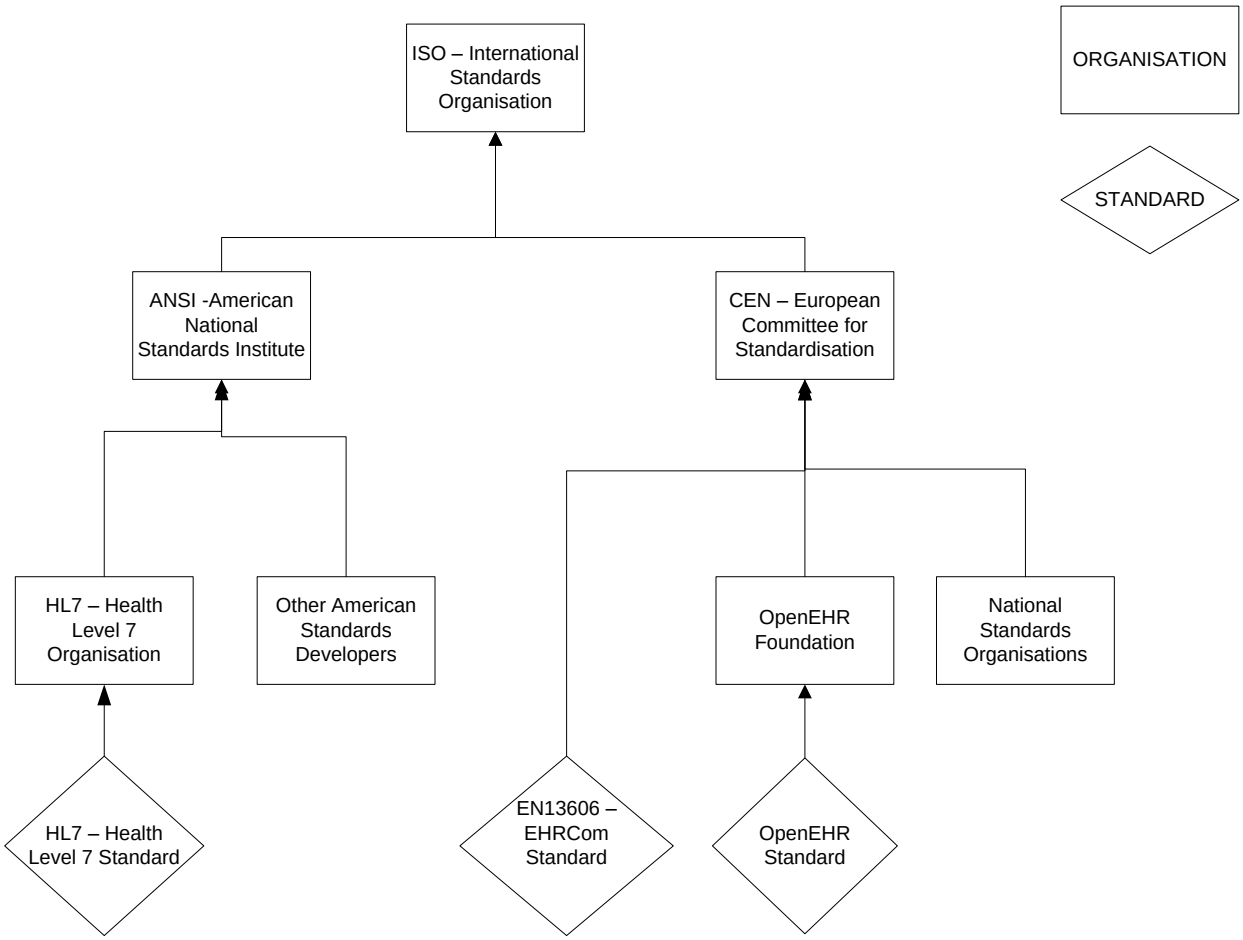


Figure 2-11 : Relationship of Organisations and Standards

CEN – Comité Européean de Normalisation

CEN is also known as the European Committee for Standardisation was founded in Paris in 1961. It is a private non-profit organisation and it is the primary recognised standards body by the European Union for development, drafting, approval and adoption of European standards in all areas with the exception of electro-technology and telecommunication.

CEN acts as a forum for agreed standards development among the 31 national members which represent standards bodies in each member country (the standards body for Ireland for example is the National Standards Authority of Ireland (NSAI)). CEN has developed the EN13606 standard which is the primary European standard defining the structure and transmission of electronic health records by a technical committee branch of CEN known as 'TC251 Health Informatics'.

ANSI – American National Standards Institute

The American National Standards Institute (ANSI) was founded in 1918 and declares itself as 'a private non-profit membership organisation' whose goal is defined as 'the development of American National Standards (ANS) by accrediting the procedures of standards developing organisation' (ANSI 2010).

ANSI is the main driver for development of standards in the United States of America. It differs from CEN in that it does not draft or develop the actual standards itself but in effect defines the standards to which the actual standards developers who are members of ANSI must adhere to. There are approximately 200 such members of ANSI who develop different standards. One such influential member of ANSI is the Health Level 7 (HL7) organisation which develops health messaging standards.

ISO – International Standards Organisation

The International Standards Organisation was formed in Geneva in 1947. ISO defines itself as 'a network of the national standards institutes of some 163 countries, with a central office in Geneva, Switzerland, that coordinates the system and publishes the finished (international) standards'. (ISO-2010).

Whereas CEN and ANSI define standards from a European and American perspective respectively, ISO acts as a forum to bridge these views. While acting as a standards body in its own right it also receives and reviews submissions from both CEN and ANSI along with the member national standards bodies. This is done with a view to publishing internationally agreed and recognised standards by a technical committee branch of ISO known as 'TC215 Health Informatics'.

CEN-ISO EN13606 - EHRCom

The main European standard in relation to representing electronic health records and sharing electronic health record data is the EN13606 standard, also known as 'Electronic Healthcare Record Communication' or 'EHRCom'. This five part standard is currently being progressed by CEN and ISO.

The original standard upon which EN 13606 evolved is known as ENV 12265 (CEN 1996). This standard was used in projects such as the Synapses project which proposed a federated electronic health record architecture (Hurlen et al. 1998). Experiences with projects such as Synapses informed the publication of the pre-standard ENV 13606 (Eichelberg et al. 2006), which was developed between 1999 and 2000 and is a four part precursor to the current EN13606.

ENV 13606 has since been substantially revised between 2006 and 2010 taking on board a number of aspects defined in the specifications for OpenEHR. The new EN 13606 consists of five separate parts and defines standards for sharing EHR extract data rather than standards for a complete EHR architecture.

The introduction to this standard states that 'this standard is for the communication of part or all of the electronic health record (EHR) of a single identified subject of care between EHR systems, or between EHR systems and a centralised EHR data repository' (Schloeffel et al., 2006).

The revision of EN 13606 included taking on board the 2-level modelling approach to EHR design and the concept of 'archetypes'. As such the EN 13606 standard can be said to be a subset of the OpenEHR standard. There is a possibility that the EN

13606 standard may be enlarged to encompass a full EHR architecture. OpenEHR is seen as one of the possible competing models upon which this might be based.

Health Level 7 – HL7

Health Level 7 defines standards for structuring health records in the form of the widely used HL7 V2.x which is a messaging based standard but is not based on any underlying information model (Kalra 2005).

However as Eichelberg et al. (2005) points out, HL7 is a major player in heath record standards arena being 'the most widely implemented standard for healthcare information in the world today'. It does not support the concept of archetypes and cannot therefore be said to be compliant with the EN 13606 standard. HL7 V3.x is a later release based on a reference model (the RIM) but does not support archetypes.

The current successor to HL7 V2.x is HL7 Clinical Document Architecture (CDA) which is an XML based messaging standard that is not based on a reference model and does not support archetypes as defined in the EN 13606 standard.

As Eichelberg et al. (2005) points out, CDA does support a conceptually similar concept known as CDA templates. However it also states that 'unlike other standards HL7 CDA does not specify services or protocols that are used to exchange a document'. HL7 therefore defines an EHR extract standard rather than a full EHR architecture. Figure 2.13 demonstrates the overall relationship of the different standards.

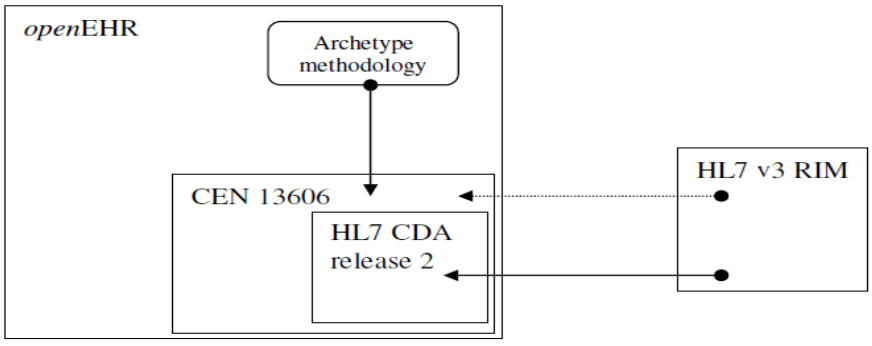


Figure 2-12: Conceptual Relationship of Standards - (Schloeffel et al 2006)

2.3.5 OpenEHR Maturity

An indication of the level of maturity of OpenEHR as a technology can be found in a literature review carried out by Wollersheim et al. (2009) which sourced academic papers from a number of peer-reviewed journals between 2000 and 2008 by selecting papers using the terms 'OpenEHR' and 'CEN 13606'. After reviewing the content of articles, a total 47 papers were returned relating to OpenEHR.

Wollersheim concluded that 'while the review found no examples of substantial archetype-based health infrastructure, there were many instances of archetype-centred research and widespread pilot usage'.

An indication of the increase in interest in the OpenEHR approach can be inferred by doing a subsequent search at the time of writing of this paper using only 'OpenEHR' as the search term. This produced 15 papers published in 2009 from PubMed alone which accounts for almost 32% of the total number of papers sourced between the years 2000 to 2008 by Wollersheim using more than one search term and multiple academic search resources. This indicates that interest in OpenEHR within the academic community is growing rapidly.

2.3.6 OpenEHR Pilot/Academic Studies

A number of papers detail practical experiences applying development of OpenEHR archetypes and templates in a range of diverse practical clinical settings. The following section summarises a selection of the content of these studies specifically referring to four key areas of interest in relation to conducting this study. These areas were:

- the clinical setting applied to establish if any previous work has been conducted in relation to applying OpenEHR in the Cystic Fibrosis domain or with reference to its use to satisfy the requirements of presenting clinical data to multi-disciplinary teams

- the archetype design approach employed to establish if there is a consensus as to what standards or guidelines are to be used when designing OpenEHR archetypes and templates that could then be applied as part of this study

- the tools used to implement archetypes and templates to give guidance on the toolset to be chosen for this study

- the conclusions and user experience using the OpenEHR approach to establish if there is a consensus on what the current strengths and weaknesses of this modelling approach are along with key discussion points or topics that may give added insight and value to this study

CHEN et al. (2009)

This study discusses the modelling of lymphoma treatment clinical guidelines using OpenEHR archetypes and templates. Use case modelling was employed to document guideline descriptions captured from interviews with oncologists. OpenEHR archetypes were used to model discreet clinical guideline concepts and OpenEHR templates were used to group archetypes together to model the collective guideline content as represented by the use cases.

Existing archetypes were used along with some newly authored archetypes where required. The archetype design approach employed was as per the 'OpenEHR guidelines' (which was not expanded upon) and Ocean Informatics tools were used for both archetype and template authoring.

The authors experience was positive concluding that 'it is feasible to represent chemotherapy guidelines using OpenEHR archetype and templates' and that one of the major benefits was that it 'facilitates integration with the EHR'.

Atalag (2007) Thesis

The OpenEHR approach was used to model clinical concepts as defined in a standard terminology set widely used in the domain of endoscopic gastroenterology called Minimal Standard Terminology for Endoscopic Gastroenterology (MST).

A number of clinical concepts such as 'colon', 'stomach' and 'oesophagus' were modelled using the Ocean Informatics Archetype Editor and the Ocean Informatics Archetype Workbench. These concepts were then brought together as template based forms using the Ocean Informatics Template Designer.

The design process involved taking visualized hierarchies of the clinical concepts as defined in MST and restructuring them for archetype modelling. No detailed description of the modelling process is given.

The conclusions of this study were positive stating that 'multi-level modelling and archetypes look promising' and that the OpenEHR approach proved 'adequate' in representing the MST clinical concepts. The author felt that system interoperability was enhanced by using this approach. However the study did highlight some areas to be improved such as modelling of clinical workflows, automatic GUI generation from templates, archetype versioning and sharing of archetypes in archetype repositories.

One of the final concluding statements elucidates a very key discussion point in relation to OpenEHR by stating that 'there exists now a big debate whether multi-level modelling and archetypes are a passing fancy and not sustainable in the larger arena' and that 'large reference implementations are definitely needed'.

Bird et al. (2003)

In this Australian based study, the two-level model known as GEHR which was a precursor to OpenEHR was used to model and construct a new trial EHR system. The data for the EHR was constructed by applying transformations to the data and feeding it from two distinct existing IT systems which contained a wide variety of

data relating to microbiology, biochemistry, haematology, radiology, medication lists and diabetes events.

Archetypes were used within the new EHR system to represent the clinical concepts related to the transferred data that had been fed in. At the time this study was done (2003) there were no extensive toolsets available for archetype modelling so they created their own 'Clinical Model Builder'. No details are given in the study to the process used to model the archetypes themselves.

Because of the diversity of data used in this trial system it represents a good commentary on the flexibility of the archetype approach to modelling different sets of clinical data. The conclusion stated that 'the archetypes approach does work' and more impressively that their experience was that 'a wide variety of clinical structures can be described using archetypes'.

A crucial challenge to using two-level modelling that was identified is that it is highly dependent on the underlying generic reference model remaining stable. If it changes then there are impacts reflected in the archetype layer of the knowledge model. In this study the underlying generic reference model did change a number of times which required software changes to be made in the archetype building tools.

This raises the interesting question as to whether or not the dependencies which instigate change in a two-level modelling have to some extent simply been pushed down a layer to the reference model layer and taken out of the archetype model layer, although the timeframe for this study needs to be considered (2003) as the OpenEHR reference model has matured and become more stable since then. It does ask the question however as to how flexible the reference model can be if it needs to change without impact elsewhere in the system.

Kashfi et al. (2009)

An investigation into the feasibility of a proposed migration from an existing medical system (MedView) to an OpenEHR based system is the subject of this study which detailed experiences at the clinic of oral medicine in Gothenburg.

Because this was a feasibility study no actual archetypes or templates are documented as having actually been built and so no approach to archetype or template modelling is detailed. A reference is made to using 'archetype editors' but no specific editor is mentioned.

The author concluded that a migration to an OpenEHR based system was possible but not without some difficulties. In particular it was highlighted that the OpenEHR specification itself is complex and concluded that 'getting a grip on this is not an easy task'.

In relation to standards and procedures for modelling archetypes, the lack of detailed documentation for clinicians was criticised and the fact that the tools themselves 'cannot be said to help inexperienced developers beyond hiding the actual syntax'.

2.3.7 OpenEHR Archetype Design Methodology

A common thread running through a number of the papers documenting pilot and trial implementations of the OpenEHR approach was that no reference to any definitive archetype design methodology is made at all. In some cases specific conclusions referred to frustration at the lack of detailed archetype usage and design guidelines.

In a developing technology such as OpenEHR this is perhaps to be expected as it still evolving and maturing. There are however some significant papers where an attempt to define an archetype design methodology is made.

Buck et al. (2009) - ODMA

The authors detail their experiences modelling a prototype neonatal EHR system at Heidelberg University Hospital. During development of this study, a total of 132 clinical concepts were identified which resulted in the creation of 67 new archetypes and the reuse of 58 existing archetypes along with 16 templates to model those clinical concepts.

This is a key paper in that it describes a five-step approach to archetype design which they used and called the 'OpenEHR Data Modelling Approach' (ODMA). This approach is given weight by the fact that it is the result of the experience gained from modelling a large number of archetypes in a practical clinical setting.

The authors also highlight the lack of published guidelines stating that 'other approaches to systematically model OpenEHR guidelines have not been previously published'. This combined with its recent publication date make it an important resource for those new to archetype design.

The detail of the approach is not comprehensively covered in the paper but it does give good guidance on the logical steps required and is a good starting point for developing and expanding it into a useable archetype design methodology. The ODMA approach to archetype modelling can be summarised at a high level as a six step approach:

1. Determine all clinical items in the domain to be modelled

2. Merge related individual clinical items to single archetype clinical concepts

3. Data model the clinical concepts identified and re-model them to eliminate duplication of items

4. Where possible, map the derived clinical concepts to existing archetypes

5. Model new archetypes for clinical concepts that cannot be mapped to existing archetypes

6. Create templates to group and constrain related archetypes that represent the contents of locally used form or document data

Gok (2008) - Thesis

This thesis paper details the application of the OpenEHR approach to developing an EHR for an Australian based hospital emergency department. Whilst the approach to modelling the archetypes itself is not fully documented the process of determining the clinical data items is described. The process followed can be summarised as follows:

1. Document the process flows for the domain to be modelled identifying the key information sources such as paper documents, electronic documents and medical devices

2. Determine all clinical items in the domain to be modelled based on the key information sources identified in the process flow analysis

3. Where possible, map the derived clinical concepts to existing archetypes

4. Model new archetypes for clinical concepts that cannot be mapped to existing archetypes

5. Create templates to group and constrain related archetypes that represent the contents of locally used form or document data

Leslie et al. (2008) - Ocean Informatics

In this key document published by Ocean Informatics, Leslie et al. (2008) document their proposed process for building archetypes which can be summarised at a high level as follows:

1. Determine all clinical concepts

2. Where possible, map clinical concepts to existing archetypes

3. Model new archetypes for clinical concepts that cannot be mapped to existing archetypes

4. Publish newly created archetypes to the OpenEHR archetype knowledgebase for validation and feedback from archetype design experts, and to allow others to share the knowledge that you have created

Leslie (2008) - NHS

A key study is detailed in this paper which discusses the pilot study carried out by the National Health Service in the United Kingdom to assess the suitability of the CEN 13606 standard for implementing an EHR to provide for their requirements. The aim of the pilot was to develop archetypes and templates for three key areas:

- recording emergency department visits for the 10 most common presentations

- recording the full clinical care lifecycle for pregnant women

- recording the full clinical care lifecycle for children presenting with hearing loss

At the end of 2007 the NHS had created approximately 650 archetypes upon which 60 NHS templates were created to support capturing data for the three scenarios detailed.

The ultimate aim of the NHS is to facilitate semantic interoperability between all of their information systems by providing the developed archetypes and templates to their clinical application developers. These could then be incorporated into their own systems and effectively provide a common electronic clinical language for sharing information between all of their information systems.

The outputs available from this project are available from the NHS public internet server. They contain an extensive library of archetypes and templates that were designed as part of the pilot study along with some excellent documentation such as their draft content model design guide.

The content of this guide is still in draft format and quite incomplete. However, it is specialised and based on practical experience. It presents a series of useful design patterns relating to specific problems that may occur during archetype design along with the proposed solutions to those issues.

The aim is to provide a consistent mechanism for implementing these features for all archetype development. This concept of design patterns for archetype development represents a real possibility for progressing archetype development to a more sophisticated level.

Whilst these guidelines are a draft work in progress, they are extremely useful to the new archetype developer and highlight the fact that well structured and robust archetype design is not provided out of the box by the archetype designer tools themselves. It needs to be documented first based on the collective knowledge and experience of good archetype design and then consistently implemented by all archetype designers. This is a step that should be incorporated into any proposed archetype design methodology.

A Hybrid OpenEHR Design Methodology

Looking at the archetype modelling methodologies detailed in these key papers it can be seen that they are quite similar at a high level. A hybrid methodology combining the approaches together provides a good starting point for developing an archetype design methodology for this study as shown in table 2.4.

Table 2-4: OpenEHR Design Methodology based on Literature Review

Literature Review Based Design Methodology	
1	Document the process flows for the domain to be modelled **identifying the key information sources** such as paper documents, electronic documents and medical devices.
2	**Determine all clinical items in the domain** to be modelled based on the key information sources identified in the process flow analysis.
3	Merge related individual clinical items to **single archetype clinical concepts.**
4	Where possible, **map the derived clinical concepts to existing archetypes.**
5	**Data model the clinical concepts** identified and re-model them to eliminate duplication of items.
6	**Model new archetypes** for clinical concepts that cannot be mapped to existing archetypes.
7	**Create templates** to group and constrain related archetypes that represent the contents of locally used form or document data.
8	**Document archetype design patterns** for reoccurring scenarios or design issues that have arisen during archetype design.

9	**Publish newly created archetypes** to the OpenEHR archetype knowledgebase for validation and feedback from archetype design experts, and to allow others to share the knowledge that you have created. Incorporate this design feedback into archetype design patterns document where appropriate.

2.3.8 OpenEHR Development Tools

The review of the case study papers identified Ocean Informatics as the primary provider of archetype and template editing tools. This is to be expected given Ocean Informatics position as a co-founder of the OpenEHR foundation. Other editors are available but for the purposes of this study the Ocean Informatics tools were chosen as the toolset of choice.

The archetype editor is available free of charge from the Ocean Informatics website. The template designer is a commercially available product which was made available to the author on a trial basis upon contact with Ocean Informatics in relation to this study.

2.4 Other Literature Topics

This section details papers that have provided interesting discussion points in relation to OpenEHR which will be expanded upon as part of this study.

Approaches to Information Modelling - Michelsen et al. (2005)

Bernstein (2004) describes the implementation in Denmark of an EHR for Aarhus County. In this paper by Michelson et al. (2005), the use of a 2-level information model as part of the Aarhus project is compared and contrasted with the implementation of the OpenEHR information model.

Two fundamental differences were highlighted:

(1) OpenEHR uses a small generic reference model (RM) with a large descriptive domain model in the form of the Archetype Model (AM). The Aarhus project used a large generic model and a small domain model. The conclusion Bernstein reaches is that OpenEHR is more descriptive and flexible to represent the knowledge domain. However it is more susceptible to changes in the underlying reference model (RM) that it is built upon and less flexible to develop new functionality.

(2) OpenEHR is designed to allow clinicians to model domain knowledge using archetype editors. The Aarhus project used technical staff to develop Act Description Definitions (ADD) which are equivalent in function to archetypes. Clinicians collaborated but did not actually carry out development. This is a fundamental question. Who should develop clinical systems: clinicians or technical staff? This is a question also tackled by Leslie et al. (2009).

Domain Knowledge Governance – Garde et al. (2007)

One of the goals of OpenEHR is to develop a freely accessible online library of maximal dataset archetypes that are freely available to use for any OpenEHR based system. This has been achieved to an impressive degree with the OpenEHR Clinical Knowledge Manager (CKM) that will be discussed later.

This paper highlights the need for organisational structures to review, validate and publish archetype designs. An interesting conclusion is that "without coordinated archetype development and maintenance, 'rank growth' of archetypes would jeopardize semantic interoperability".

The implication is that the archetype concept will not be adopted widely if sufficient organisational structures are not in place to promote, publish and make available high quality validated archetypes. OpenEHR provides such a structure in the form of the

Archetype Editorial Group. A question needs to be asked: how streamlined and evolved is the OpenEHR governance process?

3. Research Methodology

The research methodology selected for this study can be described as a prototype in applying OpenEHR archetypes and templates to a real-world practical clinical example.

Because this study involves design and prototyping of the knowledge represented in an OpenEHR based computer system, a qualitative approach will be used to assess the success of that prototype as this cannot be easily 'measured' using numerical benchmarks and quantitative methods.

A core part of the methodology will be based on implementing the OpenEHR design process developed as part of the literature review. How successful we are in practically applying this methodology will provide a measure of the success of the study.

The research steps to be followed are summarised in table 3.1.

Table 3-1: Research Methodology Steps

Research Methodology Steps	
1	**Selection of clinical domain problem.**
2	**Literature Review** to develop full understanding of clinical problem domain and to produce an OpenEHR design methodology.
3	**Obtain data sources** that fully describe the complete clinical dataset to be captured as part of the OpenEHR prototype of the selected clinical domain problem.

4	**Apply the 9 steps described as part of the literature review** based OpenEHR design process to identify existing archetypes and create new archetypes as needed.
5	**Assess the completed archetypes/templates** with respect to the goals described in section 1 to establish if we have satisfied the thesis goals.

4. Research Implementation

4.1. Selection of clinical domain problem

The requirements for the selection of a clinical problem to apply an OpenEHR design to for this study can be summarised as follows:

- the clinical domain selected must be one that is suited to a multi-disciplinary team care approach to treatment. Not all clinical domains will require multi-disciplinary team based care

- the clinical domain selected must be clearly defined i.e. the clinical data required to be captured must be available and clearly understood based on best practice treatment guidelines

The clinical domain of Cystic Fibrosis was selected based on these criteria. As detailed in the literature review, multi-disciplinary team care is essential to best practice treatment for Cystic Fibrosis patients.

Because Cystic Fibrosis is a clinically complex disease which requires treatment throughout the entire lifetime of a patient, it generates a substantial amount of data for just a single patient. It was therefore necessary to reduce the scope of the OpenEHR modelling to focus on a selected portion of the potential data available in a Cystic Fibrosis patient record, namely the periodic review record.

4.1.1 The Cystic Fibrosis Registry of Ireland

The Cystic Fibrosis Registry of Ireland is a Health Service Executive funded organisation that has been in operation since 2001 and is based on the campus of University College Dublin. The primary aim is to capture a comprehensive medical record for people with Cystic Fibrosis in Ireland (Cystic Fibrosis Registry of Ireland, 2010).

This data is accessible through the internet by selected clinicians and users. The collected data is then used as the basis for research and reporting on the prevalence, incidence and treatment of people with Cystic Fibrosis in Ireland. At the end of 2007 there were 735 patients registered in the Cystic Fibrosis Registry out of approximately 1,100 people with Cystic Fibrosis in Ireland.

Cystic Fibrosis Registry staff members kindly provided the primary contact point for clarifying Cystic Fibrosis clinical concepts and procedures.

4.2 Literature Review

The literature review was carried out and discussed as detailed in section 2.

4.3 The OpenEHR Design Process

The 9 step OpenEHR design process is applied as developed from the literature review.

4.3.1. Document process flows to be modelled

The starting point for scoping the work to be done was a meeting with the Cystic Fibrosis Registry of Ireland to discuss the registry process and what the main inputs and outputs are.

The process for enrolling and recording patient data in the in the Cystic Fibrosis registry is shown in figure 4.1.

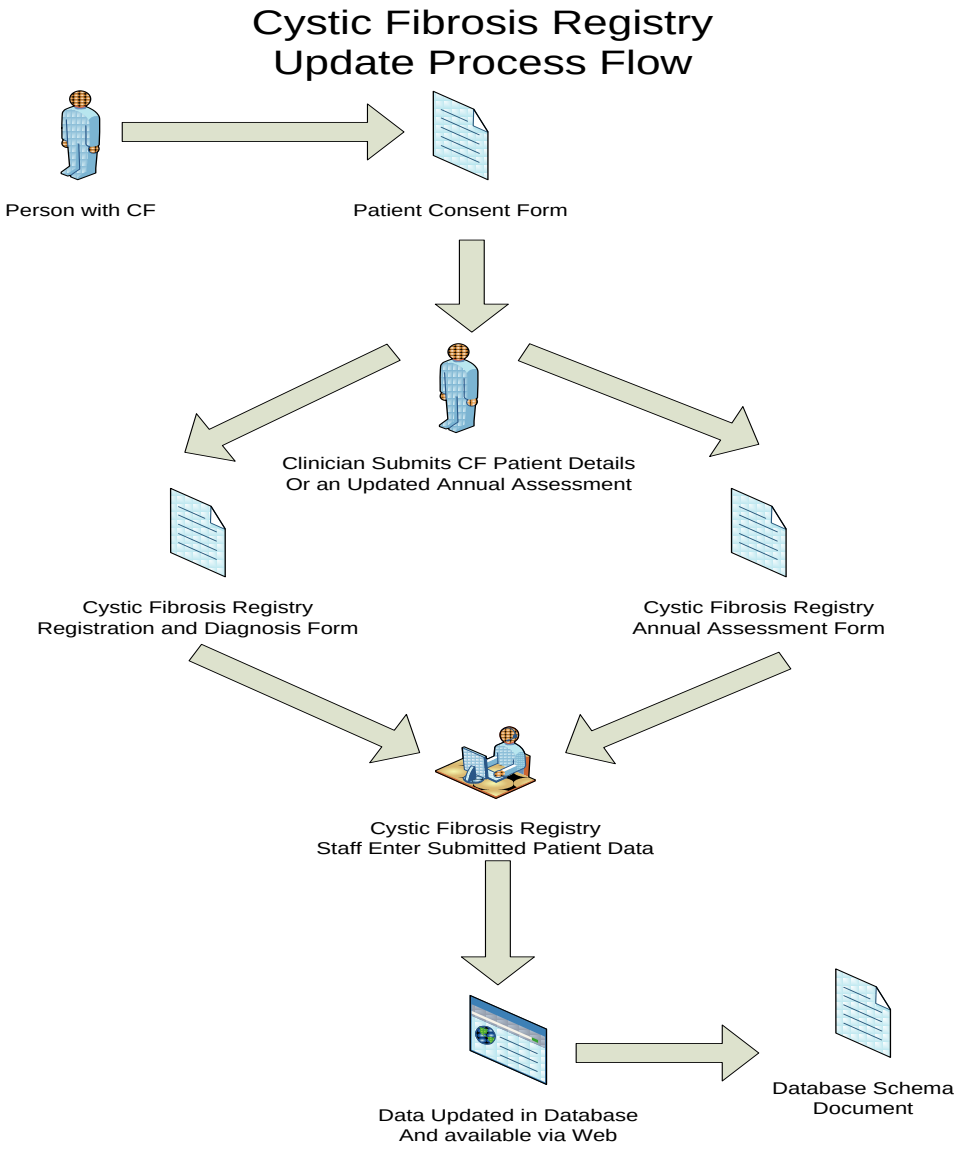


Figure 4-1: Cystic Fibrosis Registry of Ireland Process Update Flow

The primary relevant data sources identified as part of this workflow process are:

Registration and Diagnosis Form

After patient consent has been granted this form is completed by the clinician and describes the initial clinical data to be set up for the newly registered Cystic Fibrosis patient. Details captured include patient demographic data, treating clinician details

and initial diagnosis details. Refer to Appendix A which shows the cover page for this form.

Annual Assessment Form

As part of best practice care, Cystic Fibrosis patients will have a number of periodic reviews during the course of the year (every 1-6 months depending on condition severity) and a more thorough annual review which will review all aspects of their treatment.

The data contained in the registry for a particular patient will usually be updated on an annual basis to reflect the data captured as part of the annual review. Data captured includes demographic data, annual test results, radiology reports, biochemistry results, drug treatment review, physiotherapy review and nutrition review.

A subset of the annual review data defines the data captured as part of the more frequent periodic review. Refer to appendix A for details of the relevant sections from this form.

Database Schema Document

All data collected is entered into a database that is accessible by patient, clinician and cystic fibrosis registry staff via the internet. A good starting point for modelling the archetypes is a complete technical schema detailing all database tables and coded values to be stored in the database.

This document provided the definition of the data to be used for matching to the content of existing archetypes and to determine the content of new archetypes to be built. Examples of the schema are shown in Appendix A.

4.3.2. Determine all clinical items in the domain to be modelled

The importance of the cystic fibrosis periodic review was previously detailed in section 2.2.4. This data is essentially a subset of the data that is captured for the

annual review which is a more rigorous examination. In order to scope the work to be done to a manageable subset of data, the periodic review was selected as the subset of data to be modelled using OpenEHR.

Tables 4.1 to 4.6 contain a list of the data items as agreed with staff from the Cystic Fibrosis Registry of Ireland which would be required to be captured as part of periodic review. This information is grouped by the sections they are recorded under in the Cystic Fibrosis Registry data collection forms and can be considered to represent the final views of data that we require.

Table 4-1: Demographic Data required as part of Cystic Fibrosis Registry

Item Name	Description
Name	Full patient name
Address	Full address of patient
Date of Birth	Date of birth of patient
Sex	Sex of patient
Hospital	Attending hospital name

Table 4-2: Pulmonary Function Data required as part of Cystic Fibrosis Registry

Item Name	Description
Date of Report	Date pulmonary function test carried out
FEV_1	Forced expiratory volume in 1 second
FVC	Forced expiratory vital capacity
$FEF_{25\%-75\%}$	Forced Expiratory Flow during 25%-75% of expiration (middle portion of expiration)
Weight	Weight in kg of patient
Height	Height in cm of patient
BMI	Body Mass Index of patient in kg/M
Centile Weight	A measure of the centile weight which places the patient weight measurement in the context of expected weight for that age and sex as per a chosen set of clinical centile reference charts.

Table 4-3: Biochemistry Data required as part of Cystic Fibrosis Registry

Item Name	Description
Sample Date	Date sample was taken
Sample Type	Method of taking sample e.g. cough swab, sputum etc.
Culture Type	Biochemical culture type observed in sample e.g. Pseudomonas Aeruginosa

Table 4-4: Medication Data required as part of Cystic Fibrosis Registry

Item Name	Description
Name	Full patient name
Hospital	Attending hospital of patient
Antibiotic Name	The brand name and generic name of the antibiotic used to treat the patient e.g. Amoxil (amikacin)
Indication Code	Indicates reason for prescribing
Route Code	The method of administration of the antibiotic
Start Date	The start date of antibiotic treatment
Stop Date	The end date of antibiotic treatment if applicable (may be continuous)

Table 4-5: Physiotherapy Data required as part of Cystic Fibrosis Registry

Item Name	Description
Date Last Review	Date that patient had physiotherapy last reviewed.
Physiotherapy Modalities	A list of the physiotherapy methods currently being used with the patient e.g. postural drainage which is a technique used to place the patient in physical positions for 3 to 15 minutes which drain secretions from the lungs by gravity.
Exercise Level	The level of exercise the patient has been subject to.
Breathing Devices	A list of any breathing devices used to assist lung function
Nebulisers	A list of any nebulisers used to assist lung function.

Table 4-6: Nutrition Data required as part of Cystic Fibrosis Registry

Item Name	Description
Name Last Review	Full patient name
Nutrition Treatments	Attending hospital of patient
Enzymes	A list of enzyme supplements used to assist with food digestion.
Supplemental Feeding in Last	A list of dietary supplements used in the last 12 months to assist nutritional intake.

12 Months	

4.3.3. Merge related individual clinical items to single archetype clinical concepts.

The data described in the previous section consists of the data items that we wish to capture for the specific instance of modelling data that will be consistent with the format that the Cystic Fibrosis Registry of Ireland records data in.

Two key concepts need to be considered when we re-model this data to look at it from an archetype based system perspective. These concepts are highlighted in the key Ocean Informatics design document called 'Building an Archetype'. These concepts are:

- 'Identify all discrete, separate clinical concepts involved

- Each archetype is inclusive of *all* attributes clinicians might want to capture about a discrete concept'

(Leslie, Heard, 2008)

The implications of these statements are that we need to consider the views of the data to be entirely separate from the actual clinical concepts (archetypes) that they may be constructed from. The previous section in effect details the views of the data that we require as the final product. Essentially these are system views or data capture forms.

Each view may be made up of a number of discreet clinical concepts. In addition these clinical concepts are maximal datasets in that they will include all of the data that might possibly be required to be captured by any group of clinicians.

The views of data as detailed in the previous section were taken and the separate clinical concepts that relate to them were identified. The discrete clinical concepts initially are detailed in Table 4.7.

Table 4-7: Clinical Concepts to be captured as part of CF Periodic Review

Clinical Concept	Description
Patient Demographic Details	Patient demographic details to be captured including name and address.
Hospital Demographic Details	Hospital demographic details to be captured such as name and address.
Spirometry Measurement	A clinical observation of a single complete set of readings to be captured and clinically interpreted as part of a single spirometry lung function test.
Weight	A clinical observation of the recorded weight at a point in time for a patient.
Height	A clinical observation of the recorded height at a point in time for a patient.
Body Mass Index	A clinical observation of the recorded body mass index at a point in time for a patient.
Centile Weight	A clinical observation of the recorded centile weight at a point in time for a patient.
Biochemistry Result List	A clinical observation of a list of the results of multiple biochemistry tests recorded for a particular patient at different points in time.

Medication List	A clinical instruction of the current list of medications that a patient is currently using.
Physiotherapy Regimen	A clinical evaluation and record of the physiotherapy regimen that a patient is currently undergoing as part of their treatment.
Nutrition Regimen	A clinical evaluation and record of the nutrition regimen that a patient is currently undergoing as part of their treatment.

At the end of our initial process to identify the data to be modelled and the archetypes we will require to model that data, we get a view of our system shown in figure 4.2 which we will need to develop further.

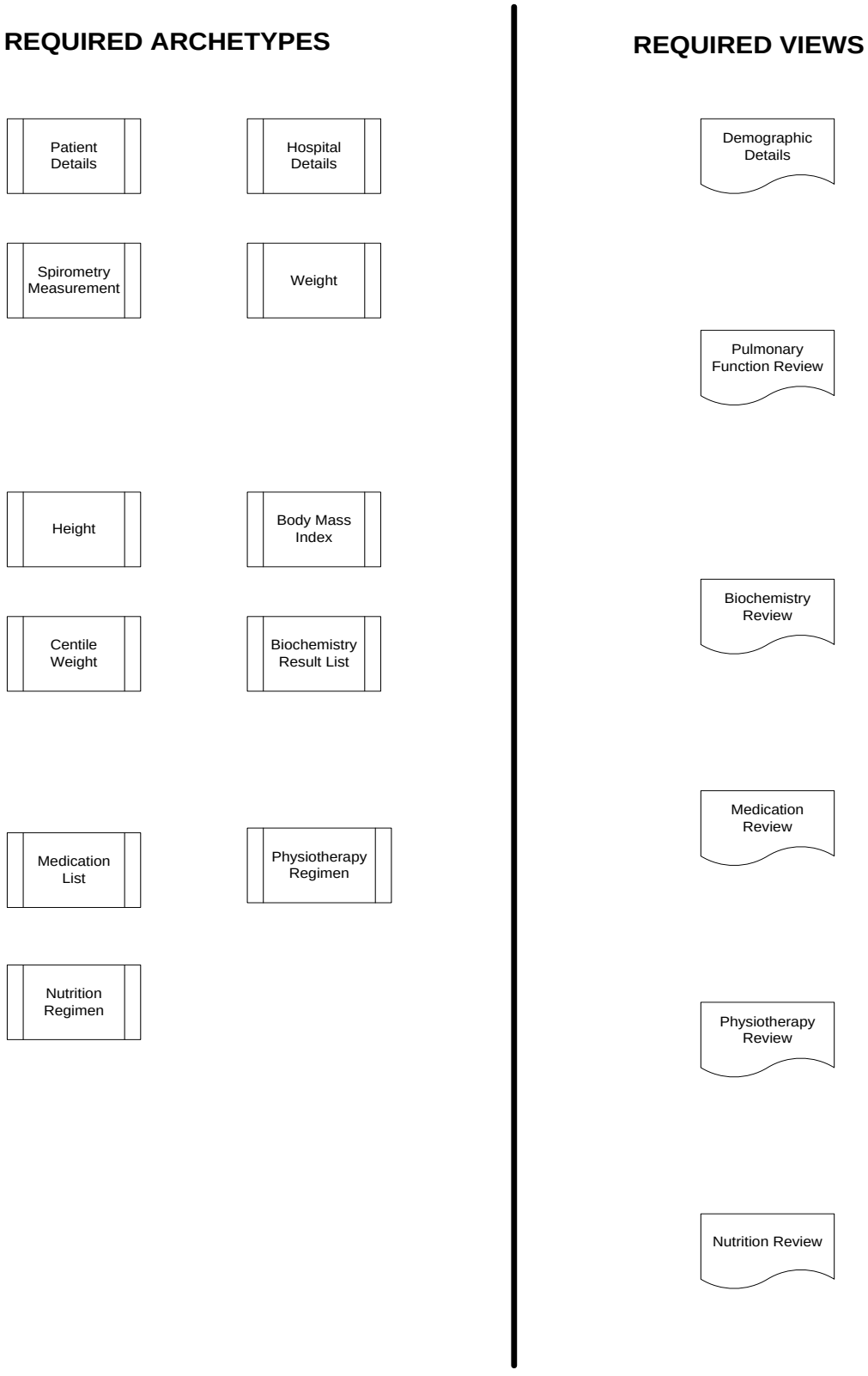


Figure 4-2: Required Archetypes and Views

4.3.4. Map the derived clinical concepts to existing archetypes

A key concept stressed in the guidance documents issued by OpenEHR is the aim to re-use existing archetype designs (Leslie et al., 2008). The goal of the OpenEHR foundation is to build a central repository of freely available high-quality archetypes which capture a complete set of clinical data that can then be re-used by anyone who has a need to capture the type of data described in those archetypes.

By re-using existing high quality archetype designs we can:

- greatly speed up the time it takes to design and develop an archetype based system assuming that existing archetypes are available which are fit for purpose

- greatly improve system and semantic interoperability of different archetype based systems to share data, if those systems are based on the same set of existing high quality shared archetypes

With a view to assessing the current state of archetype development, two main sources of existing archetypes were identified with a view to locating existing archetypes which matched the archetypes required identified in the previous section. The two main sources identified for obtaining existing archetypes were:

- the OpenEHR Clinical Knowledge Manager (CKM) which is an internet based repository of existing freely available archetypes and is accessible from the main OpenEHR website

- the NHS repository of archetypes developed for their prototype archetype based system as described by Leslie (2008)

OpenEHR - Clinical Knowledge Manager (CKM)

The OpenEHR CKM (figure 4.3) is a web based application provided by the OpenEHR foundation since 2008 which aims to promote archetype development by providing a central and freely available and fully searchable repository of archetypes which have been subjected to a rigorous review as part of a data governance process for OpenEHR based development (Garde et al.,2009). It can be accessed from http://openehr.org/knowledge/.

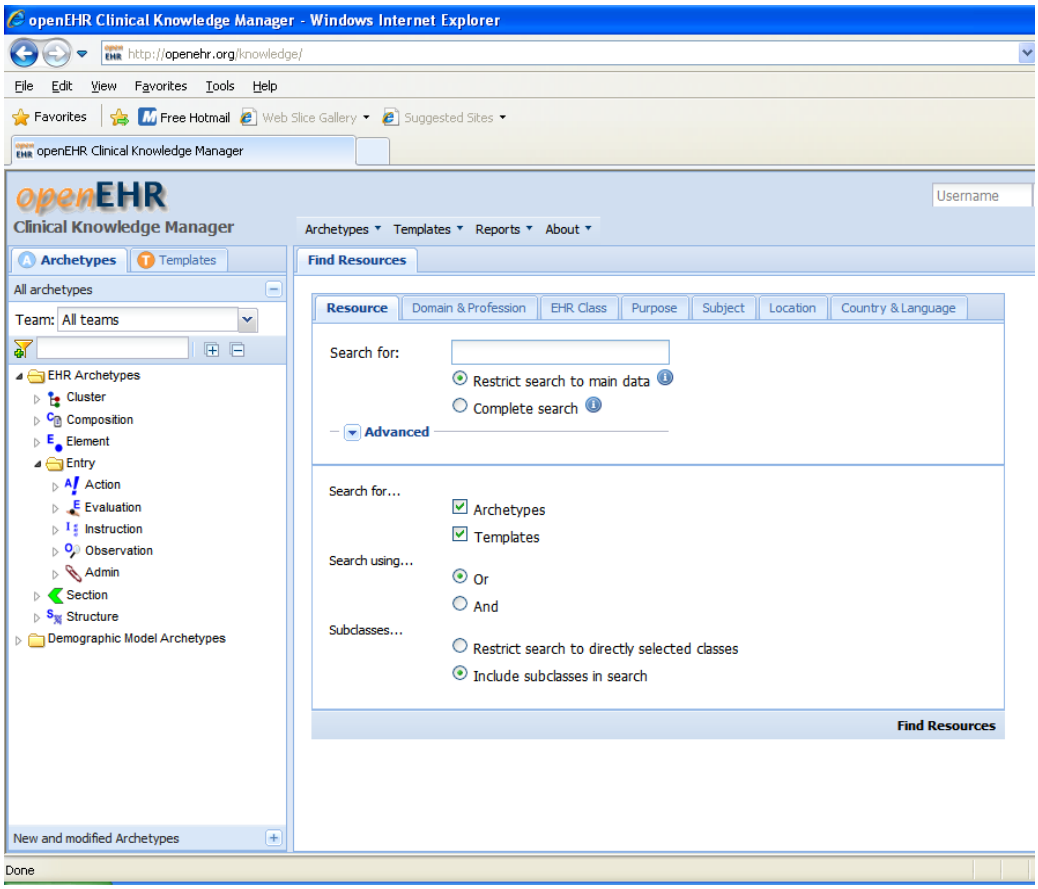


Figure 4-3: The OpenEHR Clinical Knowledge Manager (CKM)

Anyone can submit archetypes that they have designed for publication to the CKM. Once submitted the archetype will be reviewed by the Archetype Editorial Group (AEG) who are committee of clinician led collaborators and are responsible for formally assessing the quality of submitted archetype designs. They provide clinical feedback with suggestions for improving the archetype with a view to it being a

maximal dataset of all the clinical data that might potentially be required for that concept.

The OpenEHR CKM provides excellent searching facilities to identify required archetypes based on a number of possible criteria, the most useful of which are to search by resource name (figure 4.4) or by clinical domain (figure 4.5).

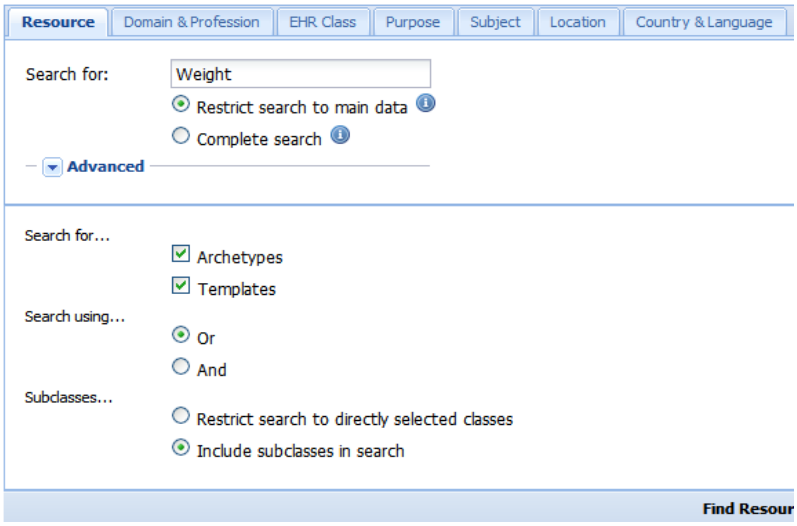


Figure 4-4: Searching for an Archetype using CKM

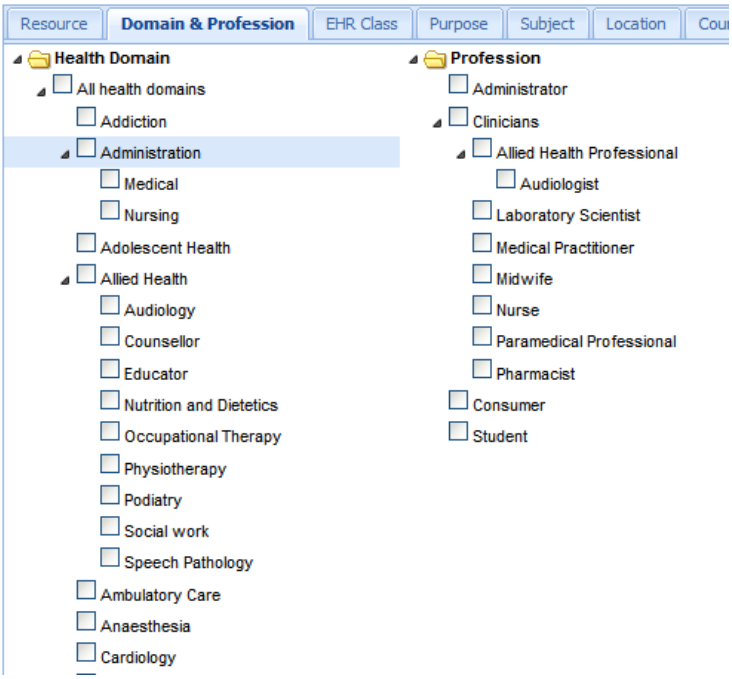


Figure 4-5: Searching the CKM by clinical domain

After running a search a list of the resource matching your search criteria are listed. Figure 4.6 shows the resources with a name of 'weight' from a search.

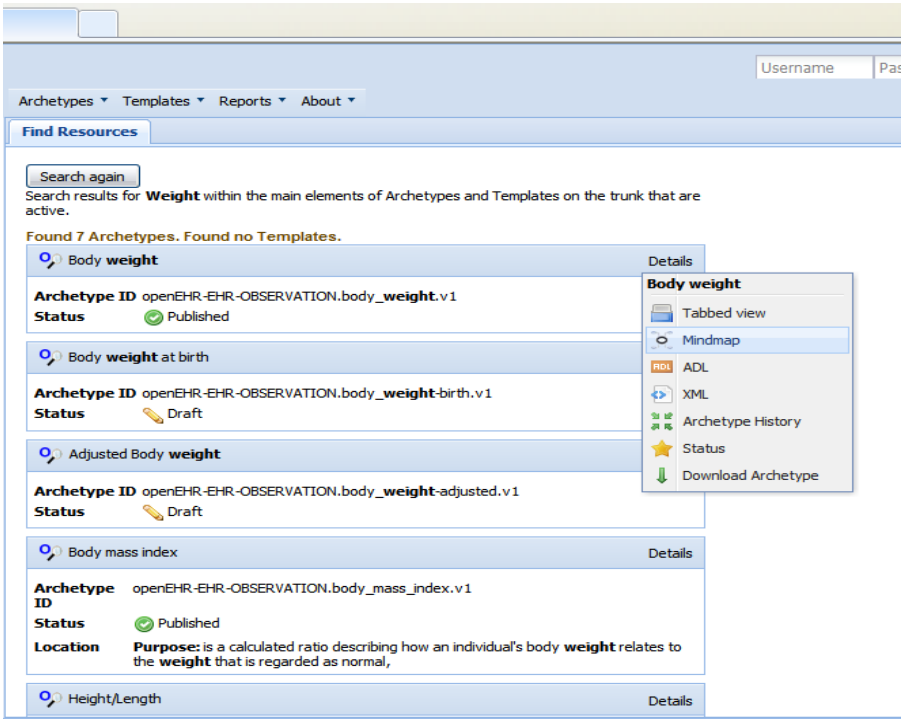


Figure 4-6: Search results and associated options with CKM

You can then view the details relating to the resource. In the case of an archetype you can:

- view and download the source ADL of the archetype
- visualise the archetype expressed as a concept mindmap (figure 4.7)
- view and download the archetype expressed as an XML file

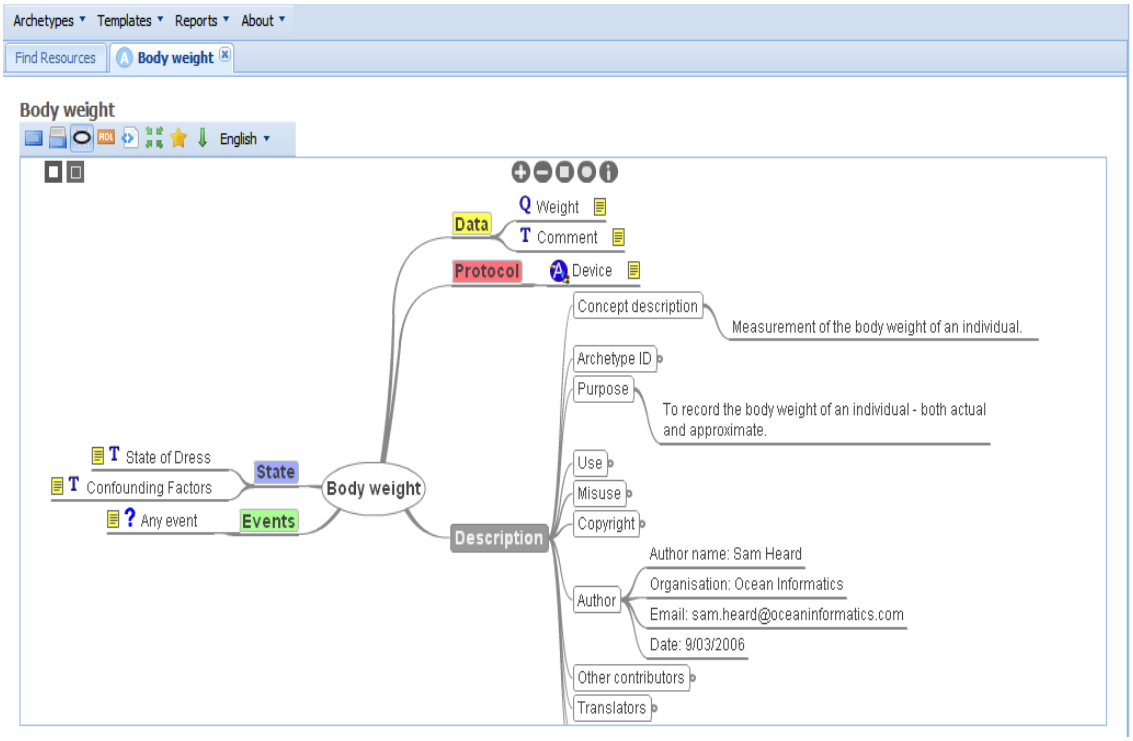


Figure 4-7: Viewing the body weight archetype mindmap in CKM

The NHS Archetype Repository

The NHS in the UK provides an internet accessible repository of archetypes that were developed as part of their investigations into prototype archetype based systems. This was only intended to share their work and is not a data governance tool. Therefore this is not provided as a functional application and is not as easy to navigate as the OpenEHR CKM as there are no search functions provided to locate archetypes.

The only mechanism available is to examine the archetype names and guess if they are applicable. In addition, these archetypes were developed for use by the NHS and are provided as is without any data governance process assessing their suitability for use outside of the NHS.

The archetype library is made available as a repository based on the Subversion version control system (which is typically used for enforcing version control for developing software systems). The easiest way to get access to their full library of

archetypes is to use a tool called a Subversion client which can connect to the repository and download an entire copy to you own local PC from where you can review the archetypes and identify those that are useful. The freely available Subversion client known as TortoiseSVN was used to do this.

After installing the TortoiseSVN client you can create a folder and right click on it to do a "SVN Checkout" (figure 4.8).

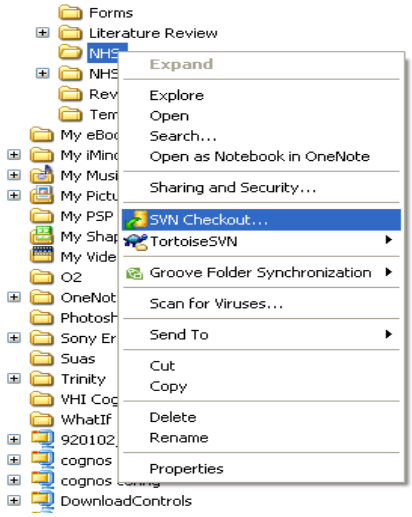


Figure 4-8: Checking out a SVN Repository using ToroiseSVN

The web address of the NHS Subversion repository was entered as per figure 4.9.

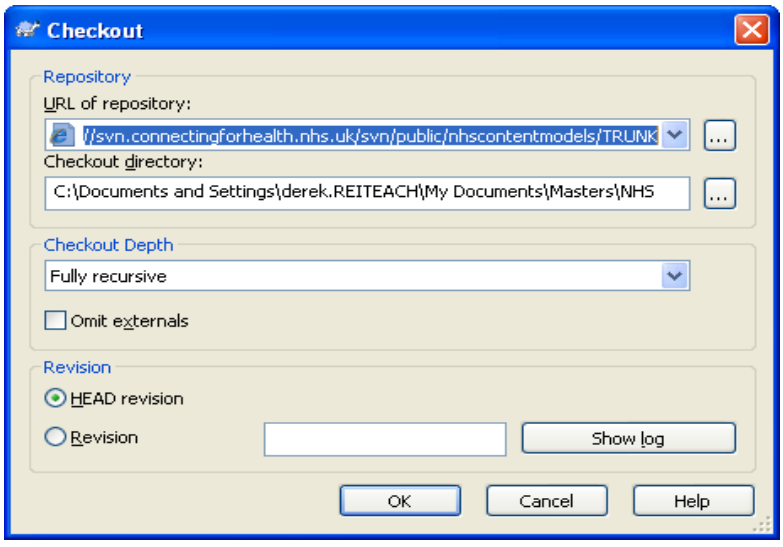


Figure 4-9: TortoiseSVN Repository Settings to connect to NHS Repository

This then downloaded and provided the entire library set of approximately 650 archetypes and 60 templates along with all supporting documentation, which was developed by the NHS and is an excellent resource for developing any new archetype based system.

Results of search for existing Archetypes

After searching and reviewing the two main sources of archetypes detailed previously, the archetypes detailed in table 4.8 were identified which matched the clinical concepts in our system and which could be used as part of this prototype.

Table 4-8: Existing Archetypes identified

Clinical Concept	Archetype Name	Location Found
Patient Demographic Details	openEHR-EHR-CLUSTER.individual_personal.v1	OpenEHR CKM
Hospital Demographic Details	openEHR-EHR-CLUSTER.organisation.v1	OpenEHR CKM
Weight	openEHR-EHR-OBSERVATION.body_weight.v1	OpenEHR CKM
Height	openEHR-EHR-OBSERVATION.height.v1	OpenEHR CKM
Body Mass Index	openEHR-EHR-OBSERVATION.body_mass_index.v1	OpenEHR CKM
Biochemistry Result List	openEHR-EHR-OBSERVATION.lab_test-microbiology.v1	OpenEHR CKM

Medication List	openEHR-EHR-INSTRUCTION.medication.v1	OpenEHR CKM
Physiotherapy Regimen	No suitable archetype found	
Nutrition Regimen	No suitable archetype found	
Spirometry Measurement	No suitable archetype found	
Centile Weight	No suitable archetype found	

As a result of this search, a total of seven existing archetypes from the OpenEHR CKM were identified leaving four clinical concepts that we did not have suitable archetypes available to reuse. These needed to be developed using an archetype development tool. The first step to do this using our archetype development methodology was to visualise the data model for the clinical concepts first as part of a mindmap.

4.3.5. Data model the new clinical concepts identified and re-model them to eliminate duplication of items.

As emphasised previously, developing maximal dataset archetypes that capture all possible aspects for a clinical concept is a key concept advocated in OpenEHR design documents. A substantial amount of effort is required however just to develop a single high quality maximal dataset clinical archetype with input from expert clinicians in the selected areas.

Therefore for the purposes of this study, it was decided from a practical point of view that one of the four archetypes would be developed as a maximal clinical dataset archetype. The other three would be developed with only the information required for the Cystic Fibrosis Registry of Ireland forms and that limitation would be accepted.

The basis for this decision was that by fully developing one high quality maximal dataset archetype, this would enable a full exploration of the archetype development process and would also allow the best chance of publishing of this archetype to the OpenEHR CKM.

The archetype that was chosen to be developed fully was the Spirometry Measurement archetype. It was felt that this provided the best scope to develop a high quality clinical archetype which could be published.

Archetype development steps

The following steps taken from Leslie et al. (2007) were identified as the main steps in the archetype development process:

I- Research the clinical concept

II- Identify the archetype class (or type)

III- Identify the relevant sections to be used for the chosen archetype class

IV- Data model the data attributes associated with each section of the archetype according to clinical references available

V- Re-iterate the development process if required by reference to existing "best practice" developed archetypes

VI- Build the archetype

I. The Spirometry Archetype – Research

It has been discussed previously that a key goal of the OpenEHR approach is that archetypes will be developed by clinicians themselves as they are the experts in their clinical knowledge domain.

The author of this study is not a clinician and therefore it was decided to use recognised clinical texts instead to provide the clinical expertise to enable development and interpretation of the Spirometry archetype. The key texts selected for this were Johns et al. (2007) and Miller et al. (2005) which comprehensively details:

- procedures on how to carry out spirometry measurements
- the equipment used to carry out spirometry measurements
- how to clinically interpret spirometry measurements

II. Identify the class of the Archetype

We described in section 2.3.3 the different classes of archetype that allow us to iteratively model the entire clinical process. These classes describe different steps in the iterative clinical process and are summarised again as follows:

- COMPOSITION – a complete clinical document or form e.g. a patient discharge form
- SECTION – a section heading within a clinical document or form for organising data e.g. a "medication summary" heading within a vital signs discharge summary
- OBSERVATION – a full set of clinical measurement data that describes the measurement of a clinical concept at points in time for a patient e.g. blood pressure

- EVALUATION – a clinical assessment or evaluation based on observations related to the patient e.g. problem diagnosis

- INSTRUCTION – a clinical instruction to medical staff based on an assessment or evaluation of a patient e.g. medicine order

- ACTION - a clinical action that is carried out on the patient e.g. the act of administering medication

Figure 4.10 illustrates an algorithm for identifying the correct class for any archetype to be developed.

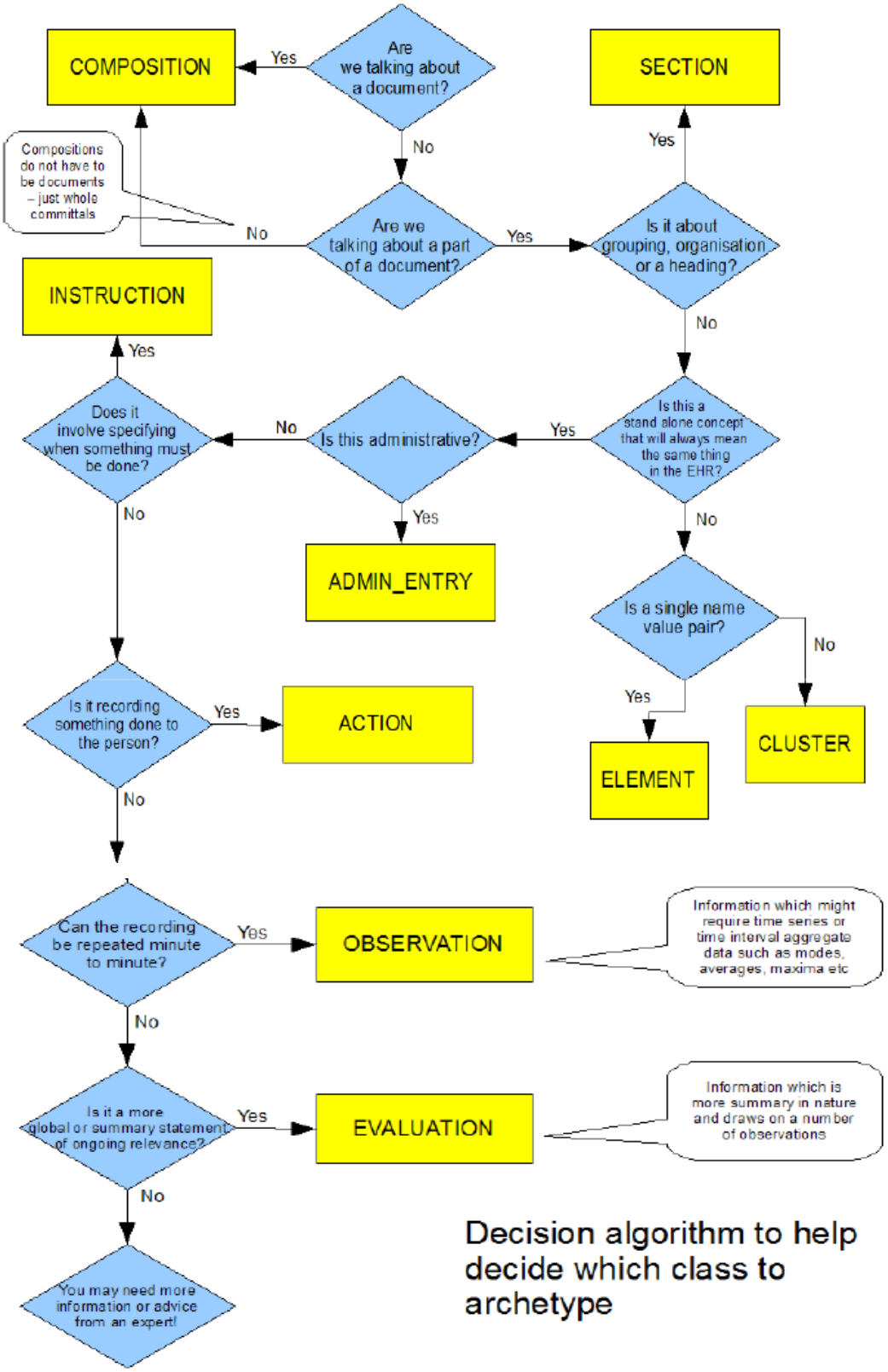


Figure 4-10: Decision algorithm for OpenEHR class selection – (Leslie et al., 2008)

Based on this algorithm, a spirometry measurement is an OBSERVATION class archetype which is an observable recorded measurement that may be carried out at a number of times.

III. Identify key class sections

Based on the chosen class of archetype, there are a number of distinct sections defined in the archetype that may represent clinical data or contextual information. An OBSERVATION may potentially include sections to describe:

- DATA – the collection of raw clinical data to be captured or measured

- PERSON STATE – contextual information about the state of the person or patient that may be useful to know in the context of the data being captured e.g. patient position when reading was taken

- EVENTS – time related information describing key time events at points when the data is collected e.g. for blood pressure you can have any measurement at any point in time, or specifically a 24 hour average

- PROTOCOL – contextual information describing how the data was collected or measured and typically relates to the equipment or method used to capture the data

- PARTICIPANTS – contextual information describing a list of all participants relating to the observation where there is more than one participant taking part e.g. a referral letter may be related to the clinician making the referral or the clinician receiving the referral

In relation to the spirometry measurement archetype, we will be collecting DATA using equipment which will have a PROTOCOL and based on the clinical research done for this archetype, the patient state is relevant so we will capture PERSON_STATE. Time related events and additional participants are not relevant.

IV. Identify key attributes in each section and mindmap archetype

Based on a review of selected clinical reference in conjunction with the main documents provided by the Cystic Fibrosis registry of Ireland the attributes in Tables 4.9 to 4.11 were identified for each section in the archetype.

Table 4-9: DATA attributes required for Spirometry Archetype

Attribute	Description
FEV1	Forced Expiratory Volume in 1 Second
FEV1 % of Predicted	Forced Expiratory Volume in 1 Second expressed as % of expected normal value.
FVC1	Forced Expiratory Vital Capacity in 1 Second
FVC1 % of Predicted	Forced Expiratory Vital Capacity expressed as a percentage of normal expected value
FEF 25%-75%	Forced Expiratory Flow during 25%-75% of expiration (middle portion of expiration)
FEF % of Predicted	Forced Expiratory Flow expressed as a % of normal expected value.
PEF	Peak Expiratory Flow
PEF % of Predicted	Peak Expiratory Flow expressed as a

	percentage of normal expected value
FEV6	Forced Expiratory Volume in 6 Seconds. Sometimes used instead of FEV1
FEV6 % if Predicted	Forced Expiratory Volume in 6 Seconds expressed as a percentage of normal expected value
FVC6	Forced Vital Expiratory Capacity in 6 Seconds. Sometimes used instead of FVC1
FVC % of Predicted	Forced Vital Expiratory Capacity in 6 Seconds expressed as a % of normal expected value.
Comment	General comments to be recorded relating to result
Result Classification	Spirometric classification of result
Obstructive Defect Grade	Where obstructive defect recorded indicate severity
Ventilatory Defect Grade	Where ventilatory defect recorded indicate severity
Patient Test Failure Reason	Patient related reason for failure of test
Instrument Test Failure Reason	Instrument related reason for failure of test result

Visual Result Graph	Image attachments of spirometric curves to aid graphical interpretation of results

Table 4-10: PROTOCOL attributes required for Spirometry Archetype

Attribute	Description
Normal Values	Free text to enter the name of the set of normal reference values used to interpret the spirometric readings e.g. UK90, WUK WHO etc.
Equipment Type	The type of spirometer used to capture the reading
Calibration Check	Record whether the spirometer was calibrated prior to the spirometry measurement

Table 4-11: STATE attributes required for Spirometry Archetype

Attribute	Description
Patient Position	The physical position of the patient when the reading was taken
Confounding Factors	Comment on any confounding or incidental factors relating to the patient that may be affecting the spirometry

	measurement

Based on the attributes identified, a mindmap was created to provide a first draft of the visualisation of the archetype to be built (figure 4.11).

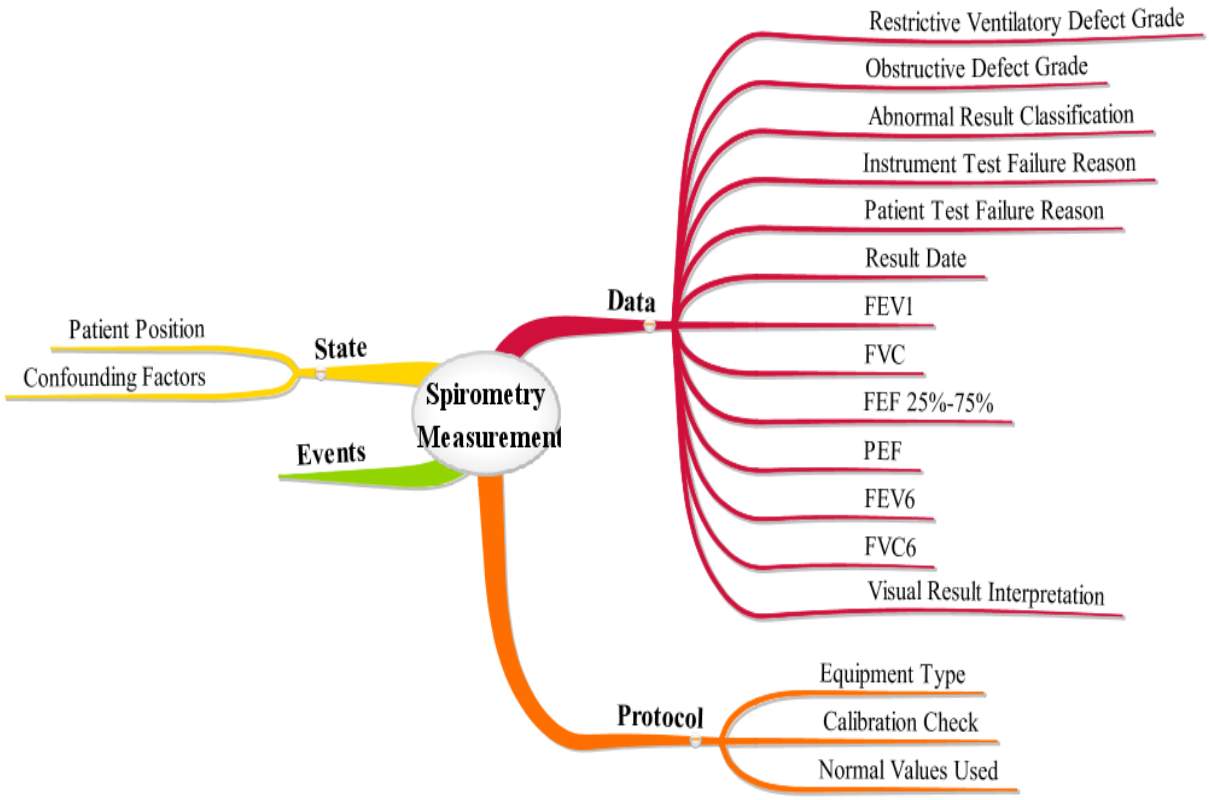


Figure 4-11: The Mindmap for the Spirometry Measurement Archetype

V. Re-iterate the development process if required by reference to existing 'best practice' developed archetypes

After producing the first draft of the visual representation of the archetype, it is useful to review that design in the context of existing archetypes that have already been designed according to best-practice and to refine the chosen design.

The OpenEHR CKM provides a large number of existing archetypes which can be downloaded and examined in detail using the Ocean Informatics Archetype Editor.

A number of existing archetypes were looked at in the context of the newly designed spirometry archetype. The current archetype review status of each archetype is visible within the OpenEHR CKM. An archetype maybe in 'draft' or 'published' status and a version number indicates how established the archetype design is.

A number of OBSERVATION class archetypes were downloaded, reviewed and compared to the newly created spirometry archetype. The mindmap in figure 4.12 is from the 'body temperature' OBSERVATION archetype that is officially published on the OpenEHR CKM.

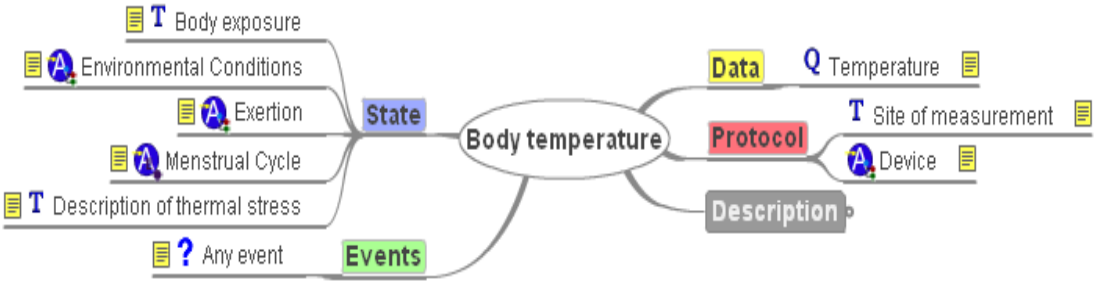


Figure 4-12: The Body Temperature mindmap from CKM – (OpenEHR Foundation)

It can be noted that this archetype also captures protocol data related to the device that is used to make the measurement. However, in this design instead of capturing the individual characteristics of the device used to capture the measurement within the archetype itself, this archetype reuses a reference to another completely separate existing archetype called 'device details' (which is denoted with the 'A' slot for archetype).

If we look at the separate 'device details' archetype which can be used in this slot it can capture the information shown in figure 4.13.

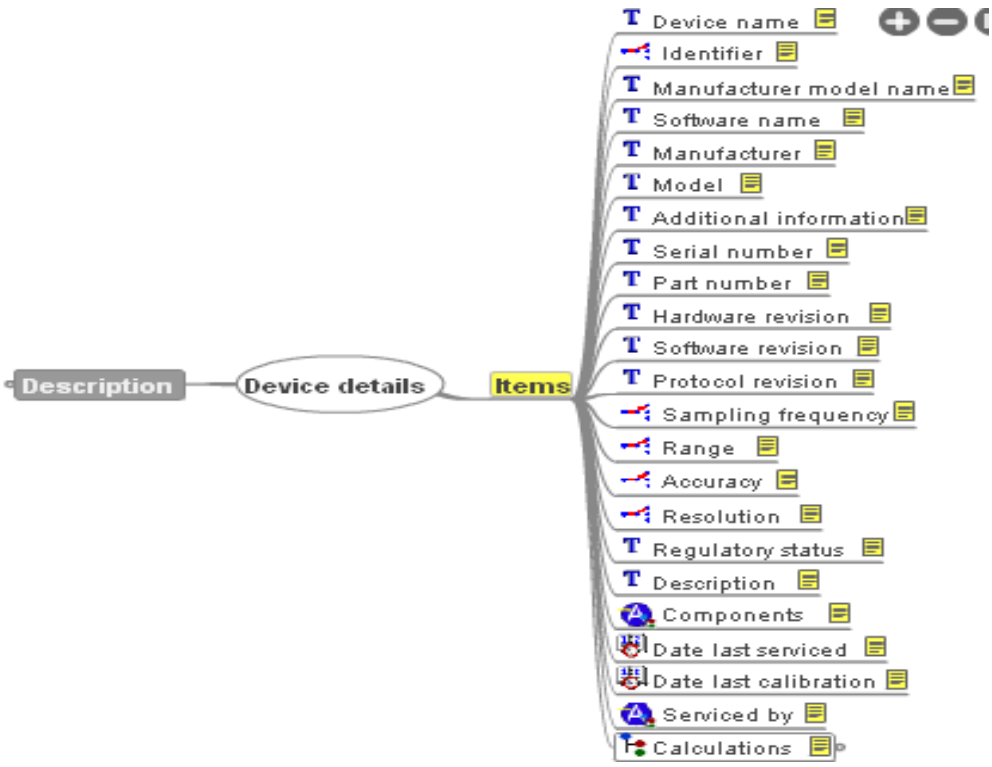


Figure 4-13: The Device Details Archetype mindmap from OpenEHR CKM – (OpenEHR Foundation)

Creating a reference to an existing 'device details' archetype in our design will improve it by allowing our archetype to also incorporate a much more complete set of device information than was previously defined if required. By doing this we are adhering to the maximal dataset concept that is a key design goal of the OpenEHR approach.

A number of archetypes were reviewed which indicated that individual data items were grouped and organised together in a 'cluster' element which groups data in related groups of information. In our spirometry archetype there are a large number of data attributes which can be differentiated more clearly.

These can be subdivided into two 'clusters' called 'spirometry measures' (the actual measurements) and 'spirometry interpretation' (the actual clinical interpretation of the measurements).

By incorporating this into our spirometry design results in the following final visual representation of the spirometry archetype which is more readable and also more complete. Figure 4.14 shows the final archetype design that will initially be built as a draft archetype.

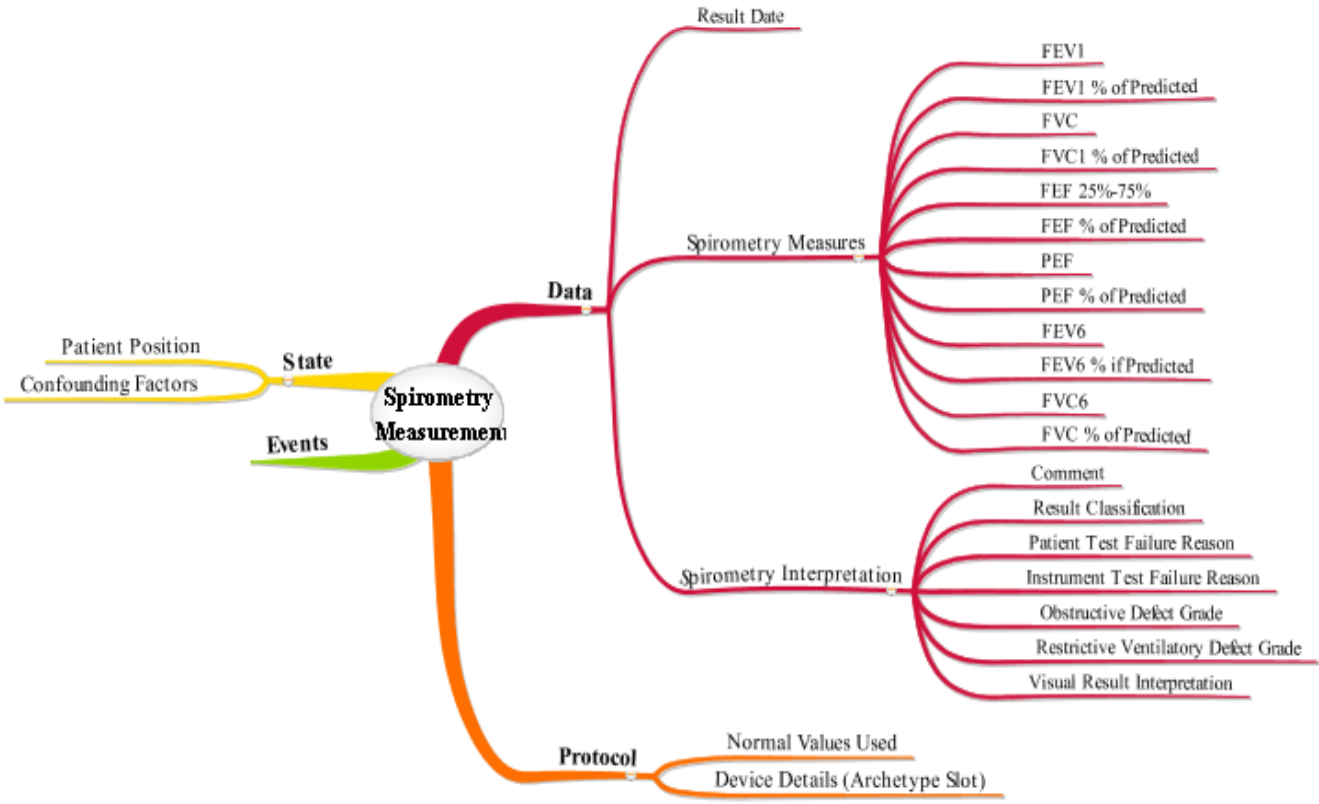


Figure 4-14: The revised Spirometry Measurement mindmap

4.3.6. Model new archetypes for clinical concepts that cannot be mapped to existing archetypes

The final step in the archetype design process is to use an archetype design tool to actually build the archetype. The archetype development tool of choice for

OpenEHR is the Ocean Informatics Archetype Editor. This is the tool that would be used by a clinician to graphically develop a new archetype. The output from the tool is a file which contains the archetype expressed in the archetype language called Archetype Definition Language (ADL) which was discussed previously in section 2.3.3).

The archetype editor has help facilities which when combined with the archetype design guide produced by Leslie et al. (2007) give an extensive overview of how to use the tool. The main steps for using the archetype editor are therefore only summarised here in the context of the new spirometry measurement archetype:

- enter the main data attributes that describe the archetype contents as per the archetype mindmap choosing appropriate data types

- add constraints to each data attribute to define rules to enforce appropriate usage of the data attributes

- add metadata to describe the purpose and use of the archetype for the benefit of others who may wish to use it

- add data binding to external clinical terminologies such as SNOMED-CT

- preview the archetype interface to assess archetype design and completeness

Enter the main data attributes that describe the archetype

The definition tab allows you to drag and drop the core descriptive attributes that fully describe the archetype into the appropriate sections in the archetype that were described earlier (DATA, PROTOCOL, STATE etc.). A separate attribute is added for each item that describes the archetype.

A number of different data types are available depending on the type of data being modelled:

- numeric : integer or real data such as counts or measurements e.g. forced expiratory volume in 1 second

- text: text data in the form of freely entered text or predefined textual choices that can be selected – obstructive defect grade

- date time: date or time data e.g. result date

- boolean: a yes or no choice

- data slot: a reference to another separately defined existing archetype

- multimedia: allows reference to incorporate multimedia images, sounds or video into an archetype e.g. a full spirometry curve image produced from a spirometer to assist interpretation of results

Figure 4.15 shows the DATA section after all attributes from the mindmap design have been added to the archetype.

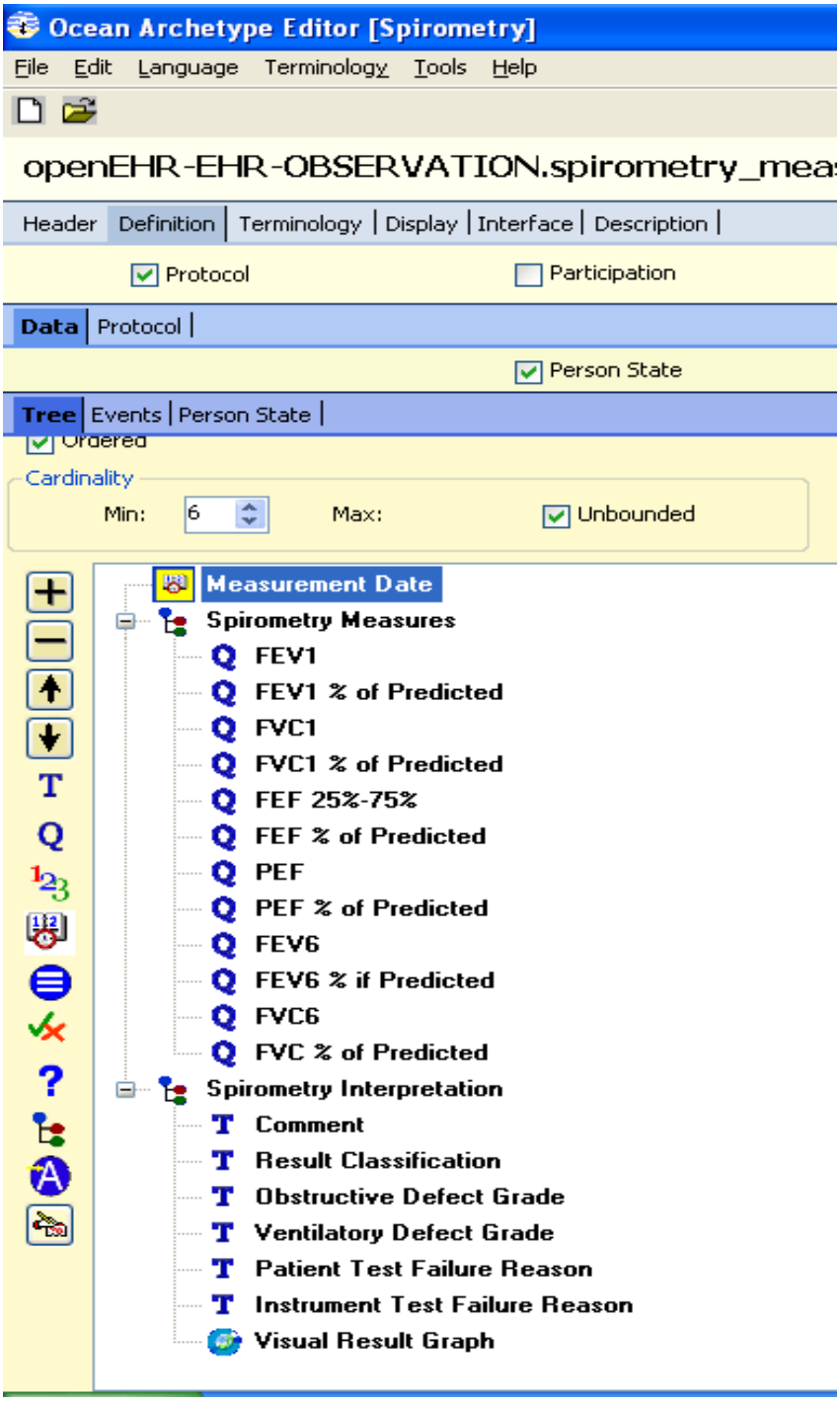


Figure 4-15: Defining the Spirometry Measurement Data in an Archetype Editor

Figure 4.16 shows the PROTOCOL section after all attributes from the mindmap design have been added to the archetype.

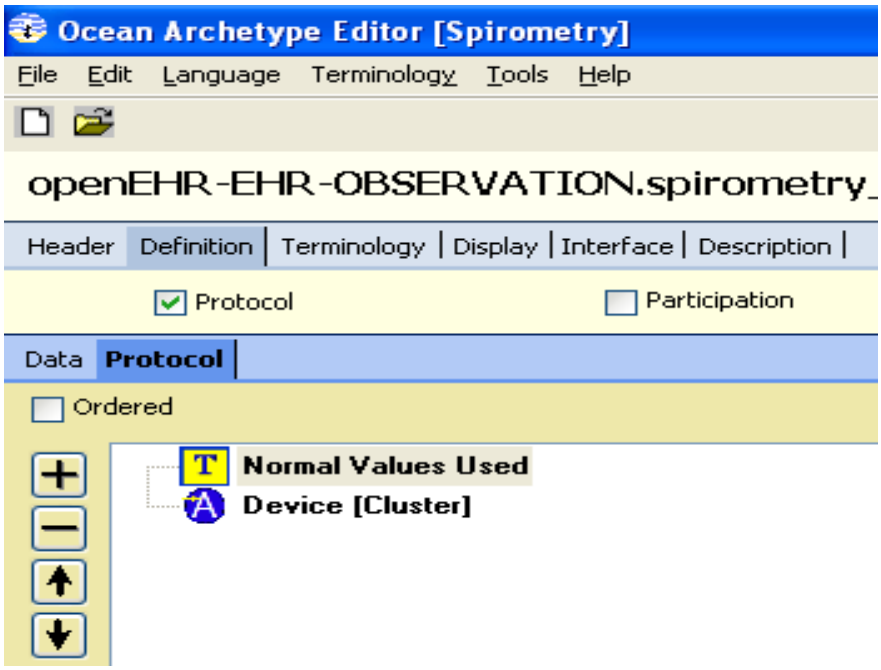


Figure 4-16: Defining the Spirometry Measurement Protocol in an Archetype Editor

Figure 4.17 shows the STATE section after all attributes from the mindmap design have been added to the archetype.

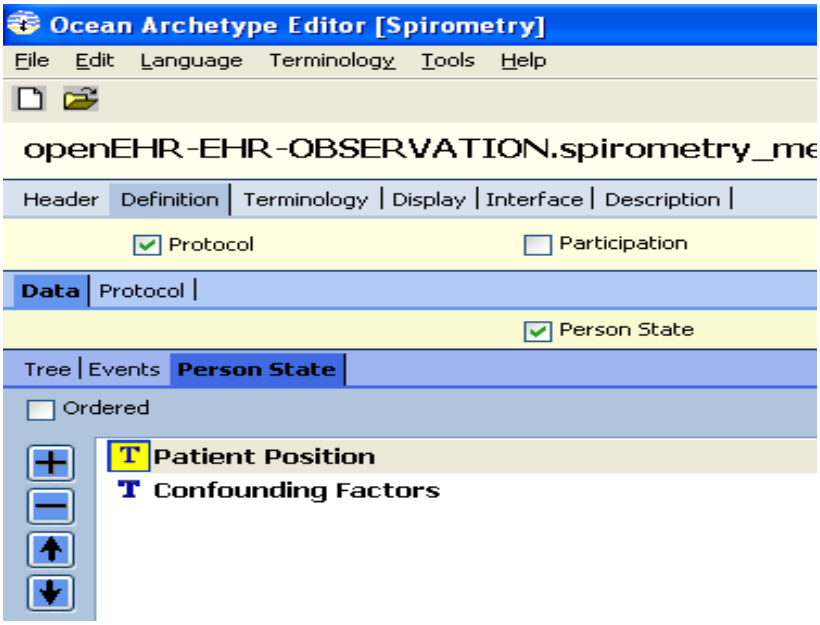


Figure 4-17: Defining the Spirometry Measurement State in an Archetype Editor

Add constraints to each data attribute

After adding the attributes that describe the archetype, each archetype attribute should be constrained if necessary to be as specific as possible about the data that may be contained in that attribute (figure 4.18). This ensures better data integrity by allowing only clinically sensible types of data to be entered against the item.

Possible types of constraints for numeric data include:

- defining the unit of measurement to aid reading of data e.g. litres, metres

- defining maximum or minimum values where known e.g. an age attribute might have minimum of 1 and a maximum value of 130 ensuring that an erroneous value entered of -10 or 200 would not be allowed

- limit the number of decimal places for real data e.g. a currency may be with two decimal places

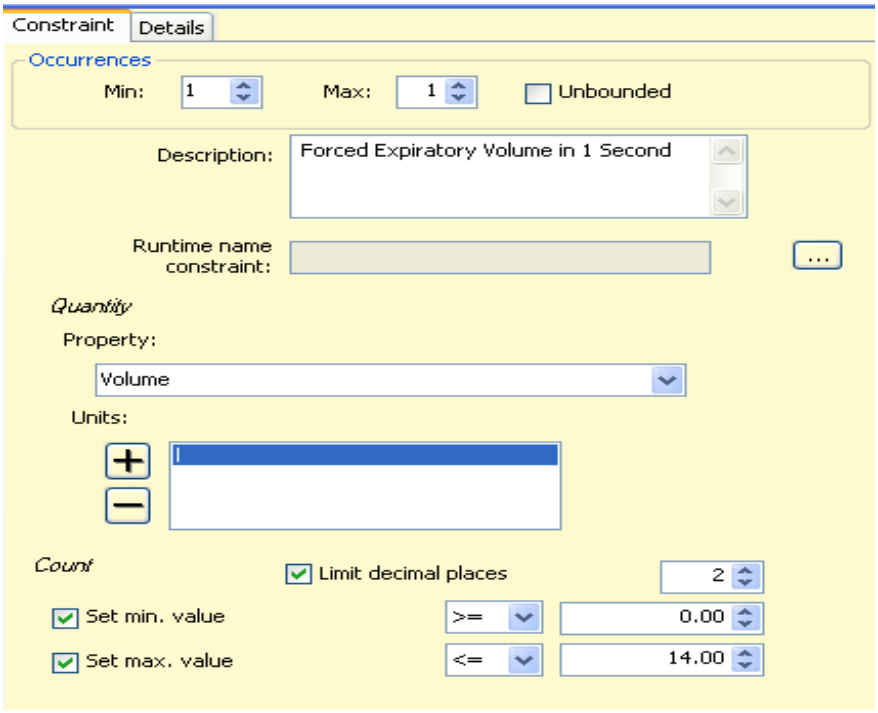


Figure 4-18: Constraining Data Attributes in the Archetype Editor

Possible types of constraints for textual data include:

- free text where any textual value can be type by the user e.g. patient name

- predefined set of textual choices defined by the designer e.g. spirometry result classification (figure 4.19)

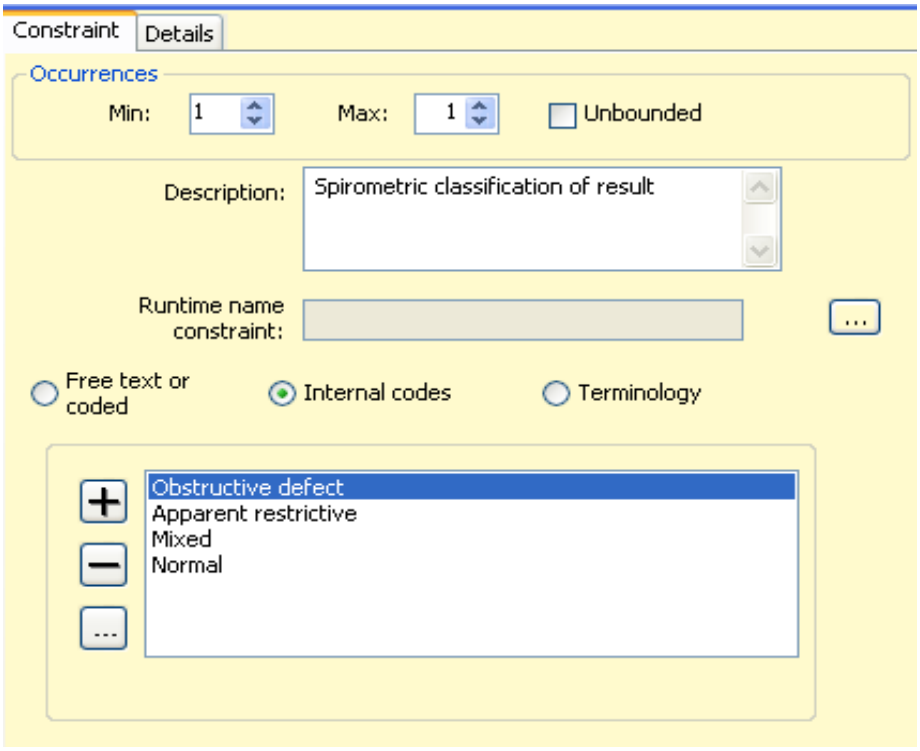


Figure 4-19: Defining predefined text choices using the Archetype Editor

Add data binding to external clinical terminologies

A crucial goal of OpenEHR is to provide system interoperability by allowing different systems to communicate using archetypes built upon a common consistent archetype definition language representation (ADL) (Beal et al., 2008).

Another crucial aspect of this is to provide for semantic interoperability which means that two systems not only can exchange data (system interoperability) but also that the two systems will interpret the contents of the exchanged data in the same way from a clinical point of view (semantic interoperability) (Gibbons et al., 2007).

To provide for semantic interoperability Gibbons et al outline the need to use agreed clinical terminologies which provide unique codes to identify clinical concepts. If two systems can interpret the same unique clinical codes then they can consistently interpret what that data represents from a clinical perspective.

The Ocean Informatics Archetype editor allows incorporating binding of data attributes to a mapped clinical terminology code which allows other systems using that terminology to understand that data based on the clinical terminology code rather than the internal text description (which may only be used in a specific organisation and not understood outside it or may be textually ambiguous).

Although this is not a mandatory part of archetype design, because of the importance of this concept it was decided to attempt to use this feature as part of the design to establish how well it worked with the spirometry archetype.

The first step was to try and identify the clinical attributes described in archetype and match them with a corresponding clinical concept found in a clinical terminology. The selected terminology for doing this is a widely used clinical terminology called SNOMED-CT.

Because of the complexity of such clinical terminologies it is necessary to use a terminology browser which allows you to browse the hierarchy of defined clinical concepts and search for the concept codes you require.

One such browser is the Snoflake Browser (figure 4.20) which is a free internet based SNOMED-CT browser. After logging into the browser you can search for clinical concepts which return any matching concepts with their corresponding SNOMED-CT code number.

Figure 4-20: The Snoflake Clinical Terminology Browser

In addition you can visualise the concept and see the hierarchical relationships that it has to other SNOMED-CT clinical concepts (figure 4.21).

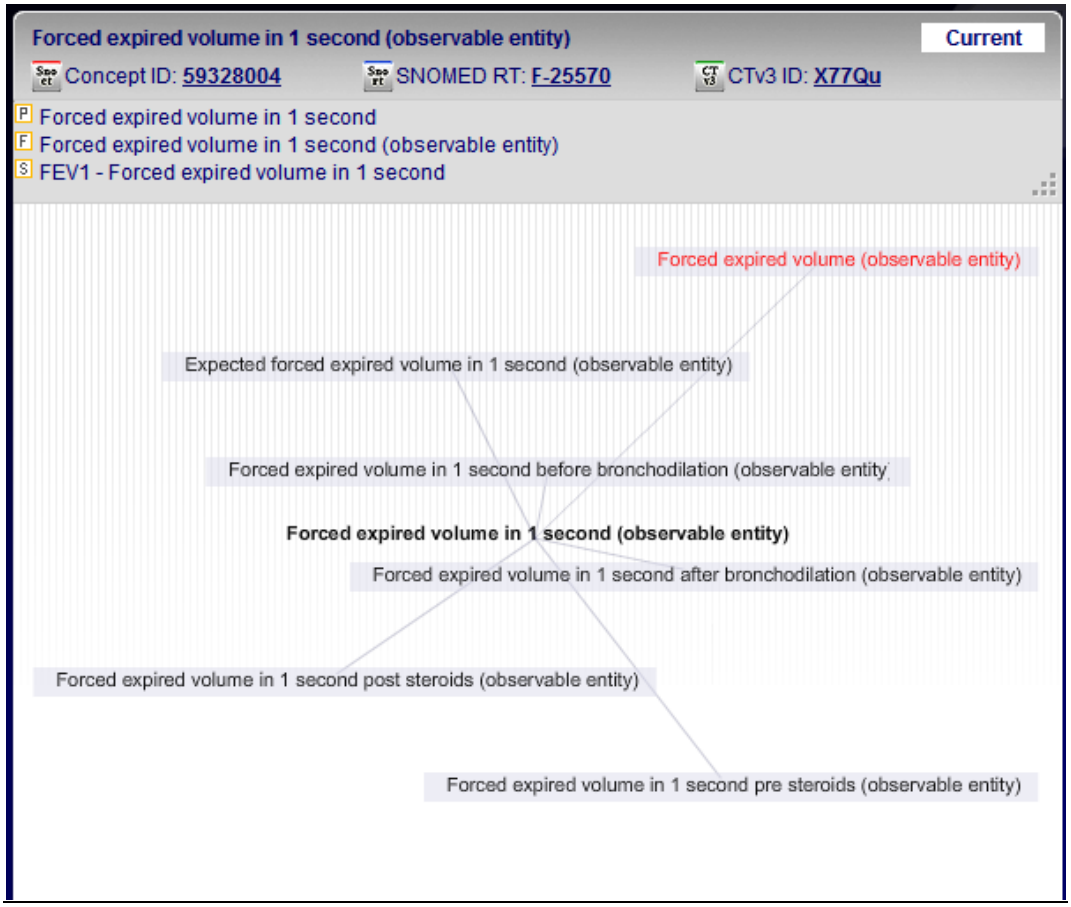


Figure 4-21: Viewing Clinical Concepts using Snoflake Browser

After identifying the clinical concept codes you can then enter those codes against the corresponding data item using the term bindings screen that is part of the terminology section of the browser.

Figure 4.22 shows codes identified and bound to the corresponding data attributes in the spirometry archetype.

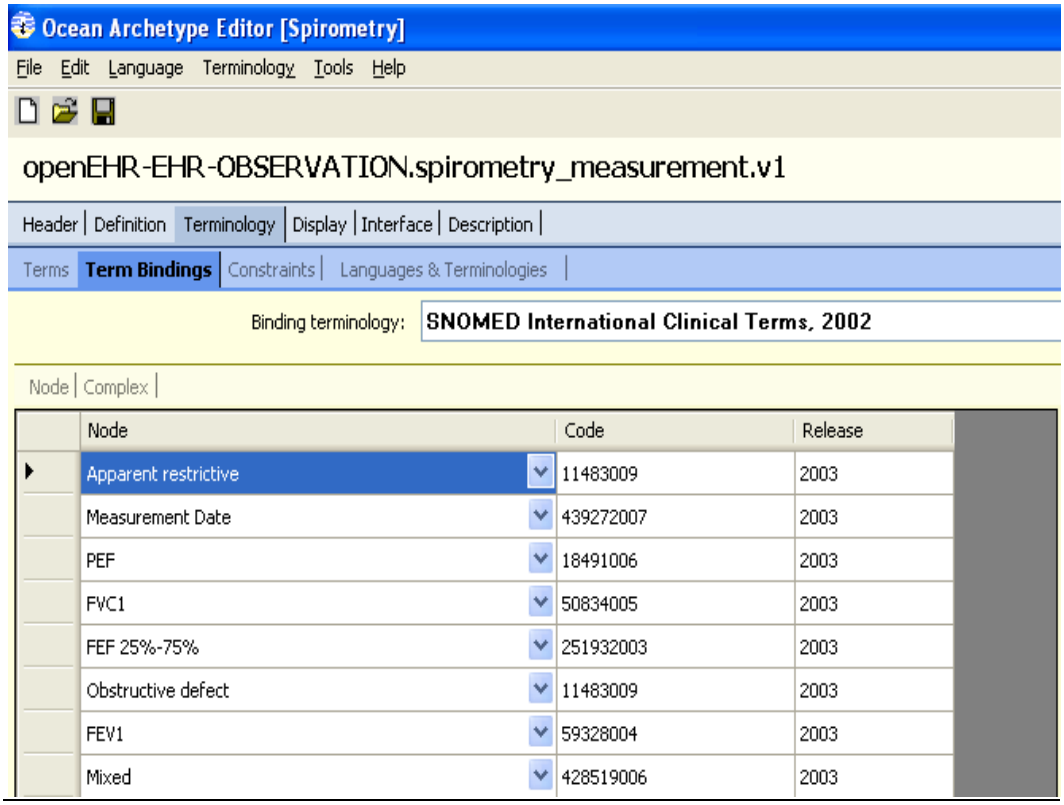


Figure 4-22: Binding Clinical Terminology to an Archetype using the Archetype Editor

Add metadata

Metadata are textual descriptions that can be added to an archetype. They are intended purely to help other users who may wish to use that archetype to understand the clinical context that the archetype may or may not be used for.

Metadata is not actually used by the archetype itself, it is purely descriptive to assist other users as shown in figure 4.23.

Examples of metadata are:

- the key clinical concept which the archetype relates to
- the author name and contact details
- a description of the archetype
- a description of the clinical use of the archetype
- a description of where the archetype is not be used if relevant
- a list of clinical references used in the design of the archetype

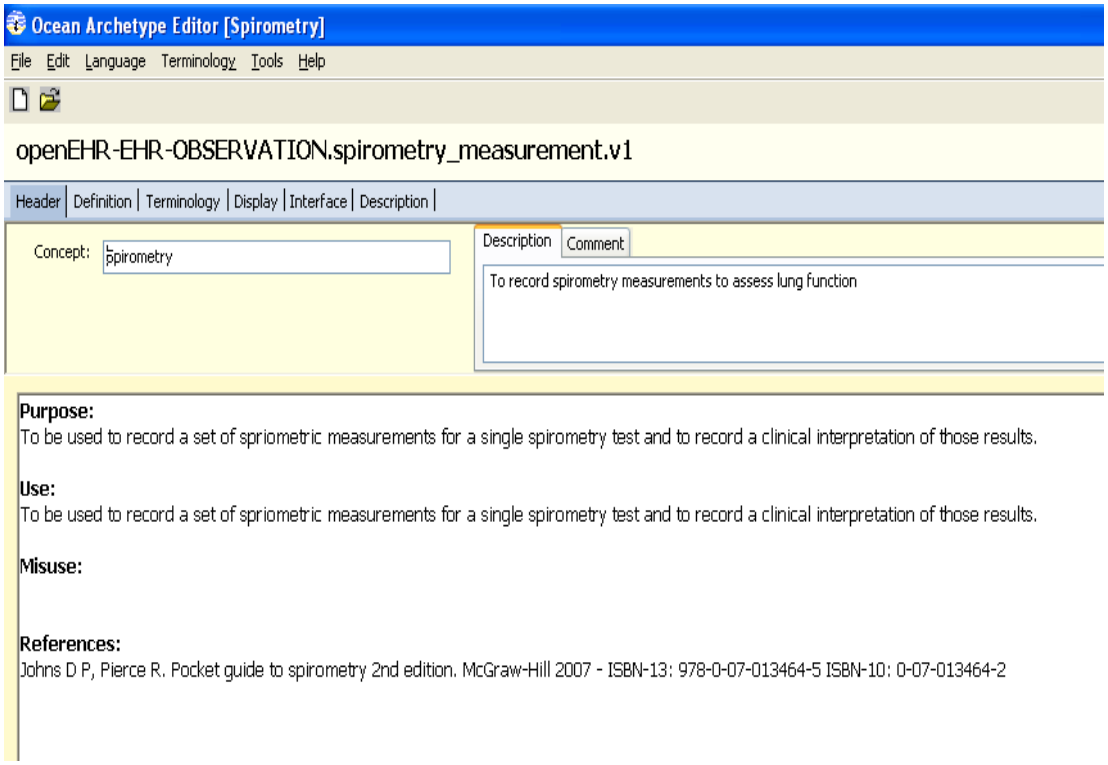


Figure 4-23: Defining Archetype metadata using the Archetype Editor

Preview the archetype interface

The interface preview allows you to visualise how the interface would appear to a user when entering data or viewing data using a template (view) which uses that archetype. This screen allows you to assess the design of your archetype and ensure that all necessary constraints have been defined (figure 4.24).

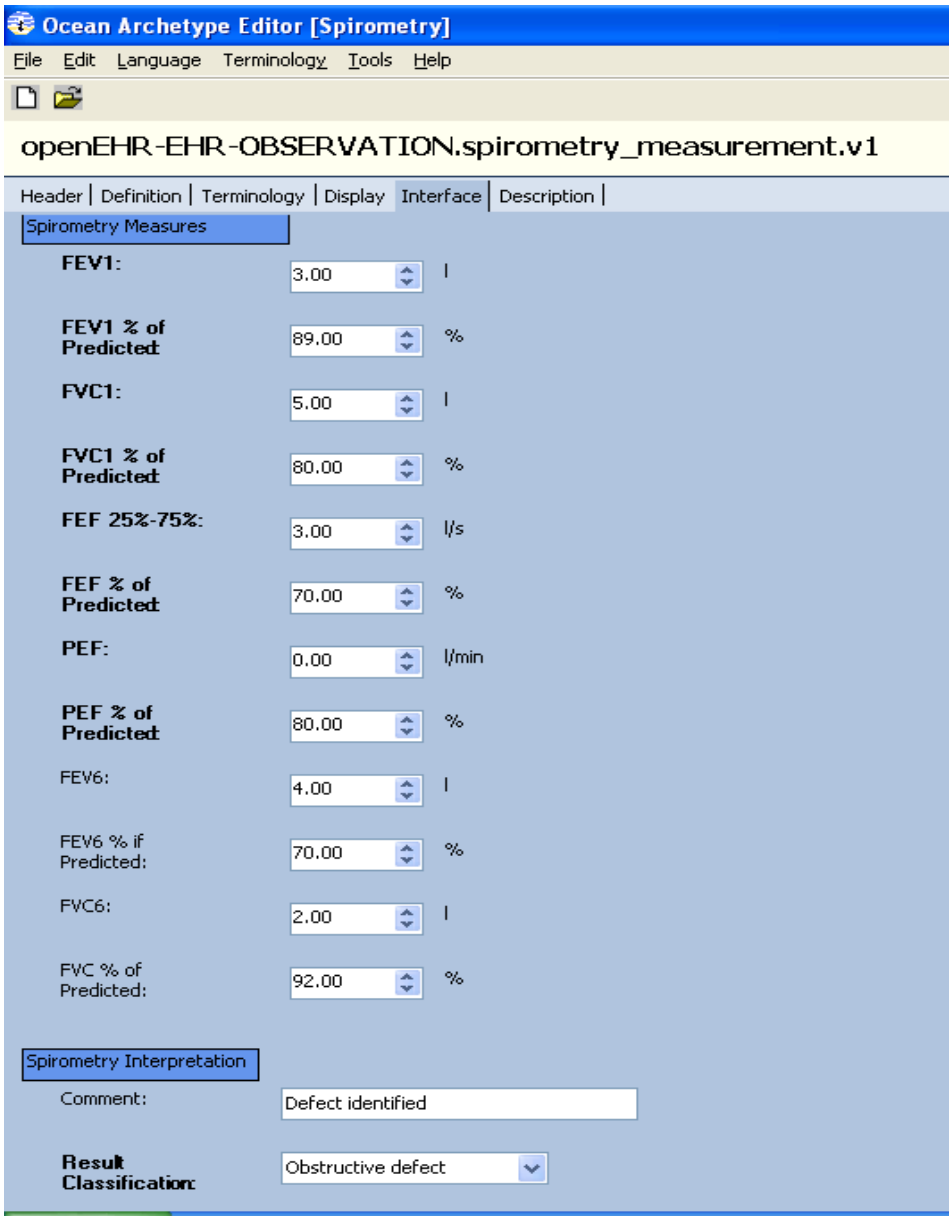


Figure 4-24: Previewing the Archetype Interface in the Archetype Editor

The actual generated ADL code that defines the archetype and is the output of the graphical editor as shown in figure 4.25.

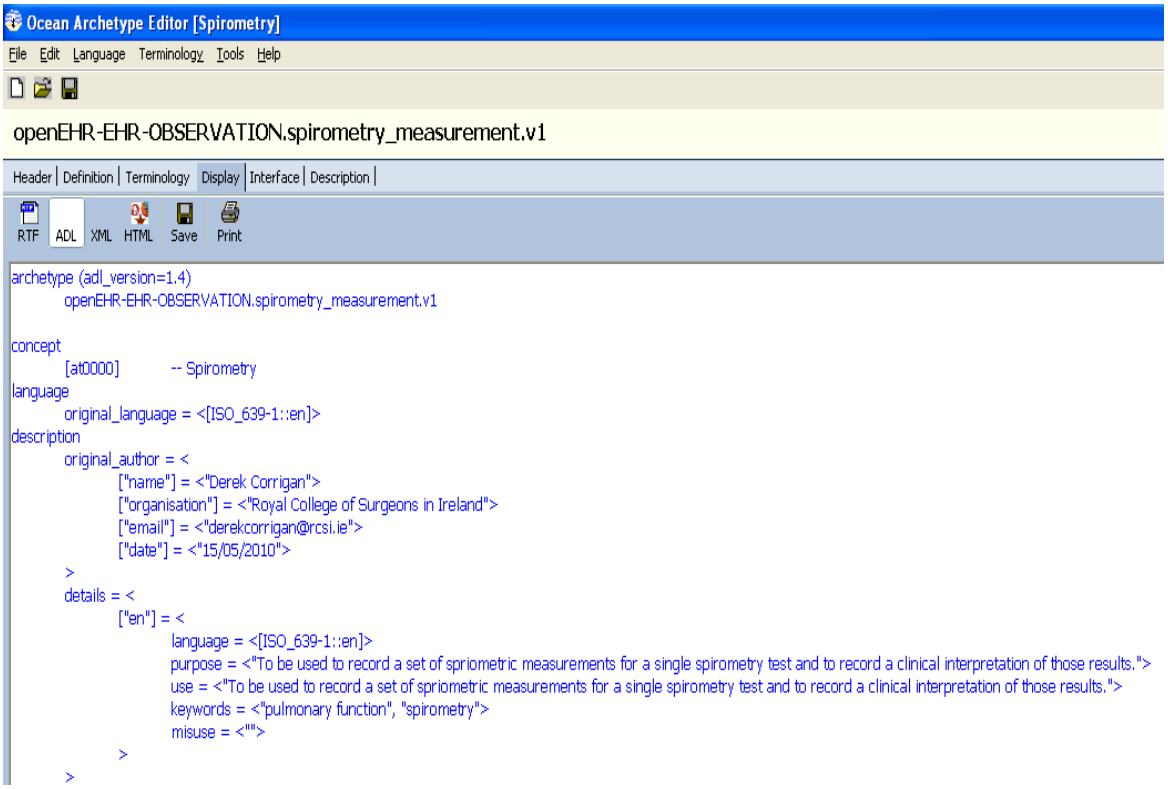


Figure 4-25: Generated ADL from the Archetype Editor

4.3.7. Create templates to group and constrain related archetypes that represent the contents of locally used form or document data.

The archetypes that we define are all separate entities. A 'blood pressure' archetype only contains information relating to blood pressure and a 'spirometry measurement' archetype only contains information relating to spirometry measurements.

The systems we create require views of data that are much more complex than an individual archetype can describe on its own and typically correspond to data entry screens or clinical forms which contain a number of different clinical concepts e.g. a 'vital signs' form.

After creating all the required individual archetypes, the next step is to define the templates or views of data that are required.

Templates allow us:

- to take a number of separately authored archetypes together and present them as one single view in a chosen order that is defined within the template

- to define exactly what individual clinical parts of each archetype we wish to use for our particular view of data i.e. to specifically localise the archetypes for our requirements because archetypes are typically designed as maximal datasets

Identify the templates of data required

In our model of the Cystic Fibrosis Registry of Ireland periodic review form, we will require a number of separate views of data that can be presented to different members of the Cystic Fibrosis multi-disciplinary team (which was described in section 2.2.3).

Each of these views of data will need to present all necessary information to each multi-disciplinary team member. Each view will therefore contain:

- patient details such as name, sex, date of birth

- hospital name

- the relevant clinical details for that particular multi-disciplinary team member

Table 4.12 lists the templates we require along with the member of the Cystic Fibrosis multi-disciplinary team who would use that form.

Table 4-12 : Templates Required for CF Multi-Disciplinary Team Members

Template Name	Description	CF Team Member
Spirometry Summary	View presenting spirometry test results with weight, height, body mass index and centile weight	Physiotherapist
Microbiology Results	View presenting list of samples taken with microbiological cultures identified	Clinical Microbiologist
Medication List	View presenting list of antibiotic treatments being taken by the CF patient	Pharmacist
Physiotherapy Review	View presenting list of the current physiotherapy regimen details being taken by the CF patient	Physiotherapist
Nutrition Review	View presenting list of nutritional treatments being taken by the CF patient	Nutritionist/Dietician

Identify the archetypes required for each template

For each template or view, we need to identify the archetypes that we require to present the required data as per the original Cystic Fibrosis Registry of Ireland review form. In addition to the clinical details we will always present the patient details and hospital name along with the required clinical details so each template or view has all the necessary information in isolation.

The archetypes required for each template are summarised in table 4.13.

Table 4-13: Archetype required for each Template

Template Name	Archetypes Required
Spirometry Summary	Patient Details OpenEHR-EHR-Cluster.Individual_Personal.v1 Hospital Details OpenEHR-EHR-Cluster.Organisation.v1 Spirometry Summary OpenEHR-EHR-Section.Spirometry_Summary.v1 Pulmonary Functions OpenEHR-EHR-Section.Pulmonary_Function.v1 Spirometry Measures OpenEHR-EHR- Observation.Spirometry_Measurement.v1 Weight OpenEHR-EHR-Observation.body_weight.v1 Height

	OpenEHR-EHR-Observation.height.v1 Body Mass Index OpenEHR-EHR-Observation.body_mass_index.v1 Centile Weight OpenEHR-EHR-Observation.centile_weight.v1
Microbiology Results	Patient Details OpenEHR-EHR-Cluster.Individual_Personal.v1 Hospital Details OpenEHR-EHR-Cluster.Organisation.v1 Medication List OpenEHR-EHR-Section.lab_test_microbiology.v1
Medication List	Patient Details OpenEHR-EHR-Cluster.Individual_Personal.v1 Hospital Details OpenEHR-EHR-Cluster.Organisation.v1 Medication Details OpenEHR-EHR-Action.Medication.v1
Physiotherapy Review	Patient Details OpenEHR-EHR-Cluster.Individual_Personal.v1 Hospital Details OpenEHR-EHR-Cluster.Organisation.v1

	Spirometry Summary OpenEHR-EHR-Evaluation.Physiotherapy_Review.v1
Nutrition Review	Patient Details OpenEHR-EHR-Cluster.Individual_Personal.v1 Hospital Details OpenEHR-EHR-Cluster.Organisation.v1 Spirometry Summary OpenEHR-EHR-Evaluation.Nutrition_Review.v1

Build Composition/Section archetypes to organise archetype structure

We saw previously that there are different classes of archetypes such as OBSERVATION, EVALUATION etc. that represent the steps in the clinical process. These are collectively known as ENTRY classes.

There are other archetype classes as well which we use for creating archetypes that represent a document or screen form. The two we use are:

- SECTION – an archetype that organises other archetypes into groups of repeatable data known as sections

- COMPOSITION – an archetype that groups other archetypes into a single archetype that represents a single clinical document

A COMPOSITION is the unit of information that can be saved against an electronic health record for a patient as was discussed previously in section 2.3.3. A number of different COMPOSITIONs may form the entire electronic health record for a patient.

The COMPOSITION can also then be used to easily create our template which provides the specific localised view of that COMPOSITION that we wish to use.

As per the original Cystic Fibrosis Registry forms, in the view of data for our spirometry measurements we want to have a section of data that repeats for six spirometry results and contains:

- spirometry measurements
- the patient weight
- the patient height
- the patient body mass index

We therefore create a section archetype called Pulmonary Function with sections that reference the appropriate archetypes for each of these items (figure 4.26).

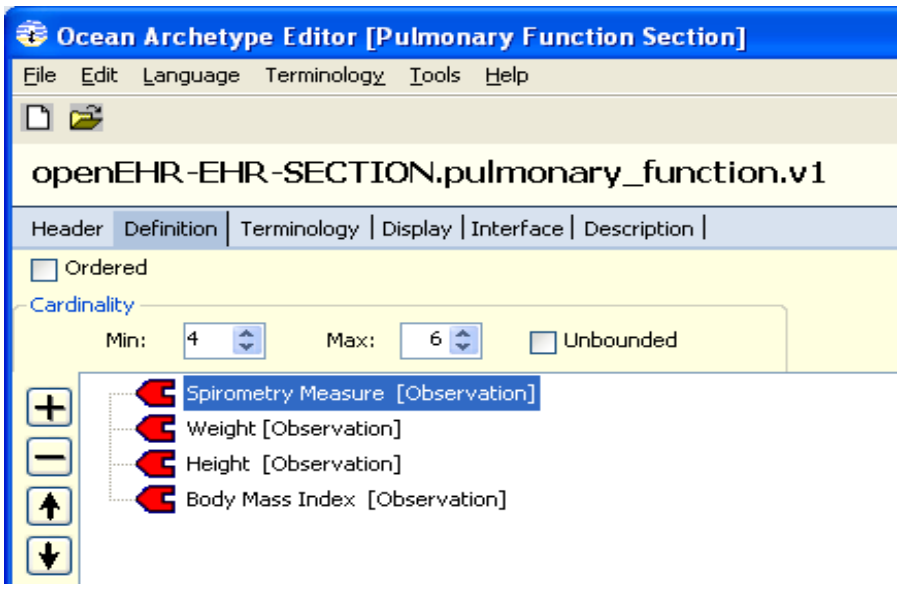


Figure 4-26: Creating the Pulmonary Function Section using the Archetype Editor

We then create another section which references the Pulmonary Function section we just created and also references the 'Centile Weight' observation archetype (figure 4.27).

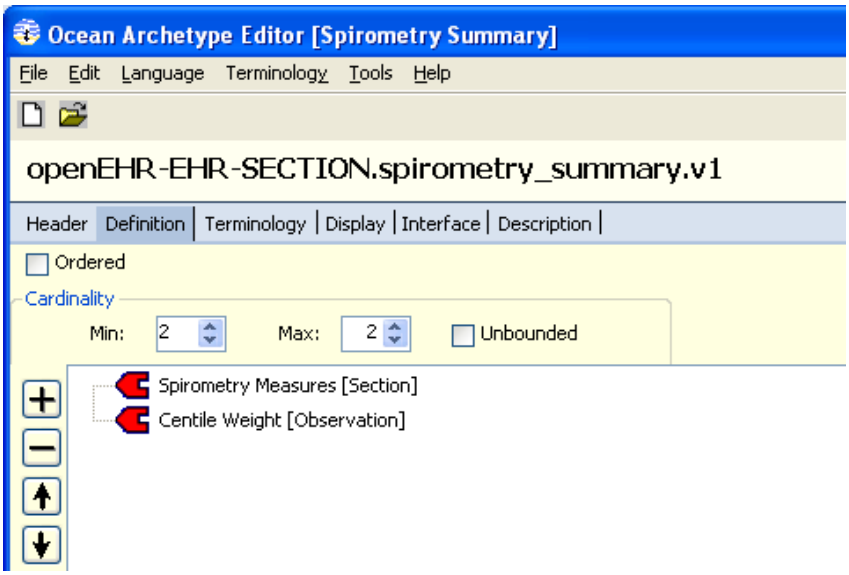


Figure 4-27: Creating the Spirometry Summary Section using the Archetype Editor

Finally we now create our COMPOSITION called 'Spirometry Summary'. Each COMPOSITION will also have a tab to be completed called 'Context' where we can set the context for the clinical document by indicating within it who the document relates to. In our case we will reference our document to the patient and the hospital to which it relates (figure 4.28).

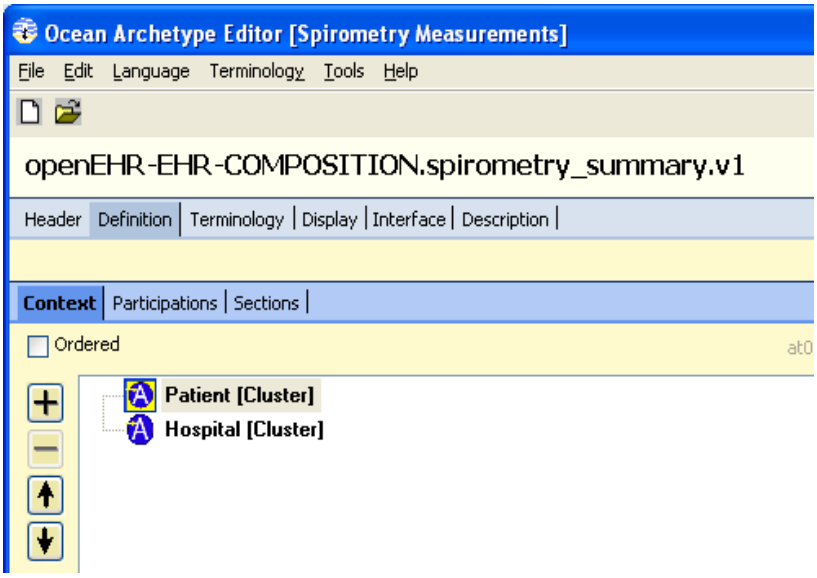


Figure 4-28: Defining the Composition Context using the Archetype Editor

The "Sections" tab shown in figure 4.29 will then reference the spirometry summary section archetype that we just created previously which contains all required clinical data.

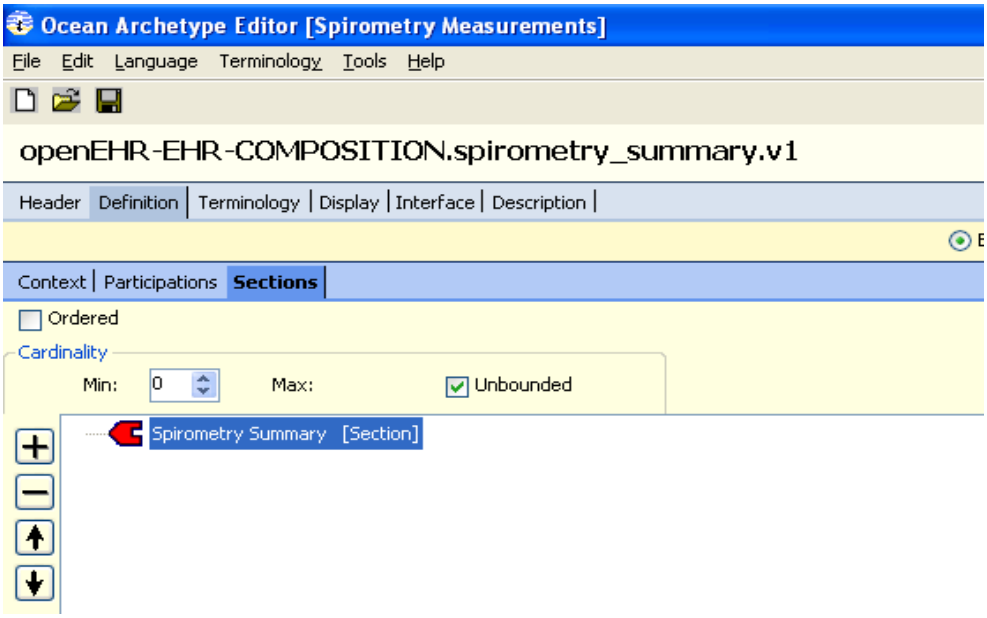


Figure 4-29: Defining the Composition Sections using the Archetype Editor

Add Compositions to template

Once the composition has been created we can then build our template. A separate development tool called the Ocean Informatics Template Designer is used to do this (figure 44). This is a commercial tool that must be purchased but an evaluation license was provided for the purposes of this study.

Within the template tool is a repository browser where you can browse to the available archetypes that you have saved in any windows folder and you can choose which archetype you want to add as the basis for your template. In our case we can select the Spirometry Summary composition and drag it to the template as shown in figure 4.30.

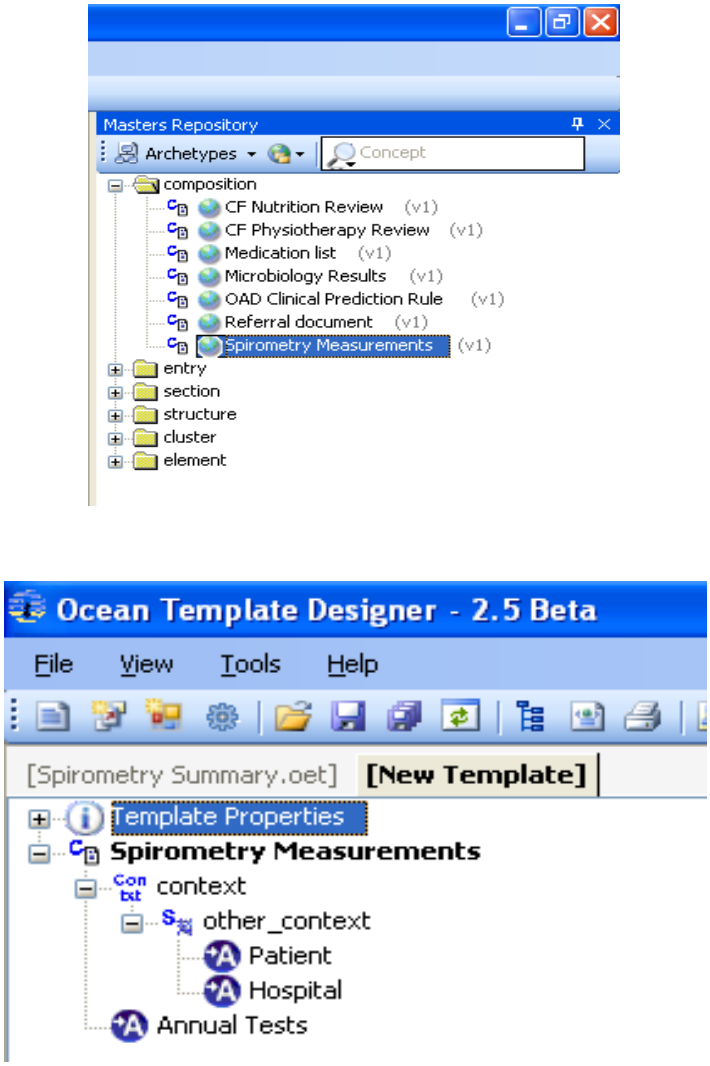


Figure 4-30: Adding a Composition to a Template using the Template Designer

When the composition has been added to the template we can see the main sections in the composition and enable the ones we wish to use for our view of data. In this example we have the context which contains the patient and hospital details and also the annual tests sections.

Enable required archetypes in composition

By right-clicking on each section we can select if we wish to enable the archetype that is used to populate that section and all of the associated archetype details are then revealed in the template (figure 4.31).

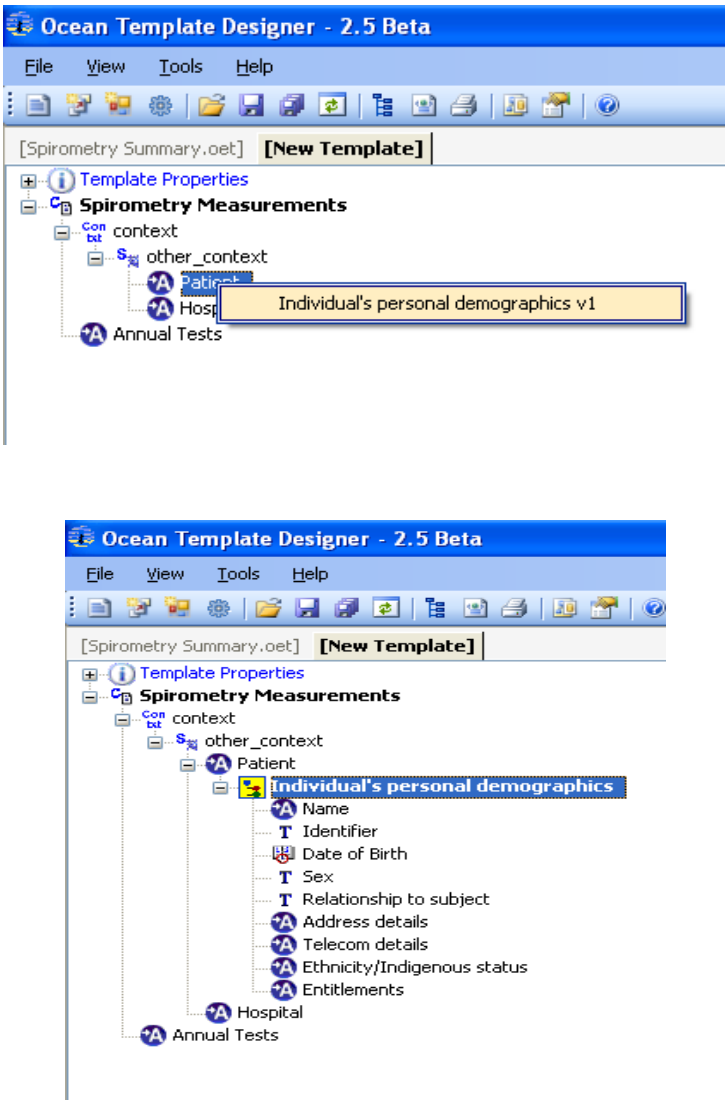


Figure 4-31: Enabling an Archetype using the Template Designer

Enable required attributes of each archetype

After enabling all the archetypes we require, we then can select which details within each of the enabled archetypes we wish to use in our view of data by right clicking on an individual item and selecting if we want a single occurrence of the data, zero occurrences of the data. If the archetype item is mandatory we can chose to hide it on the generated forms.

By doing this we can tailor the view of data to exactly our own local requirements and create forms of data that are specific to our requirements by using only the items within the archetype that are relevant to our system as shown in figure 4.32.

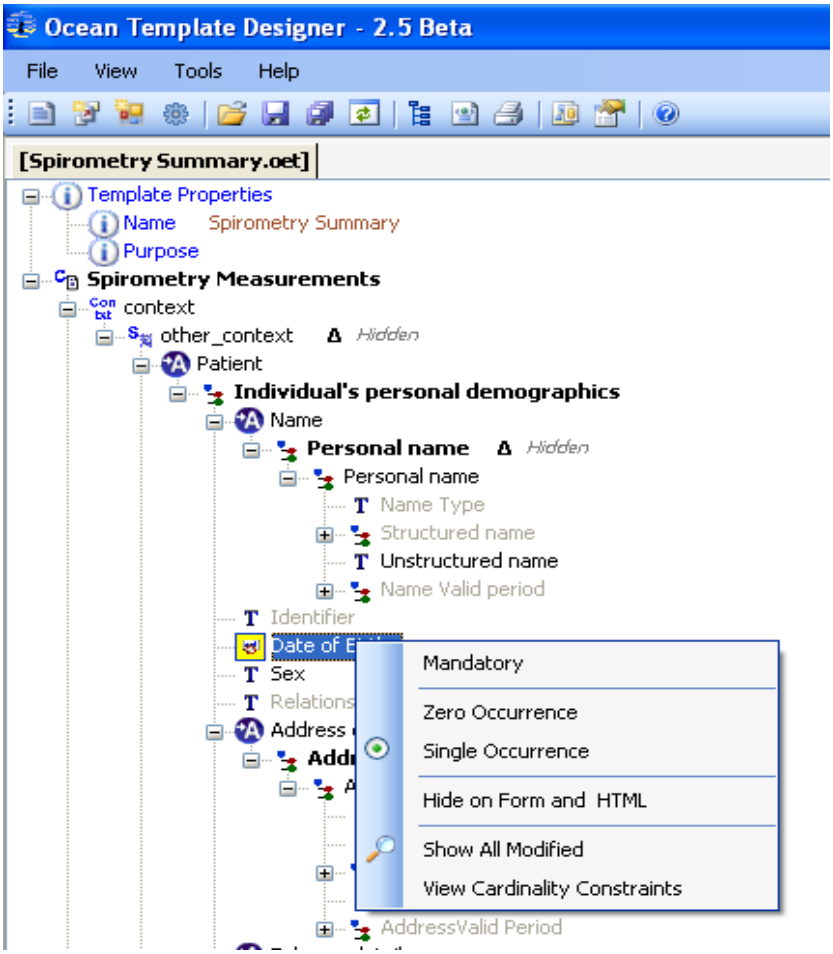
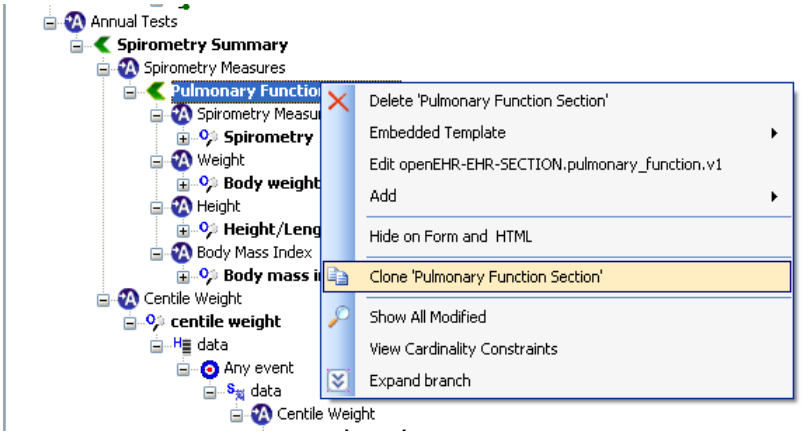


Figure 4-32: Enabling Archetype Attributes using the Template Designer

Clone repeating items

We may want to repeat certain sections of data which are repeatable. In our spirometry summary we wish to be able to record six sets of spirometry results so we can right-click on the pulmonary function section and select 'clone' to create another copy of that section of data. As shown in figure 4.33, this is done five times to give us six separate pulmonary function sections that we can capture data in.



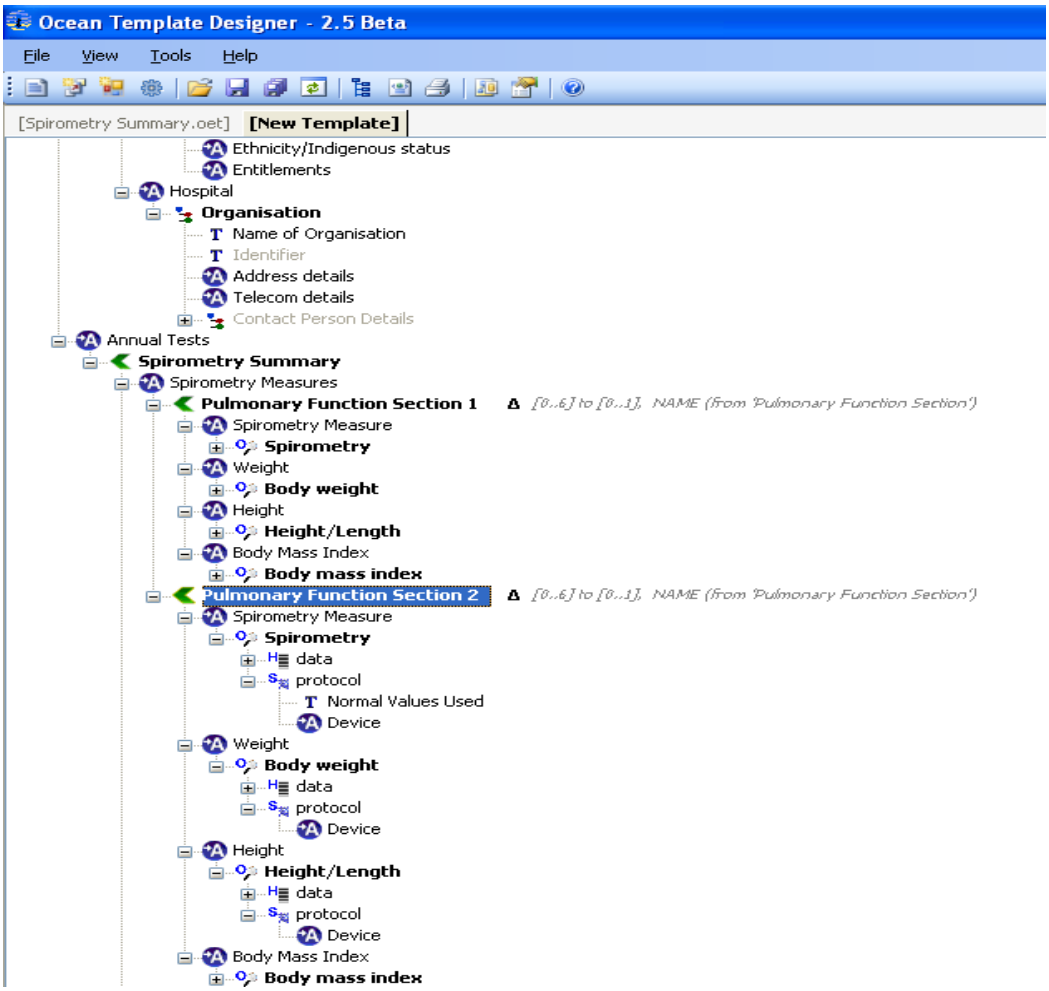


Figure 4-33: Cloning a Section using the Template Designer

Generate forms

When we have completed our template, we can then generate our form by using the Form Designer. This creates a blank form onto which you can simply drag the entire composition from the template onto the blank form (figure 4.34).

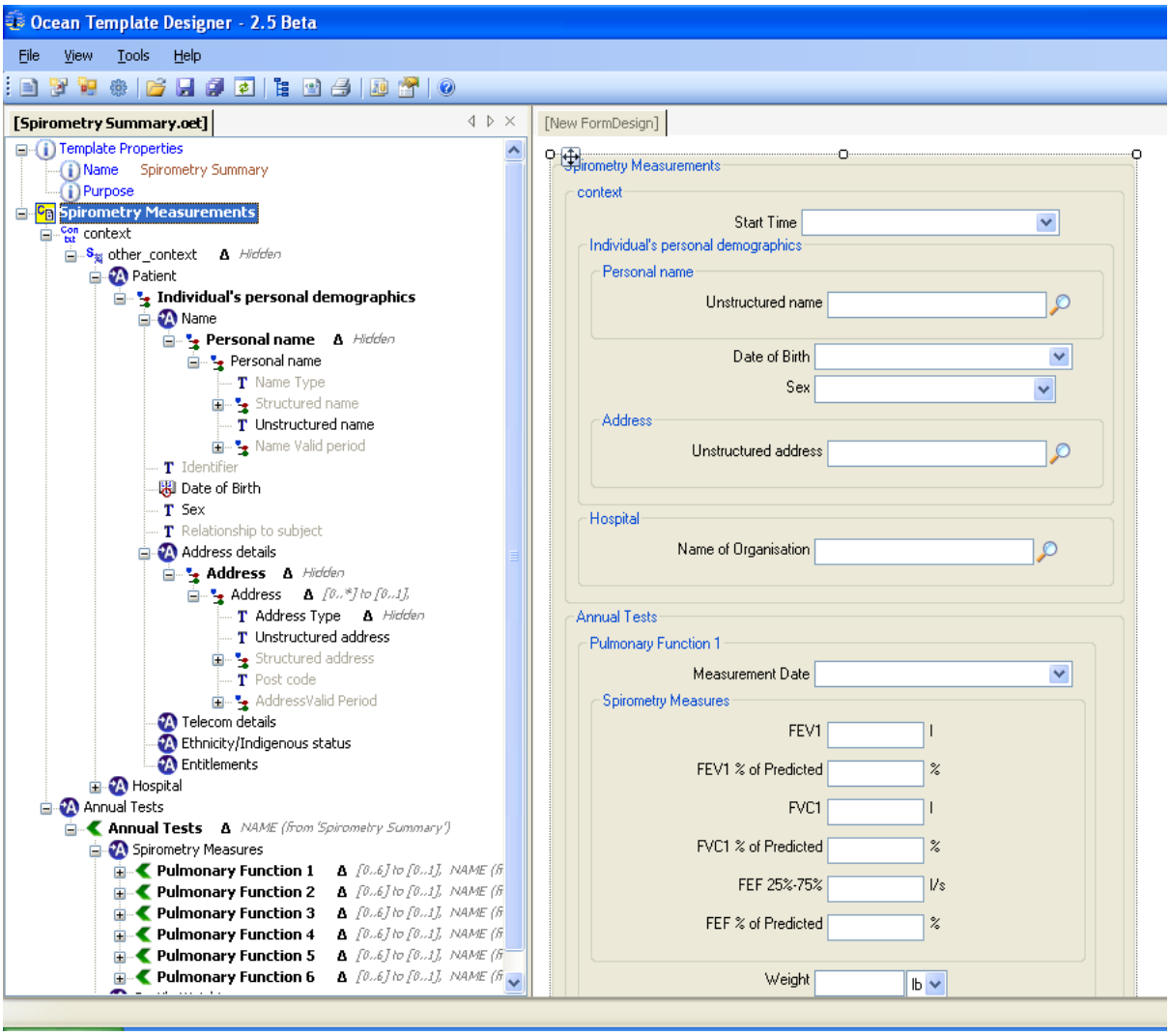


Figure 4-34: Generating a Form using the Template Designer

We then finalise our form layout by moving the items on the form by dragging them to organise the data in the sequence or layout that is required as shown in figure 4.35. In our example we have moved the pulmonary function results so that they are in pairs of two side by side, similar to the original form.

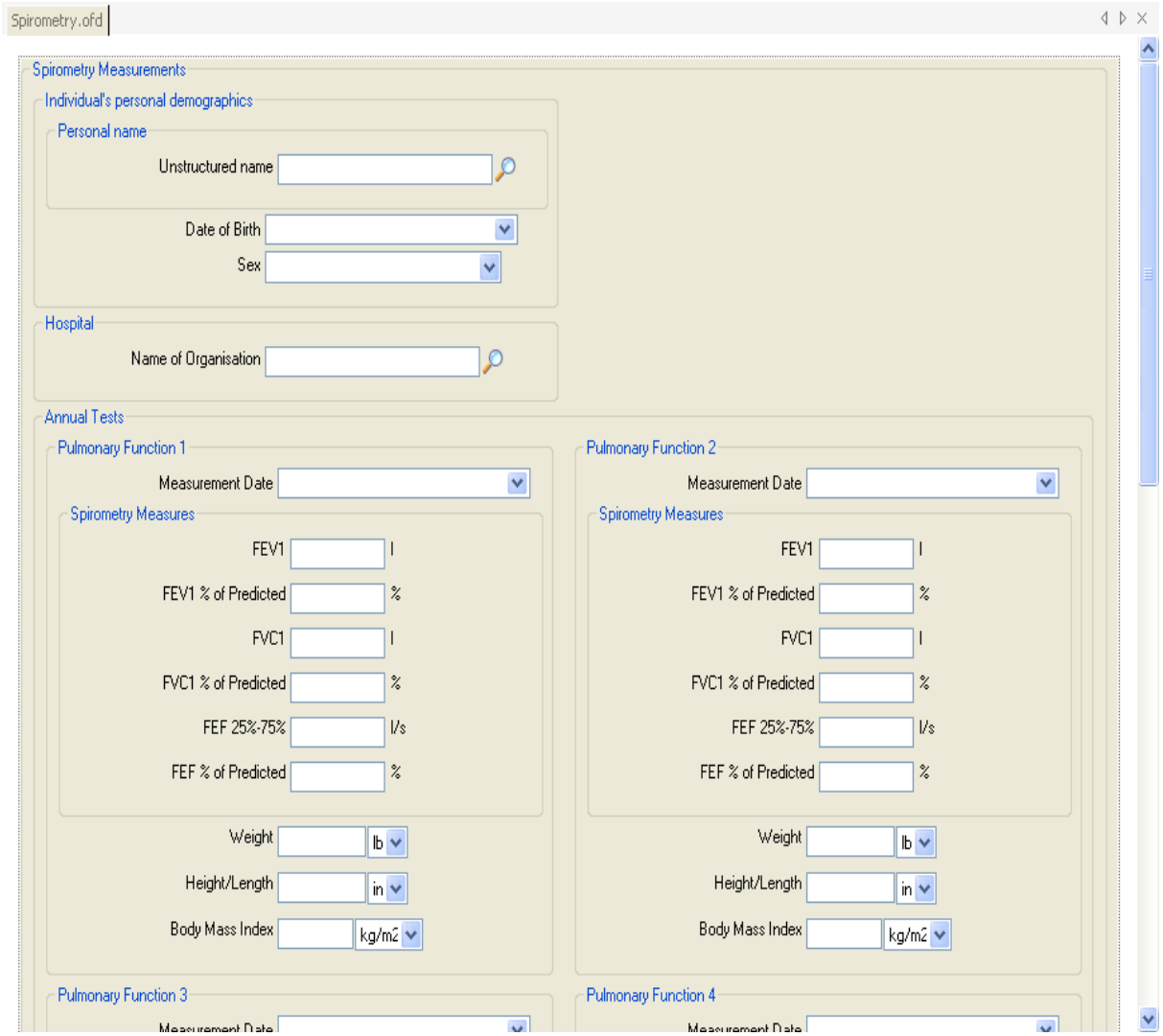


Figure 4-35: Defining Form Layout using the Template Designer

Figure 4.36 shows the final step to test the actual form and input some test data to confirm that the form works as required.

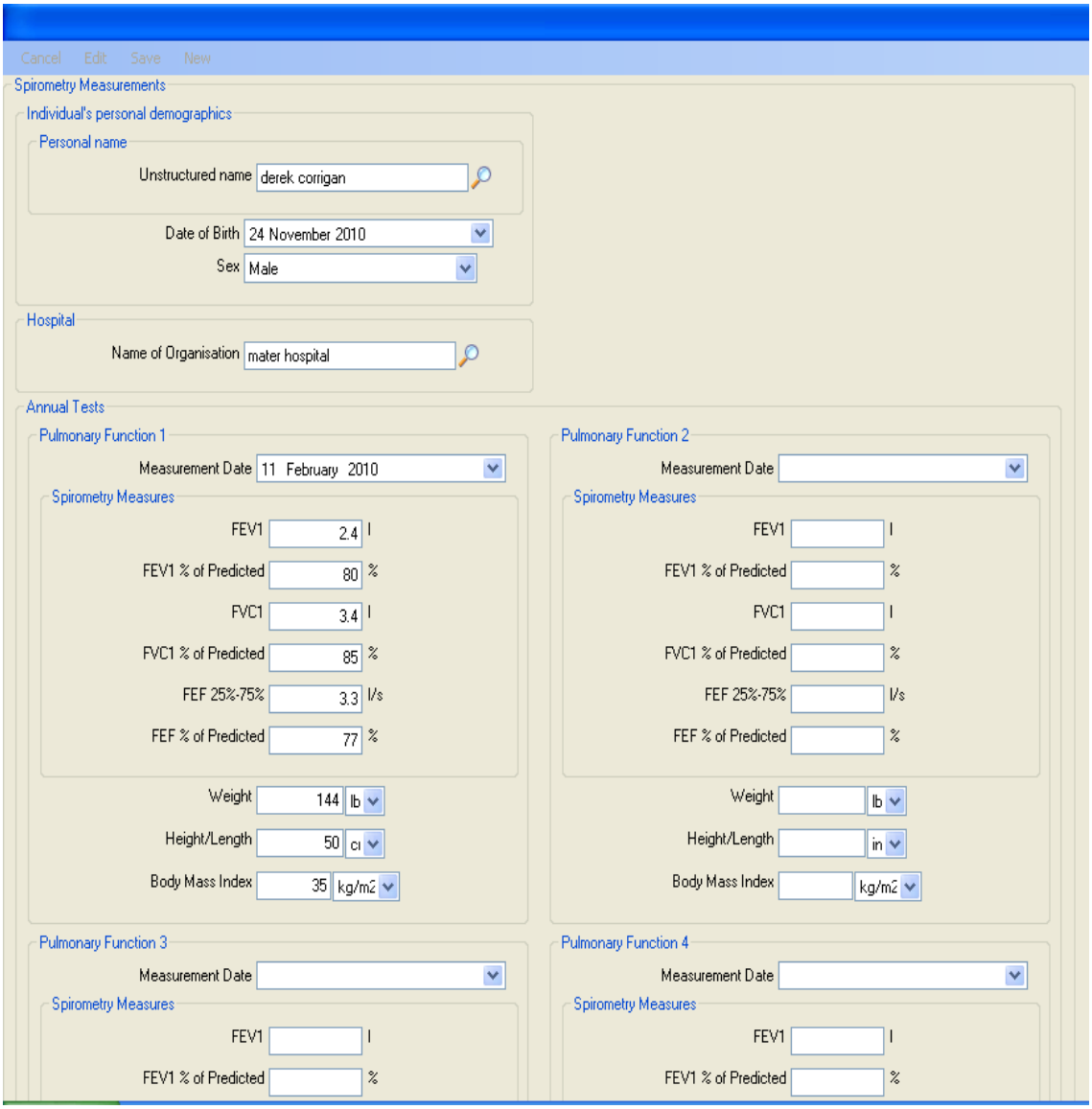


Figure 4-36: Compiling and Running a Form using the template designer

Generate third party code

Figure 4.37 shows how it is also possible to generate code for third party Windows development languages such as Microsoft Visual Basic and Microsoft C#.

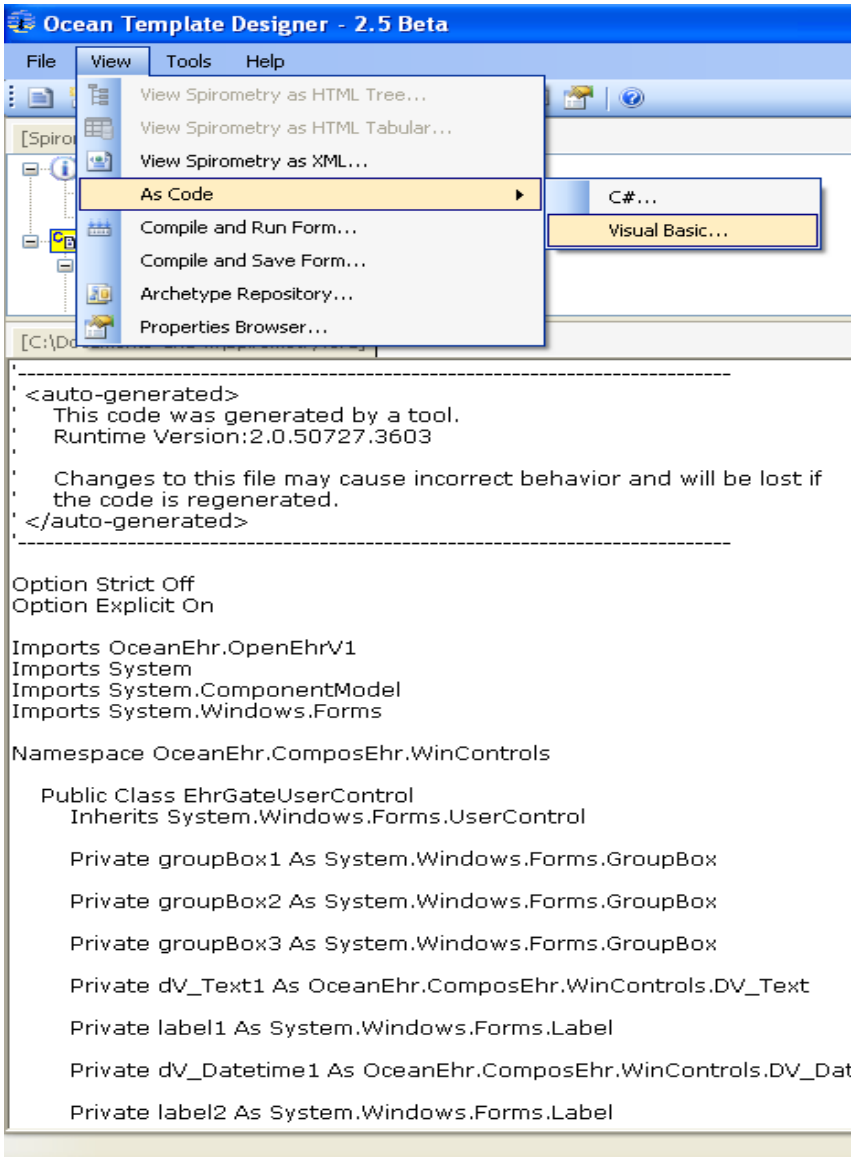


Figure 4-37: Generating Visual Basic form code using the Template Designer

4.3.8. Document archetype design patterns for reoccurring scenarios or design issues that have arisen during archetype design.

Because of the small number of archetypes developed for this study it was not feasible to identify design patterns. This step in the process was therefore omitted.

4.3.9. Publish newly created archetypes

The spirometry measurement archetype was submitted to the OpenEHR archetype editorial group for review. The correspondence detailed in appendix C was received in response. The general feedback from recognised clinical experts in the field on the submitted archetype was generally extremely positive, whilst highlighting some changes that would improve it.

The design was taken into account with a view to re-designing a new pulmonary function archetype that members of OpenEHR Foundation happened to be working for a particular clinical project at the time.

Aspects of the spirometry measurement archetype were included in a redesigned pulmonary function archetype that will be published at a future date on the OpenEHR Clinical Knowledge Manager repository. The author of this study has been credited as a contributor to the authorship of the archetype. From this point of view the creation of a viable clinical archetype represents a real contribution for this study.

4.3.10. Additional archetypes/templates developed

A number of additional archetypes, templates and forms were developed as part of this study in addition to those developed for the spirometry archetype. These were developed to satisfy the additional views of data required for each CF multi-disciplinary team member. These will not be discussed as they were developed using the same design methodologies discussed in detail for the spirometry archetype.

The additional designs were:

- a nutrition review archetype, template and form
- a physiotherapy review archetype, template and form
- medication review template and form
- biochemistry review template and form
- an archetype, template and form to investigate representing a clinical guideline incorporating a clinical prediction rule to predict obstructive airways disease (OAD) which was based on a paper by Badgett et al. (1994).

Screenshots of these additional items are contained in appendix B.

5. Study Evaluation

5.1 Study Evaluation Criteria

In order to properly evaluate this study it is useful to restate the goals that we defined for it at the outset.

The primary goal of this study was to assess the suitability of using the OpenEHR software architecture for providing dynamic views of patient data to support multi-disciplinary team care.

A secondary goal was to add to the current body of knowledge existing on OpenEHR to address the following limitations that were identified in the existing literature:

- a lack of detailed information exists on archetype design standards and methodologies

- no concrete example provided a 'how-to' complete practical walkthrough of implementing OpenEHR archetype and template design in a specific clinical case

- no archetypes currently exist that were specifically developed in the area of Cystic Fibrosis

5.2 Suitability of OpenEHR to describe clinical data

In order to provide multiple views of data to support multi-disciplinary team members, the first question that needs to be answered is whether archetypes and templates provide a sufficiently rich set of data types and interface elements to support a real-world clinical example.

In relation to data types we are referring to the raw data types that may be required to capture a specific discreet piece of data in a computerised format. A 'name' field will be a 'text' data type whereas a 'number of children' field will be a 'numeric integer' data type.

There are many other types such as 'date-time', 'real number' or a computer image such as a JPEG file. From the point of view of this Cystic Fibrosis case study, OpenEHR provided a sufficiently rich set of raw data types to describe all the necessary information that we wish to model and no fundamental limitations were encountered. This is consistent with other studies such as Bird et al., (2003).

The second question is whether the graphical presentation of data is sufficient. When referring to the interface elements we are referring to the graphical representations of the discreet pieces of data and how they are represented on a computer screen.

A 'name' field will be displayed as a free form text box in which any text can be entered whereas 'number of children' will be displayed as a number box which can only be increased or decreased by one. Other examples would be what are known as 'combo boxes' where a dropdown list of predefined choices is provided.

These elements are extremely important from a user point of view since users are used to a particular look and feel and expect rich interface elements to be available which are easy to use and already familiar to them for entering data.

OpenEHR using the Ocean Informatics tools did show some limitations in terms of the graphical representations of data when forms were generated. Where data is being represented as a single set of discreet values that needed to be captured there was no issue. However where data needed to be represented in a tabular format with one set of items that can be entered many times in a list, then there was no obvious way of representing this data in the required tabular format.

It should be stressed that this was a limitation of using the archetype editor and the template designer only as part of this case study. Other commercially available tools

are provided as part of the full OpenEHR platform that may address these issues but this was beyond the scope of this case study as the commercial costs were prohibitive.

The most problematic example of this was the antibiotics/medication summary (figure 5.1). In order to capture multiple items of medication details we used an existing medication archetype and it was necessary to replicate the same medication activity numerous times to capture multiple sets of the data.

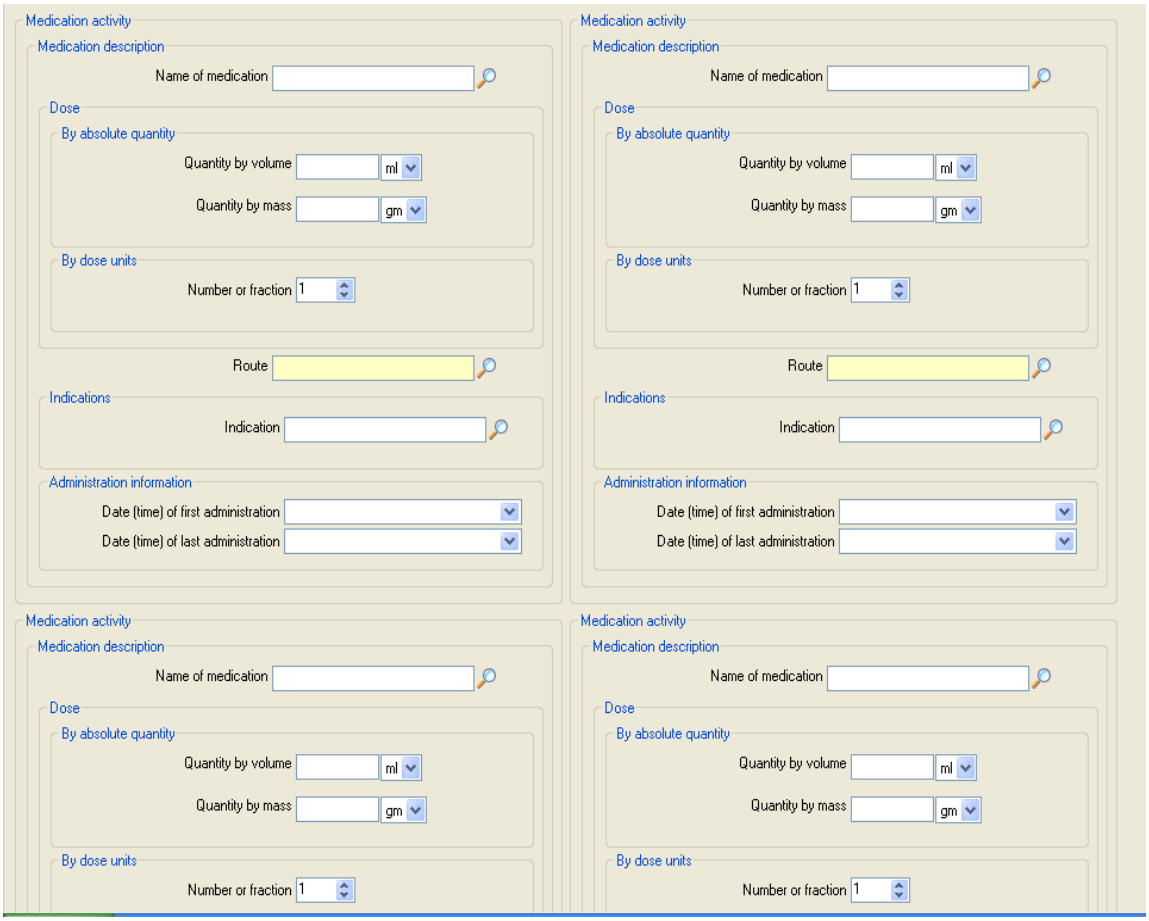


Figure 5-1: Poor Layout of Medical Summary Form

This is very inefficient and clumsy from a user point of view. A more efficient representation would be to have the medication activity headings as a table of headings and allow multiple values to be entered in a list format multiple times under these headings.

On a more general note, the look a feel of the generated forms was not a polished as you would expect in a commercial Windows application. You do not get the richness of available screen controls such as tabbed views and tree lists of data for example.

Again it should be stated that these may be available as part of the fully implemented OpenEHR platform that is available commercially. However from a functional point of view, with the exception previously mentioned, the controls that are available behaved as one would expect from a typical Windows application. This is extremely important from a user point of view.

To conclude, it was felt that OpenEHR provides all the required data descriptive elements to express clinical data but the graphical representation could be improved. This needs to evolve further to provide a richer toolset to graphically represent the data as per users expectations.

5.3 Suitability of OpenEHR to provide views for CF multi-disciplinary teams

In this study the primary goal was to apply archetypes and templates to a specific clinical example in the form of data captured as part the periodic review data captured by the Cystic Fibrosis Registry of Ireland.

We were able to successfully design new archetypes and re-use existing archetypes that were able to fully capture all of the data as defined in the Cystic Fibrosis Registry of Ireland forms and in the database schema provided. There were no elements of data that we could not represent as part of an archetype. OpenEHR was very successful from this point of view.

In section 4.3.2 we identified the required views of data that were to be provided for the different multi-disciplinary team members. We were successful in being able to produce the required views of data that would be required for each of the relevant

multi-disciplinary team members typically found in a Cystic Fibrosis clinical team. This was achieved through design of templates.

In figure 5.2 we summarise the relationship between the archetypes and templates that were used or built to satisfy each of the multi disciplinary team view requirements and have demonstrated how this may be done in practice.

In conclusion, we were successful in providing multi disciplinary team views of data. The OpenEHR approach to software design worked well and as part of the process and produced some new archetypes. These new archetypes could be used in other clinical areas and not just Cystic Fibrosis.

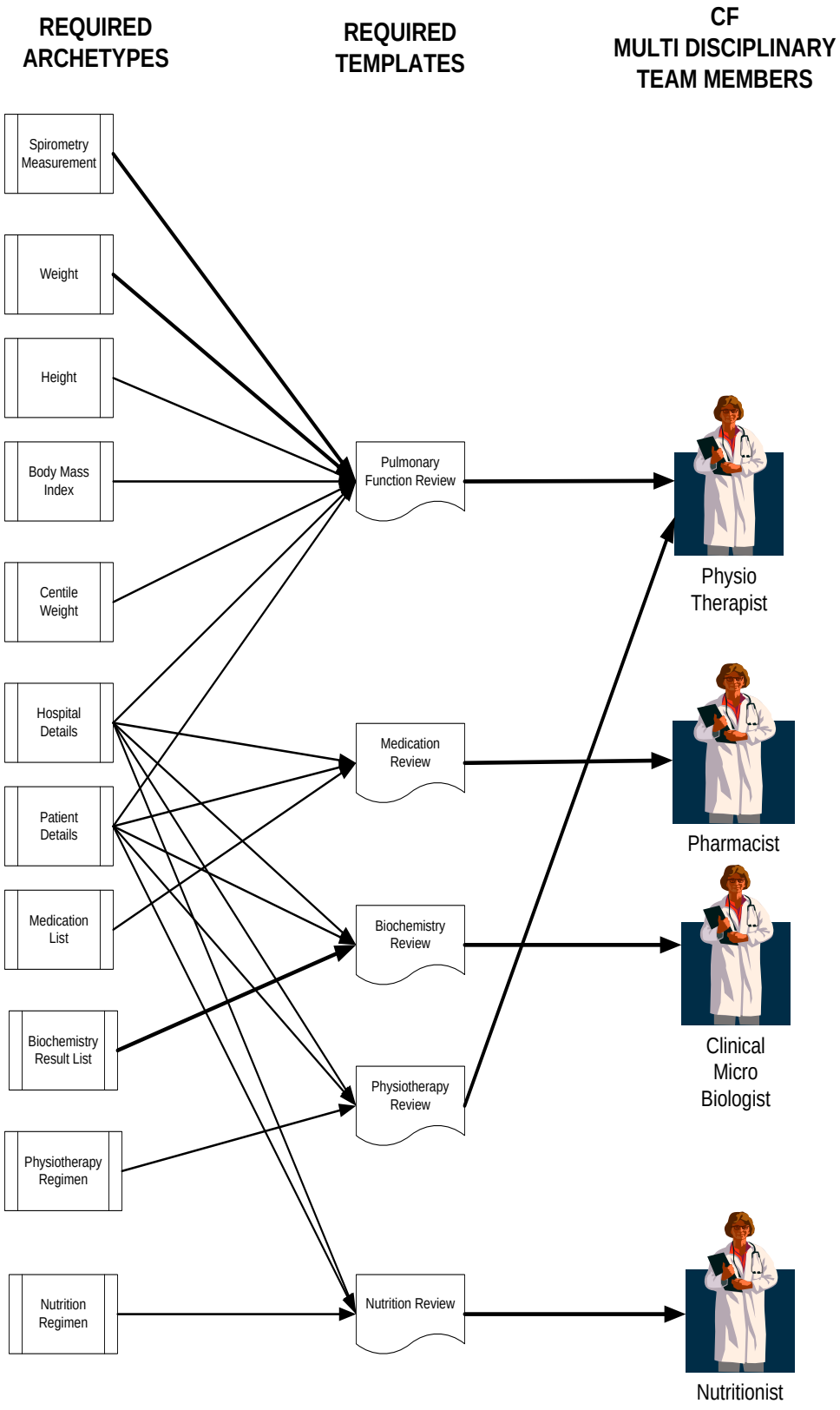


Figure 5-2: Relationship of Archetypes, Templates and CF Multi-Disciplinary Team Members

5.4 How successful is OpenEHR in achieving its stated aims

5.4.1 Can clinicians design archetypes?

A primary aim of the OpenEHR approach identified in the literature is to make it 'clinician-friendly' and to make the clinician very much part of the process. A stated goal is to take the task of modelling the knowledge domain in software away from the IT specialist and to enable the clinicians with that knowledge, to do this instead (Leslie et al. 2009).

Based on the amount of work done in this study it is clear that designing good quality archetypes is not a trivial matter. A contributing factor is the lack of formalised design methodologies and the still relative immaturity of the available tools.

It is the opinion of the author that whilst tools such as the Ocean Informatics Archetype Editor are quite user-friendly, there is still a substantial element of data modelling and data awareness that is required to design and produce a good quality archetype. This is consistent with studies such as Kashfi et al., 2009 which stated that the tools 'cannot be said to help inexperienced developers beyond hiding the actual syntax'.

There is no questioning the value of having more clinician input into designing clinical systems. It is a fundamental question as to whether working clinicians have the time, the data modelling skills and the wish or desire to be involved in an area that has traditionally been an IT skills area.

These concerns were articulated succinctly by a clinician named John on a clinical forum website when he stated: "I'm having trouble cutting through much of the technical jargon, I wonder how many doctors will want to participate in this discussion. This seems like a really noble goal, but I can't help but question if CKM and openEHR are not keeping EHR interoperability simple". The alternative argument is that interoperability quite simply is not simple (Gibbons et al., 2007).

It has been argued in other papers (Leslie et al. 2009) that clinicians are enthusiastic for this role. Other papers (Bernstein et al. 2004) have proposed an alternative implementation structure which seems more practical by arguing for more specialist roles for health informaticians to design archetypes in conjunction with clinicians.

The assessment of whether OpenEHR succeeds on this point is very subjective. On the basis of this study the opinion put forward is that the tools and the design process are not yet sufficiently evolved to enable general working clinicians to design and develop good quality archetypes.

We need to distinguish between clinicians working in the research arena and clinicians working in the field. It is clear from the literature review that a lot of effort is currently being invested in addressing these deficiencies and the tools will inevitably develop and improve with time.

5.4.2 Is OpenEHR truly dynamic?

A simple experiment was devised to test how changes are dynamically reflected in OpenEHR systems. The test involved:

- adding a new element to an existing archetype

- assess the level of manual intervention required to reflect that change in any associated templates and forms

The spirometry measurement archetype was changed to add a new element called 'Test Dynamic' to it as shown in figure 5.3.

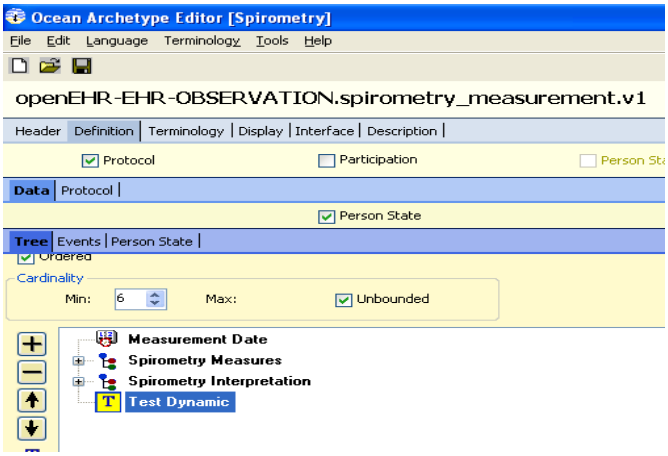


Figure 5-3: New element added to Spirometry Measurement

An associated template that uses this archetype was opened to see if the change was dynamically reflected in the template. It can be seen in figure 5.4 that the new element added to the archetype was automatically brought into the template.

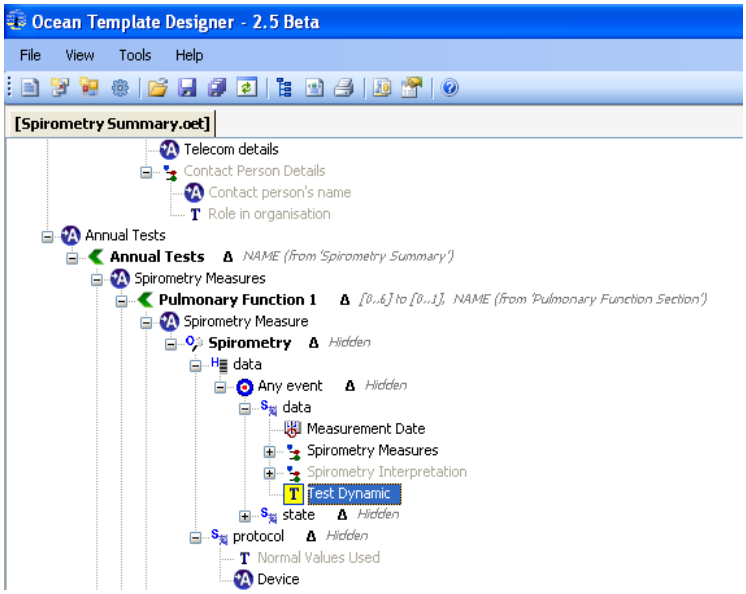


Figure 5-4: New element incorporated into Template

Depending on the section in the archetype to which the new element was added, the template may need to be manually changed to enable or disable the element and constrain it as required in the localised template. In addition, any forms created from this template need to be manually updated to add the new elements onto the form. The form then needs to be recompiled.

A question with more far-reaching implications when discussing the dynamic nature of OpenEHR is what happens when the underlying reference model (RM) changes?

The answer to this is provided by Bird et al. (2003) where he states that this situation was very problematic since 'to reflect changes in the reference model, modifications to the core software components became necessary'.

This situation has not changed with OpenEHR. The main tools such as the archetype editor are built on a specific version of the underlying reference model and therefore a substantially different release of the reference model will impact directly on these tools and the archetypes that have been built using them.

Depending on the nature of these changes it may be necessary to recreate new versions of the development tools as potentially these changes could break them. The underlying assumption as pointed out by Bird et al. (2003) is that 'the two level approach is based on the premise that the reference model will remain fairly stable'. This is a crucial assumption and needs to be investigated further as the implications of such changes are not currently clear and beyond the scope of this study.

In conclusion, OpenEHR is not as dynamic as hoped. While the archetypes themselves are truly dynamic, the templates and forms built from them may require manual intervention to propagate changes made throughout the system. A more fundamental issue is what happens when the underlying reference model is changed.

5.4.3 Are archetypes reusable?

Another stated goal is to make archetypes truly reusable by designing them as maximal dataset archetypes that can then be applied and used in any clinical situation by localising them using templates.

In the course of this study we reused a number of existing archetypes taken from the OpenEHR clinical knowledge manager. These were used in the format as provided without any changes. Therefore we conclude that on this point the OpenEHR approach to software design works very well.

There are some definite caveats to this. In order to be useful to other people, archetypes need to be designed as maximal dataset archetypes. Only these archetypes can be made available through any centrally available shared repository. The OpenEHR Clinical Knowledge Manager represents an excellent attempt at this but currently the number of completed and reviewed archetypes and templates remains low.

The success to date of the OpenEHR data governance process can be measured to some degree by looking at the statistics of fully published archetypes and templates on the CKM as shown in figures 5.5 and 5.6.

states	Count	Legend
Draft	249	
Team review	15	
Published	9	
Rejected	14	
Obsolete	0	

Figure 5-5: Archetype Development Statistics from OpenEHR CKM

states	Count	Legend
Draft	2	
Team review	0	
Published	0	
Rejected	0	
Obsolete	0	

Figure 5-6: Template Development Statistics from OpenEHR CKM

These figures would suggest that the data governance process is not moving as quickly as is required. The speed at which archetypes are reviewed and validated will be crucial to the success of the OpenEHR approach.

If users cannot access high quality, validated maximal dataset archetypes, they will then design their own archetypes for their own local implementations. This may result in the loss of a core strength of OpenEHR, which is the ability to build systems using pre-built validated clinical concepts. As highlighted in the literature review, the

NHS approach of documenting archetype design patterns could potentially be crucial to this.

5.5 Have we added to body of OpenEHR knowledge?

At the outset of this study we identified a number of limitations in the existing body of knowledge available, namely:

- lack of design methodologies for archetypes
- lack of design methodologies for templates
- lack of any practical 'how-to' documents which demonstrate the design process from start to finish
- no archetypes designed specifically in the area of Cystic Fibrosis

All of these limitations have been addressed in a comprehensive document detailing the application of an archetype design methodology and a template design methodology using a step-by-step 'how-to' approach. This document can be used as a practical guide to use OpenEHR and is aimed at those new to the technology and its possibilities.

The following summarised archetype design methodology in table 5.1 was successfully applied to a real world clinical example.

Table 5-1: Study Archetype Design Methodology

Summarised Archetype Design Methodology	
1	**Document the process flows for the domain.**

2	**Determine all clinical items in the domain**.
3	**Merge related individual clinical items to single archetype clinical concepts.**
4	**Map the derived clinical concepts to existing archetypes.**
5	**Data model the clinical**.

6	**Model new archetypes**.
	• Research the clinical concept
	• Identify the archetype class (or type)
	• Identify the relevant sections to be used for the chosen archetype class
	• Data model the data attributes associated with each section of the archetype according to clinical references available
	• Re-iterate the development process if required by reference to existing 'best practice' developed archetypes
	• Build the archetype
	  • Enter the main data attributes that describe the archetype contents as per the archetype mindmap choosing appropriate data types
	  • Add constraints to each data attribute to define rules to enforce appropriate usage of the data attributes
	  • Add metadata to describe the purpose and use of the archetype for

	the benefit of others who may wish to use it • Add data binding to external clinical terminologies such as SNOMED-CT • Preview the archetype interface to assess archetype design and completeness
7	**Create templates.**
8	**Document archetype design**.
9	**Publish newly created archetypes**.

The summarised template design methodology in table 5.2 was successfully applied to a real world clinical example.

Table 5-2: Study Template Design Methodology

Summarised Template Design Methodology	
1	**Identify the templates of data required.**
2	**Identify the archetypes required for each template**
3	**Build Composition/Section archetypes to organise archetype structure**
4	**Add Compositions to template**

5	**Enable required archetypes in composition**
6	**Enable required attributes of each archetype**
7	**Clone repeating items**
8	**Generate forms**
9	**Generate third party code**

The final goal was to develop a maximal dataset archetype that could practically be used in a real clinical setting. The spirometry measurement archetype was fully designed and implemented and submitted for publication with this goal in mind. Aspects of its design were subsequently incorporated into an archetype developed by the OpenEHR foundation.

6. Conclusion

The following section summarises the work done as part of this study and suggests further possibilities for building upon it.

Section 1 detailed the challenges that currently exist when trying to represent domain knowledge as part of designing computer systems. As part of this a number of key research questions were highlighted and addressed as part of this study.

The literature review highlighted the relative immaturity of two-level information modelling, and more specifically the OpenEHR implementation. A number of current deficiencies in the existing body of knowledge relating specifically to OpenEHR were identified and served as a focus for investigation as part of this study.

The study detailed the use of a real-world clinical case study in the form of data captured as part of the Cystic Fibrosis Registry of Ireland as the basis for applying OpenEHR with a view to investigating the research questions identified.

OpenEHR was found to be sufficiently descriptive from a data point of view to represent clinical data. The graphical representations of this data from a functional perspective need to evolve further.

OpenEHR fulfilled its potential in satisfying the ultimate goal of the study in being able to produce templates which fully described the views of data that we wished to capture for a periodic Cystic Fibrosis review, tailored to the requirements of each multi-disciplinary clinician team member.

It was established that templates are dependent on the underlying archetypes they are designed from, which are in turn highly dependent on the underlying reference model that they impose constraints on. It was concluded that OpenEHR displays enough significant dependencies between these three levels of information to state that

changes made in one level will not be dynamically passed through to the dependant level without some manual intervention or third party intervention such as a scripting language.

The most successful aspect identified of the OpenEHR design methodology was the ability to re-use maximal dataset archetypes which are freely available through the excellent OpenEHR Clinical Knowledge Manager. A new archetype was successfully designed and submitted for publication resulting in aspects of its design being incorporated into a new archetype currently in development by the OpenEHR foundation.

The final deliverable from this study was methodologies for designing both archetypes and templates. These have been presented in a step-by-step fashion which provides a focus point for pulling together the current multiple and disparate sources of information currently available on OpenEHR. This has added to the body of knowledge currently available to those who wish to start using OpenEHR in a practical clinical setting.

The overall conclusion of this study is that despite some concerns highlighted, OpenEHR has huge positive potential to address the challenges identified for developing clinical systems. The success or otherwise of OpenEHR in fulfilling that potential is dependent on 3 key factors:

- 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

Without these developments, local implementations will bypass the quality data governance process and will design archetypes fit for their local purposes. This will prevent other implementations from building on the work that has already been done by other clinical teams thus rendering redundant one of the key strengths of OpenEHR which could limit its further uptake.

Limitations of this study

The biggest limitation of this study is that it focuses solely on the key OpenEHR tools available to develop archetypes and templates. Archetypes and templates are only one part of an overall fully functional OpenEHR architecture and solution. Additional available tools may have helped to solved some of the issues highlighted in this study.

Ideally a fully functional prototype incorporating a working application using a persistent database layer would have been implemented. This was deemed to be beyond the scope of this study, and was justified on the basis that a core aspect of investigation of OpenEHR is the two-level representation of information provided by archetypes and templates.

Future Work

Additional work would be beneficial to analyse in more detail the dependencies that exist between the OpenEHR reference model, archetypes, templates and forms. The aim would be to provide a completely dynamic information model through all information levels which reflects the ever-changing clinical knowledge domain.

The design methodologies for archetypes and templates suggested in this study are only a starting point for consolidating the multiple sources of information currently available in a more coherent manner. There is significant scope for developing these methodologies further in practice and expanding and refining them through further studies, specifically investigating the area of archetype design patterns.

7. References

ANSI . (2010) Frequently asked questions. American National Standards Institute Website [Internet]
http://www.ansi.org/about_ansi/faqs/faqs.aspx?menuid=1#overview
[Accessed 29th August 2010]

Atalag K. (2007) Archetype Based Domain Modelling For Health Information Systems. OpenEHR Foundation Website [Internet]
http://www.openehr.org/publications/archetypes/KorayAtalag-THESIS_Final.pdf
[Accessed 29th August 2010]

Badgett R G, Tanaka D J, Hunt D K, Jelley M J, Feinberg L E, Steiner J F, Petty T L. (1994) The Clinical Evaluation for Diagnosing Obstructive Airways Disease in High-Risk Patients. *Chest* 106:1427-1431

Beale T. (2002) Archetypes: Constraint-based Domain Models for Future-proof Information Systems. In OOPSLA 2002 workshop on behavioural semantics. OpenEHR Foundation Website [Internet]
http://www.openehr.org/publications/archetypes/archetypes_beale_oopsla_2002.pdf
[Accessed 29th August 2010]

Beale T, Heard S. (2007) OpenEHR Archetype Definitions and Principles. OpenEHR Foundation Website [Internet]
http://www.openehr.org/svn/specification/TAGS/Release-1.0.2/publishing/architecture/am/archetype_principles.pdf
[Accessed 29th August 2010]

Beale T, Heard S. (2007) The *open*EHR Archetype Model Archetype Definition Language. OpenEHR Foundation Website [Internet] http://www.openehr.org/svn/specification/TRUNK/publishing/architecture/am/adl1.4.pdf [Accessed 29th August 2010]

Beale T, Heard S. (2008) OpenEHR Architecture Overview. OpenEHR Foundation Website [Internet] http://www.openehr.org/svn/specification/TAGS/Release-1.0.2/publishing/architecture/overview.pdf [Accessed 29th August 2010]

Bennett K H, Rajlich V T. (2000) Software maintenance and evolution: a roadmap. *Proceedings of the 22nd International Conference on Software Engineering*. ACM Press: New York NY, 2000; 75–87.

Bernstein K, Bruun-Rasmussen M, Vingtoft S, Andersen S K, Nøhr C. (2005) Modelling and implementing electronic health records in Denmark. *International Journal of Medical Informatics* 74:213–220.

Buck J, Garde S, Kohl C D, Knaup-Gregori P. (2009) Towards a comprehensive electronic patient record to support an innovative individual care concept for premature infants using the openEHR approach. *International Journal of Medical Informatics* 78(8): 521-531.

CEN. (2010) Frequently asked questions. Comité Européean de Normalisation Website [Internet] http://www.cen.eu/cen/Pages/FAQ.aspx [Accessed 29th August 2010]

Chen R, Georgii-Hemming P, Åhlfeldt H. (2009) Representing a Chemotherapy Guideline Using *open*EHR and Rules. *Studies in Health Technology and Informatics* 150:653-657.

Corrigan D. (2009) An ICT application to support Shared Care for Cystic Fibrosis Patients. Assignment for Msc Health Informatics. Trinity College Dublin

Creswell J. (2009) Research Design: Qualitative, Quantitative and Mixed Methods Approaches. *Sage* ISBN 978-1-4129-6557-6

Cystic Fibrosis Association of Ireland. (2010) What is CF? Cystic Fibrosis Association of Ireland Website. [Internet]
http://www.cfireland.ie/articles.php/what_is_cf?
[Accessed 29th August 2010]

Cystic Fibrosis Registry of Ireland. (2010) Registry Information Booklet. Cystic Fibrosis Registry of Ireland Website. [Internet]
http://www.cfri.ie/docs/cfregistry.pdf
[Accessed 29th August 2010]

Davies J C, Alton E W F W, Bush A. (2007) Cystic Fibrosis. *British Medical Journal* 335: 1255-1259

Eichelberg M, Aden T, Riesmeier J. (2005) A Survey and Analysis of Electronic Healthcare Record Standards. *ACM Computing Surveys* 37(4):277–315.

Eichelberg M, Aden T, Riesmeier J, Dogac A, Laleci G B. (2006) Electronic Health Records Standards – a Brief Overview. *Proceedings of the 4th IEEE International Conference on Information and Communications Technology*

Garde S, Knaup P, Hovenga E, Heard S. (2007) Towards Semantic Interoperability for Electronic Health Records: Domain Knowledge Governance for *open*EHR Archetypes. *Methods of Information in Medicine.* 46(3):332–343

Garde S, Chen R, Leslie H, Beale T, McNicoll I, Heard S. (2009) Archetype-Based Knowledge Management for Semantic Interoperability of Electronic Health Records. *Studies in Health Technology and Informatics* 150:1007–1011

Gibbons P, Noam A, Burke-Beebe S, Chute C, Dickenson G, Flewelling T, Jepsen T, Kamens D, Larson J, Ritter J, Rozen M, Selover S, Stanford J. (2007) Coming to terms: Scoping Interoperability for Health Care. Health Level Seven, EHR Interoperability Work Group, Feb 7, 2007

Gok M. (2008) Introducing an openEHR-Based Electronic Health Record System in a Hospital. OpenEHR Foundation Website [Internet] http://www.openehr.org/publications/archetypes/goek-masters-thesis_2008.pdf [Accessed 29th August 2010]

Health Level 7. (2010) About HL7. HL7 Website [Internet] http://www.hl7.org/about/index.cfm?ref=nav [Accessed 29th August 2010]

HSE. (2009) Services for People with Cystic Fibrosis in Ireland. Health Service Executive Website [Internet] http://www.hse.ie/eng/services/Publications/topics/reptcysticfibrosis.pdf [Accessed 29th August 2010]

Hurlen P (ed.) (1995) ENV 12265: Electronic Healthcare Record Architecture. CEN TC/251 PT 1-011. Brussels

Hurlen P, Skifjeld K, Andersen E P. (1998) The basic principles of the synapses federated healthcare record Server. *International Journal of Medical Informatics* 52:123–132

Ingram D. (1995) The Good European Health Record, In Health in the new communication age, MF Laires, MF Ladeira and JP Christensen (Eds), IOS, 1995, 66-74

ISO. (2010) Frequently asked questions. International Standards Organisation Website [Internet] http://www.iso.org/iso/support/faqs.htm [Accessed 29th August 2010]

Johns D, Pierce R. (2007) Pocket Guide to Spirometry 2nd Edition. Mc Graw-Hill's ISBN-10: 0-07-0134642

Kay S, Marley T (ed). (1999) ENV 13606: EHCR Communications: Part 1 Electronic Healthcare Record Architecture. CENTC/251, Brussels.

Kalra D. (2006) Electronic Health Record Standards. *IMIA Yearbook of Medical Informatics 2006* 45 Suppl 1:136-144

Kerem E, Conway S, Elborn S, Heijerman H. (2005) Standards of care for patients with cystic fibrosis: a European consensus. *Journal of Cystic Fibrosis* 47(26):1569-1993

Kashfi H, Torgersson O. (2009) A migration to an openEHR-based clinical application. *Studies in Health Technology and Informatics* 150:152-156.

Knight A, Dai N. (2002) Objects and the Web. *IEEE Software* 19(2):51-59

Leslie H. (2008) International developments in openEHR archetypes and templates. *Heath Information Management Journal* 37(1):1833-3583

Leslie H, Heard S. (2008) Building an Archetype. Ocean Informatics Website [internet] http://www.oceaninformatics.com/Media/docs/2008-06-Building-Archetypes-5c9eaef0-62de-47c6-a155-2ff853e0045f.pdf
[Accessed 29th August 2010]

Leslie H, Heard S, Garde S, McNicoll I. (2009) Engaging clinicians in clinical content: herding cats or piece of cake? *Studies in Health Technology and Informatics* 150: 125-129.
Mahadeva R, Webb K, Westerbeek R C, Carroll N R, Dodd M E, Bilton D, Lomas D A. (1998) Clinical outcome in relation to care in centres specialising in cystic fibrosis: cross sectional study. *British Medical Journal* 316:1771-1775

Mens T, Wermelinger M, Ducasse S, Demeyer Serge, Hirschfeld Robert, Jazayeri M.

(2005) Challenges in Software Evolution. In: 8th International Workshop on Principles of Software Evolution, 5-6 September 2005, Lisbon, Portugal

Michelsen L, Pedersen S S, Tilma H B, Andersen S A. (2005) Comparing Different Approaches to Two-Level Modelling of Electronic Health Records. *Studies in Health Technology and Informatics* 116:113-8.

Miller M R, Crapo R, Hankinson J, Brusasco V, Burgos F, Casaburi R, Coates A, Enright P, Van der Grinten C P M, Gustafsson P, Jensen R, Johnson D C, MacIntyre N, McKay R, Navajas D, Pedersen O F, Pellegrino R, Viegi G, Wanger J. (2005) General Considerations for lung function testing. *European Respiratory Journal* 26(1):153–161

OConnor T, Manning P. (2005) Spirometry: Performance and Interpretation A Guide for General Practitioners. Irish Thoracic Society Website [Internet] http://www.irishthoracicsociety.com/documents/SpirometryGuidelinespdf.pdf [Accessed 29th August 2010]

Ocean Informatics. (2010) About Ocean Informatics. Ocean Informatics Website [Internet] http://www.oceaninformatics.com/about-ocean/Overview.html [Accessed 29th August 2010]

OpenEHR Foundation. (2006) Introducing OpenEHR. OpenEHR Foundation Website [Internet] http://www.openehr.org/svn/specification/TAGS/Release-1.0.1/publishing/openEHR/introducing_openEHR.pdf [Accessed 29th August 2010]

Pollock R M. (2005) The treatment of Cystic Fibrosis in Ireland: Problems and Solutions. Cystic Fibrosis Association of Ireland Website [Internet] http://www.cfireland.ie/publications/booklets/cf_rep_inside.pdf [Accessed 29th August 2010]

Schloeffel P, Beale T, Hayworth G, Heard S, Leslie H. (2006) The relationship between CEN 13606, HL7, and *open*EHR. Ocean Informatics Website [Internet] http://www.oceaninformatics.com/Media/docs/Relationship-between-CEN-13606-HL7-CDA--openEHR-2ba3675f-2136-4069-ac5c-152139c70bd0.pdf
[Accessed 29th August 2010]

Spackman K A, Campbell K E, Cote R A. (1997) SNOMED-RT: a reference terminology for health care. Proceedings of the 1997 AMIA Annual Fall Symposium; 640-644.

Sunblad S, Sunblad P. (2000) Designing for Scalability with DNA. *Microsoft Press.* ISBN-10: 0735609683

Wollersheim D, Sari A, Rahayu W. (2009) Archetype-based electronic health records: a literature review and evaluation of their applicability to health data interoperability and access. *Health Information Management Journal* 38(2):7-17.

Appendix A – CF Registry of Ireland Forms

CYSTIC FIBROSIS REGISTRY OF IRELAND
ANNUAL ASSESSMENT

Name: _____

Hospital: _____

Items missing from Annual Assessment

- _____
- _____
- _____
- _____
- _____
- _____
- _____
- _____

Cystic Fibrosis Registry of Ireland
CF House
24 Lower Rathmines Road,
Rathmines,
Dublin 6, Ireland
Tel: 353 1 491 2722
Fax: 353 1 491 2723

Form filled in by _____ (initials)

Name: _____

Hospital: _____ Chart No. _____

Date of Registry Update (Clinical exam) _____ dd/mm/yyyy

Date of Previous Registry Update _____ dd/mm/yyyy

Number of Months between Updates _____ (Calculated field)

Number of Hospitalisations since last Registry Update _____

Admission Date	Discharge Date	Admission Date	Discharge Date
1. _____	_____	5. _____	_____
2. _____	_____	6. _____	_____
3. _____	_____	7. _____	_____
4. _____	_____	8. _____	_____

Number of Respiratory Exacerbations (requiring IV antibiotics) _____

Number of Other Exacerbations _____

Complications in last period: Tick **ALL** that apply:

☐ **Had NO complications in last period**

Cardio/Respiratory

- ☐ Chronic Pseudomonas Infection (>2 isolates/yr)
- ☐ Chronic Staphylococcus Infection (>2 isolates/yr)
- ☐ Burkholderia Cepacia Complex/Syndrome
- ☐ MRSA
- ☐ Nasal Polyps
- ☐ Allergic Broncho Pulmonary Aspergillosis (ABPA)
- ☐ Massive haemoptysis (>240cc in 24 hrs; transfused)
- ☐ Asthma
- ☐ Pneumothorax requiring chest drain
- ☐ Cor pulmonale

Gastrointestinal

- ☐ Distal Intestinal Obstruction Syndrome (DIOS)
- ☐ Haematemesis
- ☐ GI Reflux requiring treatment
- ☐ Colonic Stricture
- ☐ Rectal prolapse
- ☐ Gallbladder disease
- ☐ Pancreatic insufficiency
- ☐ Pancreatitis
- ☐ Abnormal Liver Function Tests
- ☐ Liver disease other than cirrhosis
- ☐ Cirrhosis with portal hypertension

Miscellaneous

- ☐ Diabetes requiring insulin/oral hypoglycaemic drugs
- ☐ Micro albuminuria
- ☐ Renal failure requiring dialysis
- ☐ Arthropathy
- ☐ Clubbing
- ☐ Cancer
- ☐ Had IV port replaced?
- ☐ Bone fracture
- ☐ Osteopenia / Osteoporosis
- ☐ Hearing loss
- ☐ Depression
- ☐ Other morbidity: specify_____

Total number of boxes calculated from list above: ☐ **(Calculated Field)**

ANNUAL TESTS

Pulmonary function tests (fill in boxes with values)
Date of report: ____________ **dd/mm/yy**

	Value	**% Predict**
FEV_1		
FVC		
$FEF_{25-75\%}$		

Weight ______ kg Height ______ cm
BMI (This value is calculated by computer) ______ (kg/M²)

Pulmonary function tests (fill in boxes with values)
Date of report: ____________ **dd/mm/yy**

	Value	**% Predict**
FEV_1		
FVC		
$FEF_{25-75\%}$		

Weight ______ kg Height ______ cm
BMI (This value is calculated by computer) ______ (kg/M²)

Pulmonary function tests (fill in boxes with values)
Date of report: ____________ **dd/mm/yy**

	Value	**% Predict**
FEV_1		
FVC		
$FEF_{25-75\%}$		

Weight ______ kg Height ______ cm
BMI (This value is calculated by computer) ______ (kg/M²)

Pulmonary function tests (fill in boxes with values)
Date of report: ____________ **dd/mm/yy**

	Value	**% Predict**
FEV_1		
FVC		
$FEF_{25-75\%}$		

Weight ______ kg Height ______ cm
BMI (This value is calculated by computer) ______ (kg/M²)

Pulmonary function tests (fill in boxes with values)
Date of report: ____________ **dd/mm/yy**

	Value	**% Predict**
FEV_1		
FVC		
$FEF_{25-75\%}$		

Weight ______ kg Height ______ cm
BMI (This value is calculated by computer) ______ (kg/M²)

Pulmonary function tests (fill in boxes with values)
Date of report: ____________ **dd/mm/yy**

	Value	**% Predict**
FEV_1		
FVC		
$FEF_{25-75\%}$		

Weight ______ kg Height ______ cm
BMI (This value is calculated by computer) ______ (kg/M²)

Centile (weight)
Tick one box

<3	3-10	10-25	25-50	50-75	75-90	90-97	>97
☐	☐	☐	☐	☐	☐	☐	☐

Maturity Indices

♀ Age at Menarche ____ yrs ♂ Has voice broken yet? Yes / No

Skinfold measures

Mid-arm circumference cm Triceps skinfold thickness mm Subscapular skinfold thickness mm

- 3 -

CULTURES

Time Period: From:	To:						
Sample Number	Example	1	2	3	4	5	6
Sample Date	dd/mm/yy						
Sample Type (Tick sample type in each column)							
Cough Swab							
Sputum	✓						
BAL							
Axilla Swab							
Groin Swab							
Nasal Swab							
Other							
Culture Type							
Normal Flora							
Acinetobacter species TYPE:							
Aspergillus fumagatus							
Beta haemolytic streptococcus GROUP:							
Burkholderia Cepacia Complex TYPE or Genomovar:							
Candida: Albicans							
Candida TYPE:							
Candida not specified							
Chryseomonas TYPE:							
Coagulase negative staphylcocci							
Comamonas acidovorans							
Escherichia coli							
Enterobacter TYPE:							
Favimonas species TYPE:							
Flavobacterium TYPE:							
Gram negative bacillis							
Gram positive bacillis							
Gram positive cocci							
Group G streptococci							
Haemophilius influenza							
Helicobacter TYPE:							
Klebsiella pneumoniae							
Moroxella TYPE:							
MRSA							
Mycobacteria tuberculosis							
Mycobacteria (Non-tubercular)							
Neisseria							
Pseudomonas aeruginosa (Mucoid)	✓						
Pseudomonas aeruginosa (Non-Mucoid)	✓						
Pseudomonas aeruginosa (Mucoid status not reported)							
Other Pseudomonas species TYPE:							
Ralstonia picketti							
Serratia TYPE:							
Staphylococcus aureus	✓						
Stenotrophomonas maltophilia (xanthomonas)							
Streptoccus pneumoniae							
Streptoccus viridans							
Vancomycin Resistant Enterococcus (VRE)							
Other organisms, please note:							

ANTIBIOTICS

Name:		Hospital:		
Time Period: From:		To:		
Antibiotic Name AND Dose (e.g., 180mg TDS)	**Indication Code** 1 Prophylaxis 2 Exacerbation of RTI 3 Exacerbation, Other	**Route Code** 1 IV in hospital 2 IV at home 3 Inhaled 4 Oral 5 IM 6 Sub Cutan	**Start Date** dd/mm/yy Tick box if Start Date unknown	**Stop Date** dd/mm/yy Tick box if Continuous
Example: TobramycinIV, 160mg tds	***2***	***1***	***05/03/03***	***19/03/03***

Antibiotics/Antifungals – Generic Name (Brand Name)

amikacin (Amikin)
amoxycillin (Amoxil, Clonamox)
azithromycin (Zithromax)
aztreonam (Azactam)
cefaclor (Distaclor LA, Keftid)
cephradine (Velosef)
cefixime (Suprax)
cefipime (Maxipime)
cefotaxime (Claforan)
ceftazidime (Fortum)
cefuroxime (Zinacef, Zinnat)
chloramphenicol (unbranded)
ciprofloxacin (Ciproxin)
clarithromycin (Klacid)
clindamycin (Dalcin C)
co-amoxiclav (Augmentin, Clavamel Forte)
colistin sulphomethate (Colomycin)
doxycycline (By-Mycin, Vibramycin)
erythromycin (Erythrocin, Erythroped SF)
flucloxacillin (Floxapen)
gentamicin (Cidomycin Injectable)
levofloxacin (Tavanic)
linezolid (Zyvox)
meropenem (Meronem)
minocycline (Minocin)
netilmicin (Netillin)
ofloxacin (Tarivid)
oxytetracycline (Clinimycin)
penicillin G (Crystapen)
pipericillin+tazobactam (Tazocin)
quinupristin+dalfopristin (Synercid)
rifampicin (Rimactane)
sodium fusidate (Fucidin)
teicoplanin (Targocid)
ticarcillin+clavulanic acid (Timentin)
tobramycin (Nebcin, Tobi)
trimethoprim+sulphamethoxazole (Septrin)
vancomycin (Vancocin Matrigel)

Anti-fungal Class:
fluconazole (Diflucan)
itraconazole (Sporanox)
metronidazole (Flagyl)

OTHER TREATMENTS

Physiotherapy

Date last seen by physiotherapist

_____ dd/mm/yy

Physiotherapy modalities
(Circle up to 3 modalities)
Postural Drainage
Percussion
Active cycle of breathing techniques (A.C.B.T.)
Autogenic Drainage
Flutter
Positive expiratory pressure mask (PEP)
Other: Specify _____

_____

Exercise?
Regular ☐ or Irregular ☐

Breathing Devices

Compressors

High Flow: ✓ one	Standard Flow: ✓ one
☐ CR60	☐ CR 50
☐ Turboneb	☐ Portaneb
☐ Acquilon	☐ Pulmo-aide/escort
☐ Medix high-flow	☐ Freeway lite
	☐ Halolite

☐ Other: Specify _____

_____

Nebulisers ✓ one
☐ Micromist
☐ Sidestream
☐ Ventstream
☐ Pari LC Plus
☐ Medix CMS
☐ Cirrhus
☐ Microcirrhus
☐ Other: Specify _____

_____

Nutrition

Date last seen by dietician

_____ dd/mm/yy

Nutritional Treatments:
(tick ✓ those that apply)

☐ Calorie Supplements
☐ Vitamins ☐ ADEK?
Brand name: _____
☐ Minerals
☐ Gastrostomy Feed

Enzymes: Enter No. Capsules per Day
____ Creon 10,000
____ Creon 25,000
____ Pancrease
____ Nutrizym
____ Nutrizym 10,000
____ Nutrizym 25,000

Supplemental Feeding in last 12 Months: (tick those that apply)

Did patient receive supplemental feeding? Y/N?

☐ Oral Supplements
☐ Nasogastric
*Date of insertion: _____
☐ Gastrostomy
*Date of insertion: _____
☐ Parenteral
☐ Other Supplemental Feeding

**Provide date only if occurred in last period.*

Research Treatments

Research Treatments (text box for description)

e.g., antibiotic, bronchodilator, etc

_____ Pharma company _____ Clinical Trial number/code.

CYSTIC FIBROSIS REGISTRY OF IRELAND
REGISTRATION AND DIAGNOSIS FORM

Name: _____

Hospital: _____

Items missing from First Registration/Diagnosis

- _____
- _____
- _____
- _____
- _____
- _____
- _____
- _____

Cystic Fibrosis Registry of Ireland
CF House
24 Lower Rathmines Road,
Rathmines,
Dublin 6, Ireland.
Telephone: 353 1 491 2722
Fax: 353 1 491 2723

Has a CONSENT FORM been signed? Y / N

Returned to Registry Office? Y / N

Form filled in by _____ (initials)

(Display: RTF)

Header
Concept: Initial demographic information

Definition
ADMIN_ENTRY

DATA = {
Structure = TREE
Items
Patient name details (0..1)
- Use to record patient name information / identification
Items

ID number (0..1)
Data base ID number assigned on entry in chronological order
DataType = Count
Constraint: *

Date on first entry (0..1)
Date when patient was first entered on database.
DataType = DateTime
Constraint: Full date

Date Consent rec'd by CFRI (0..1)
Date when signed Consent rec'd by CFRI. Must be BEFORE the 'first entry date'.
DataType = DateTime
Constraint: Full date

Date Consent signed (0..1)
Date Consent form signed by PWCF or parent. Must be BEFORE 'Date consent rec'd by CFRI'; and BEFORE 'Date on first entry'
DataType = DateTime
Constraint: Full date

Has Re-Consent been signed? (0..1)
If patient was enrolled on parent consent when patient was under 18 years of age; and patient is now 18 or over; has the patient been re-consented?
DataType = Boolean
Constraint: *

Re-consent Date (0..1)
If 'yes' to Re-consent', then select date of signature.
DataType = DateTime
Constraint: Full date

Who signed Consent Form? (0..1)
Drop down list of Self, Mother, Father, Other
DataType = Text
Constraint: Internal; 'Self', 'Father', 'Mother ', 'Other'

If under 18, Assent signed? (0..1)
If PWCF is less than 18 years, did they sign the Assent area of Consent Form?
DataType = Boolean
Constraint: *

Last name (1..1)
Patient last name
DataType = Text
Constraint: Text;

First name (1..1)
Patients first name

DataType = DateTime
Constraint: Full date

Date of Discharge (0..1)
Date of discharge from hospital
DataType = DateTime
Constraint: Full date

Reason for admission (0..1)
Reason for hospital admission from drop down
DataType = Text
Constraint: Internal; 'Respiratory exacerbation', 'Other exacerbation, not respiratory'

Pulmonary Function Tests (0..1)
- Pulmonary function test results listed chronologically by date. Unlimited number of tests allowed.
Items

Date of Test (0..1)
Date of Pulmonary Function test
DataType = DateTime
Constraint: Full date

FEV1 value (0..1)
Forced expiratory volume in one second in litres; must be LESS than FVC
DataType = Quantity
Constraint: Physical property = Volume;
Units = l;

FEV1 - % predicted (0..1)
FEV1 % predicted according to local references
DataType = Quantity
Constraint: Physical property = ;

FVC value (0..1)
Forced Vital Capacity in litres; must be greater than FEV1
DataType = Quantity
Constraint: Physical property = Volume;
Units = l;

FVC - % predicted (0..1)
FVC % predicted according to local references.
DataType = Quantity
Constraint: Physical property = ;

Height (0..1)
Height in cm at date of PFT; without shoes and socks
DataType = Quantity
Constraint: Physical property = Length;
Units = cm;

Weight/mass (0..1)
Weight at date of PFT; without shoes and socks
DataType = Quantity
Constraint: Physical property = Mass;
Units = kg;

BMI (0..1)
Body Mass Index calculated. Metric BMI = weight(kg) / height in meters squared
DataType = Quantity
Constraint: Physical property = Qualified real;

Centile for weight & age (0..1)

DataType = Boolean
Constraint: *

Post transplant treatments (0..1)
Multi select list: azathioprine, cyclosporin, tacrolimus
DataType = Text
Constraint: Internal; 'Azathioprine', 'Cyclosporin', 'Tacrolimus', 'Other product'

Other medications (0..1)
Text box. Applies to current AA. List any other medications taken every day.
DataType = Text
Constraint: Internal;

Physiotherapy details (0..1)
- Annual Physiotherapy test results. These can be listed separately because the walk test and shuttle test can be administered during the year
Items

Date of Annual Assessment (0..1)

DataType = DateTime
Constraint: Full date

Date last seen by physio (0..1)
Date last seen by physiotherapist for AA
DataType = DateTime
Constraint: Date only

Physiotherapy modalities (0..1)
Type of physiotherapy done daily. Copy list from RT Admin. NB: make list multi-select
DataType = Text
Constraint: Internal; 'Postural drainage', 'Percussion', 'etc'

Other Physiotherapy modality (0..1)
Text box for extra modalities and comments
DataType = Text
Constraint: Text;

Exercise Tolerance Tests (0..1)
Results for 3 types of tests: 6MWT, 12 MWT, MSWT. Attach boxes for results. Units probably in metres.
DataType = Text
Constraint: Internal; '6MWT', '12MWT', 'MSWT'

Walking test result (0..1)
Walking test result. Choose type of walking test[6 min walk test; 12 min walk test; Modified shuttle walk test] and show result in this field. Allow space for 3 results. Result in metres.
DataType = Quantity
Constraint: Physical property = Length;
Units = m;

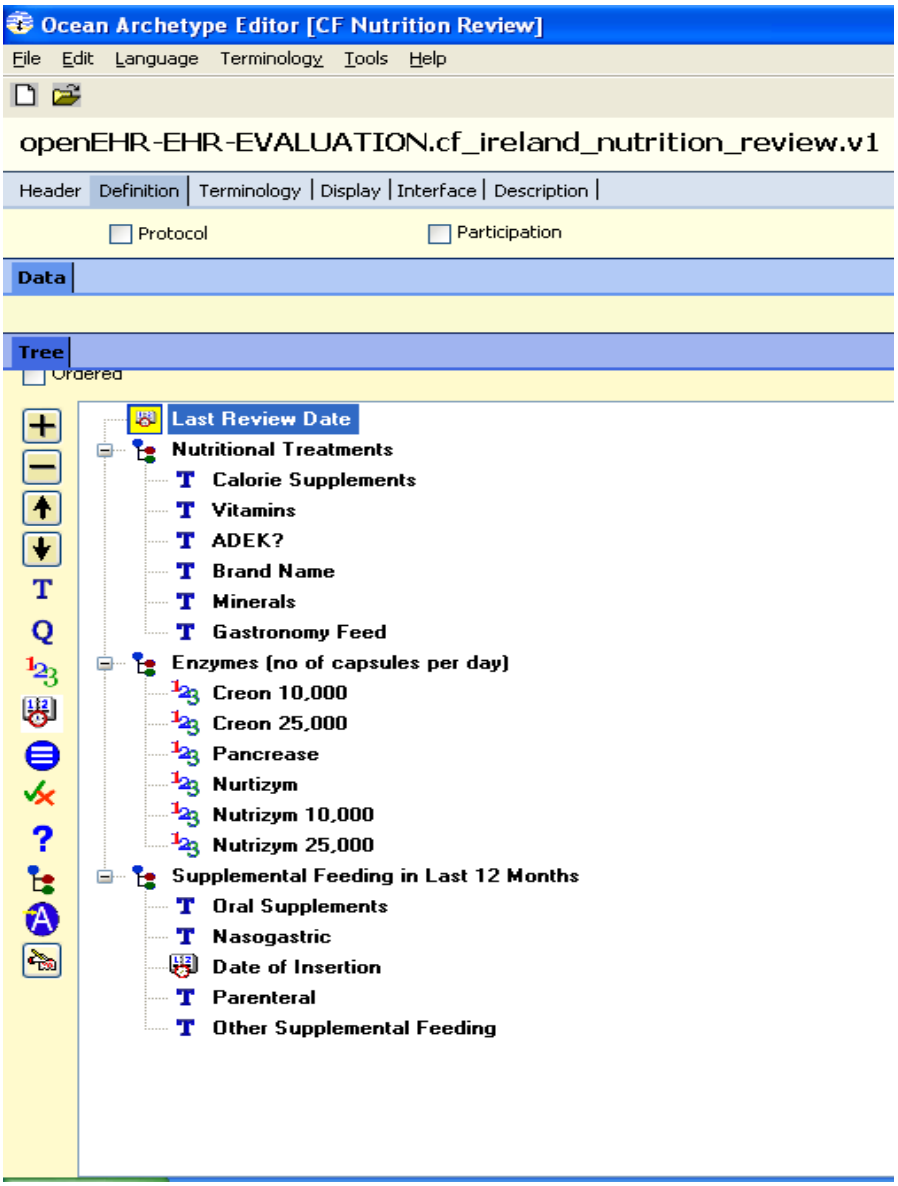
Date of Walk test (0..1)
Date of walk test
DataType = DateTime
Constraint: Date only

Walk test FiO2 (0..1)
FiO2 result
DataType = Quantity
Constraint: Physical property = ;

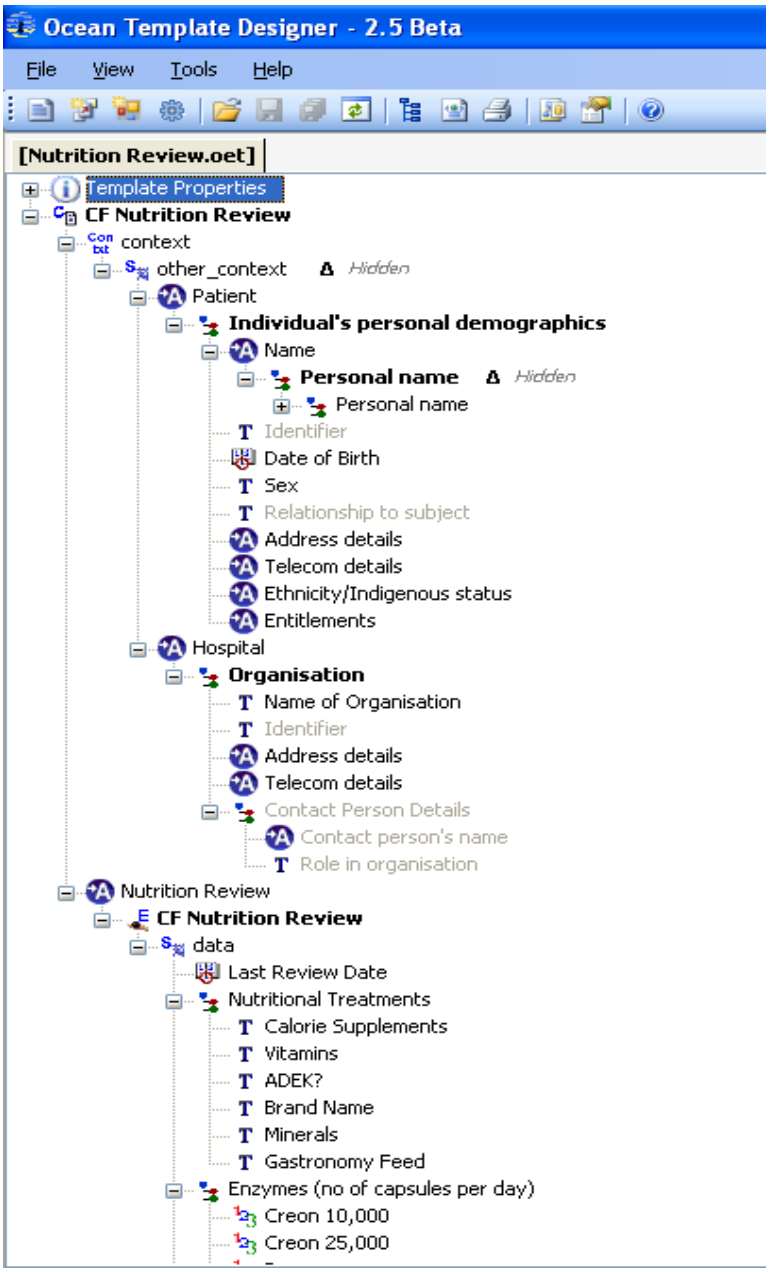
Resting SaO2 (0..1)
Resting O2 saturation result
DataType = Quantity
Constraint: Physical property = ;

Appendix B – Additional Archetype/Template/Form Designs

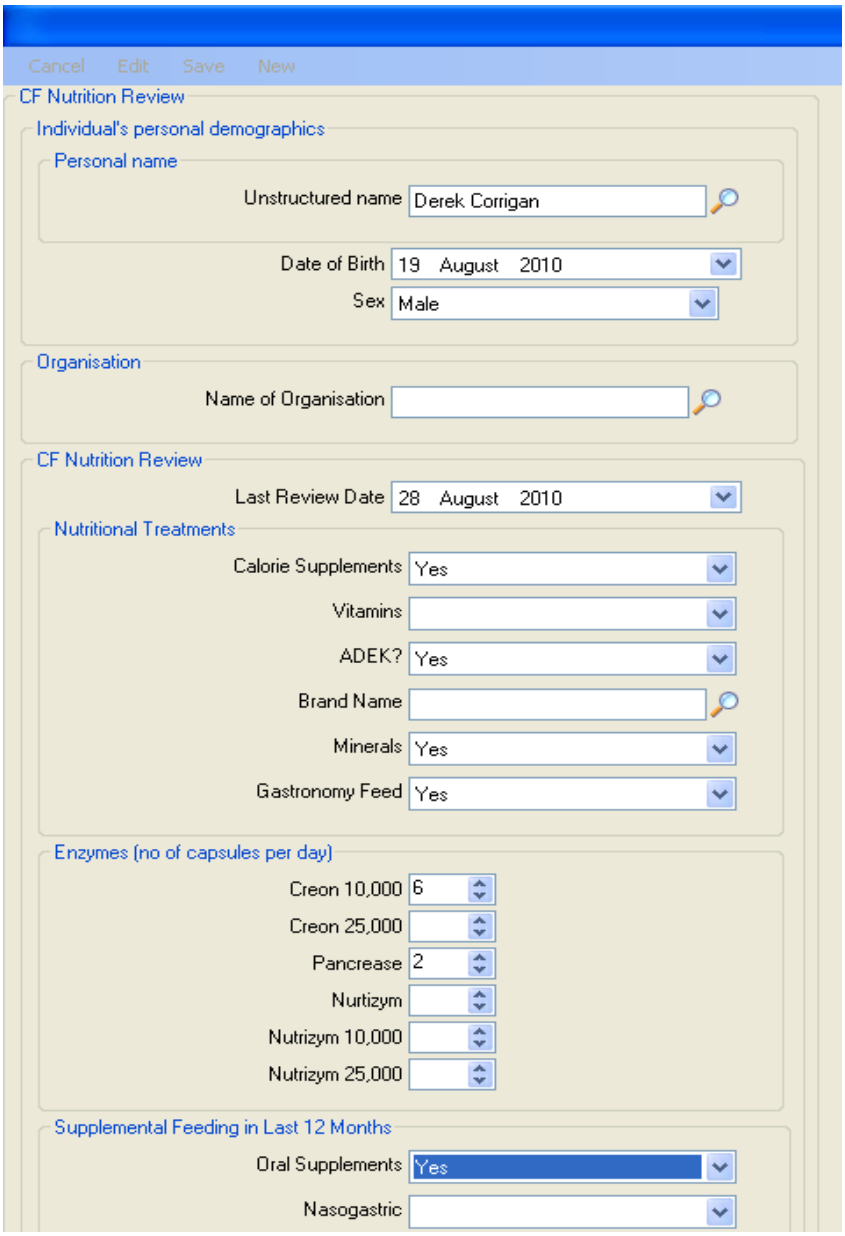
Nutrition Review Archetype



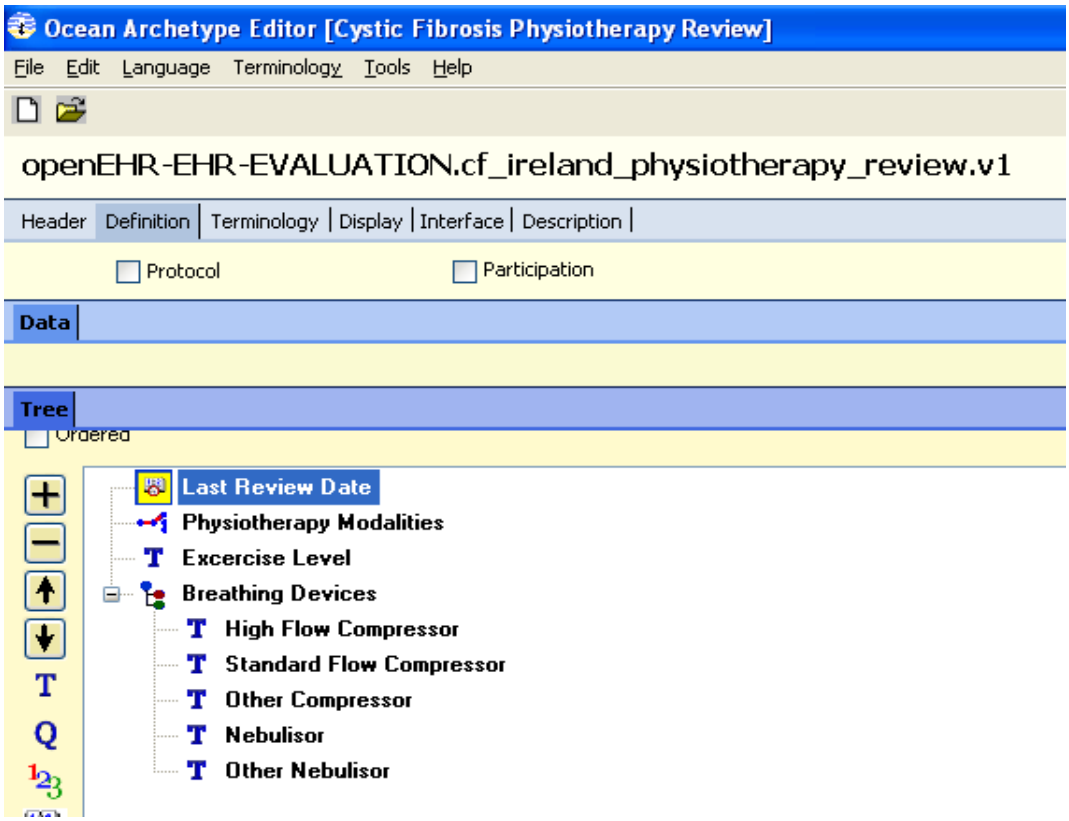
Nutrition Review Template



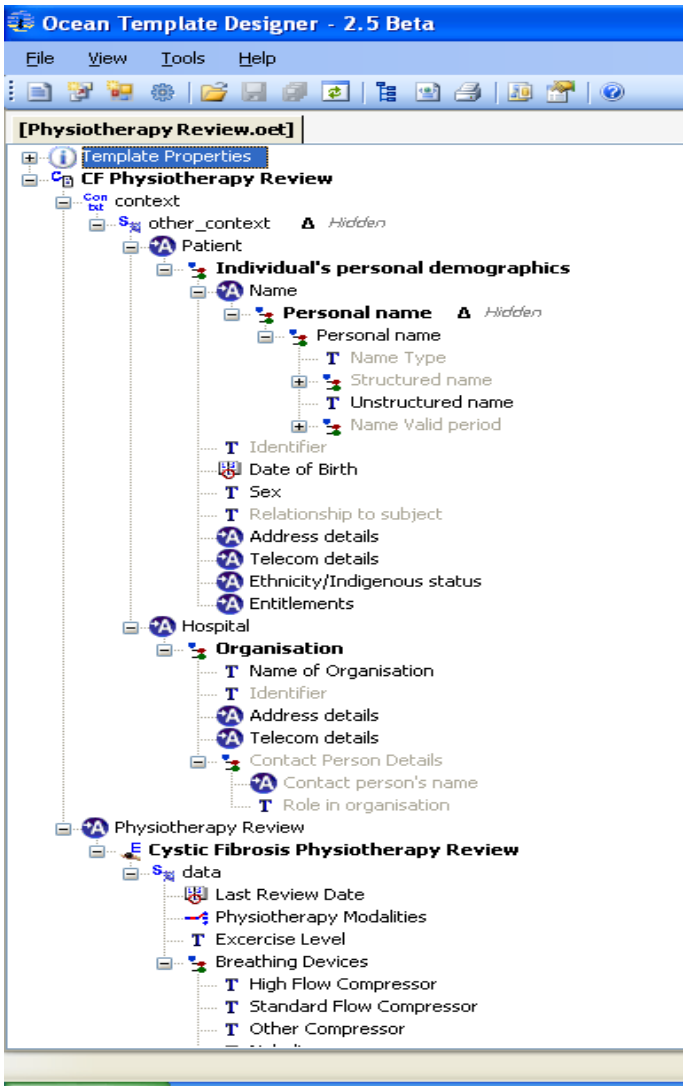
Nutrition Review Form



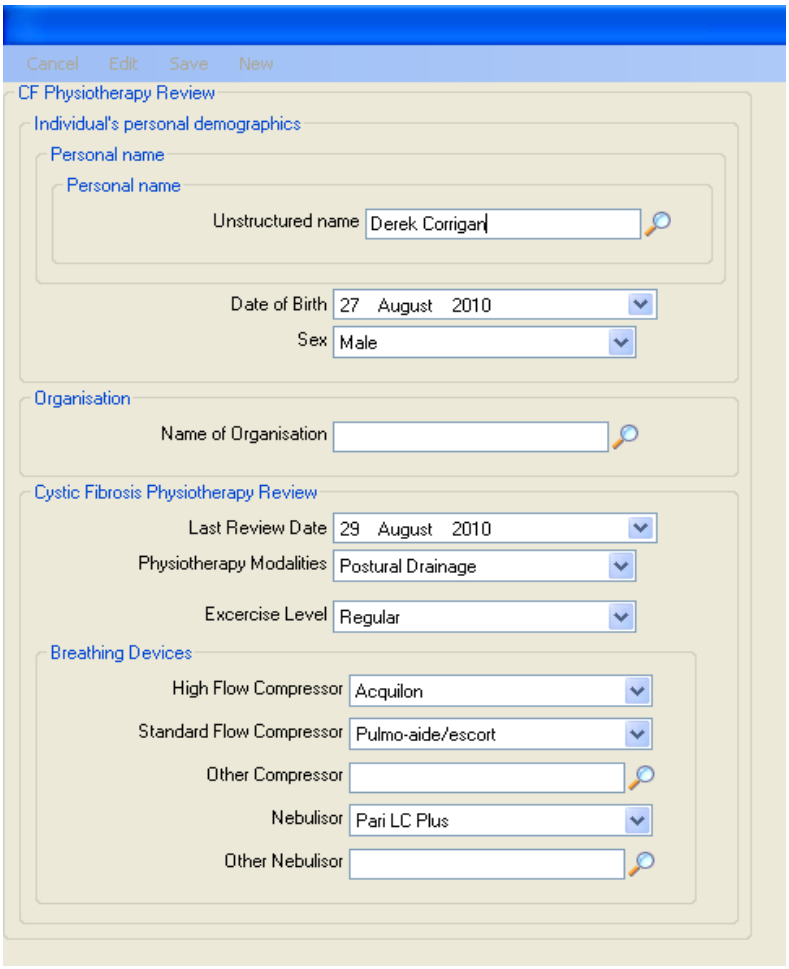
Physiotherapy Review Archetype



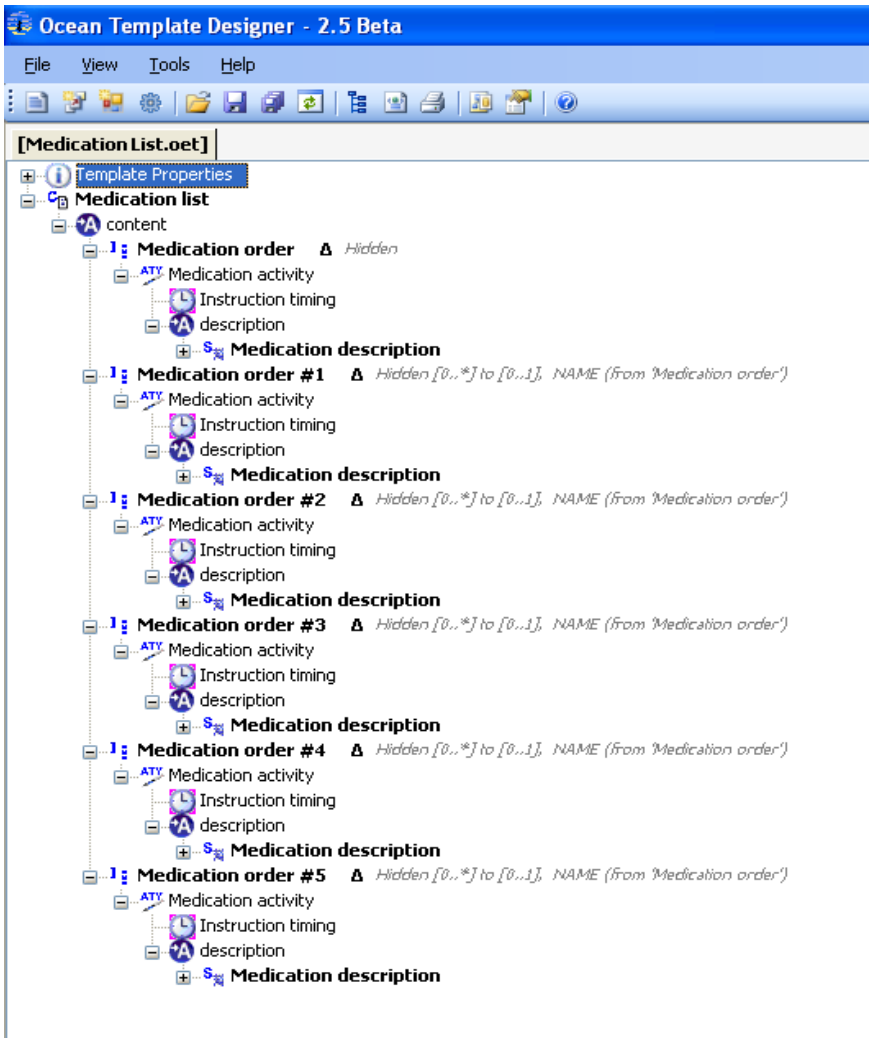
Physiotherapy Review Template



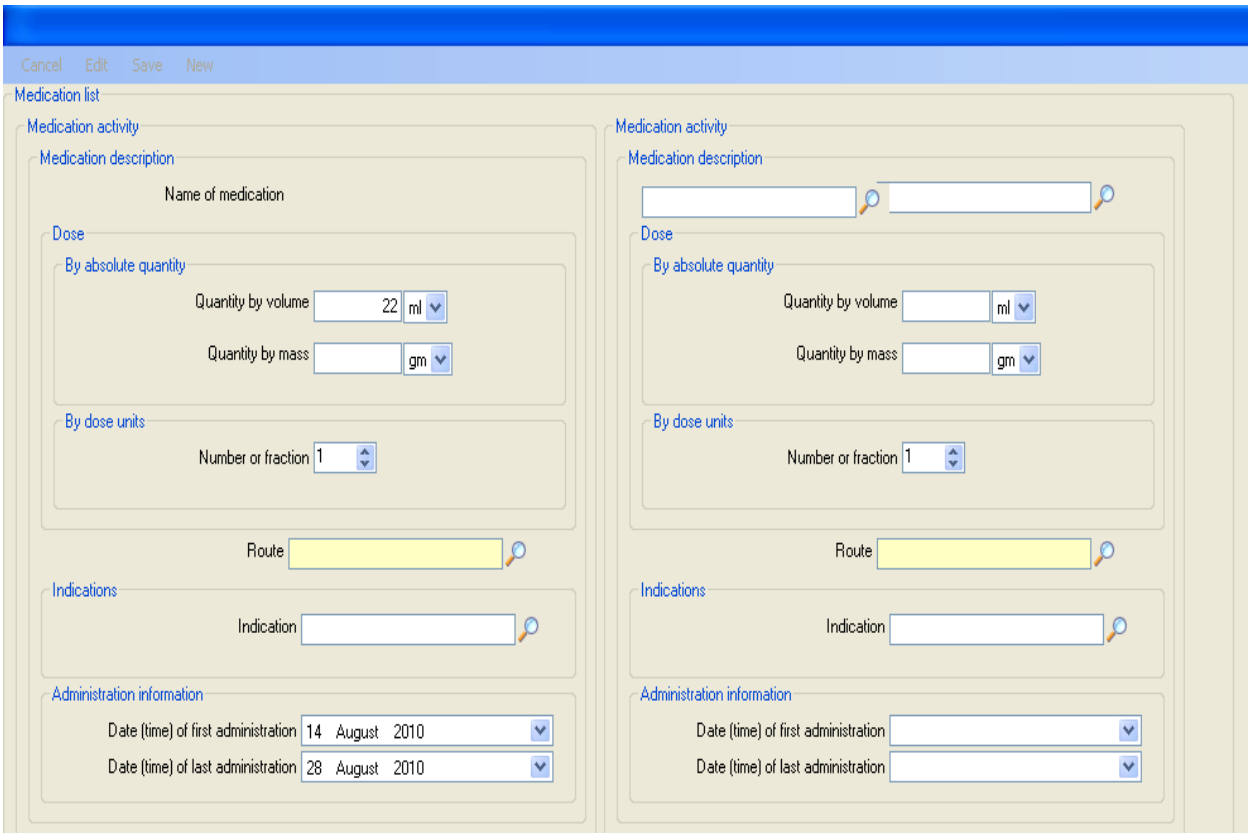
Physiotherapy Review Form



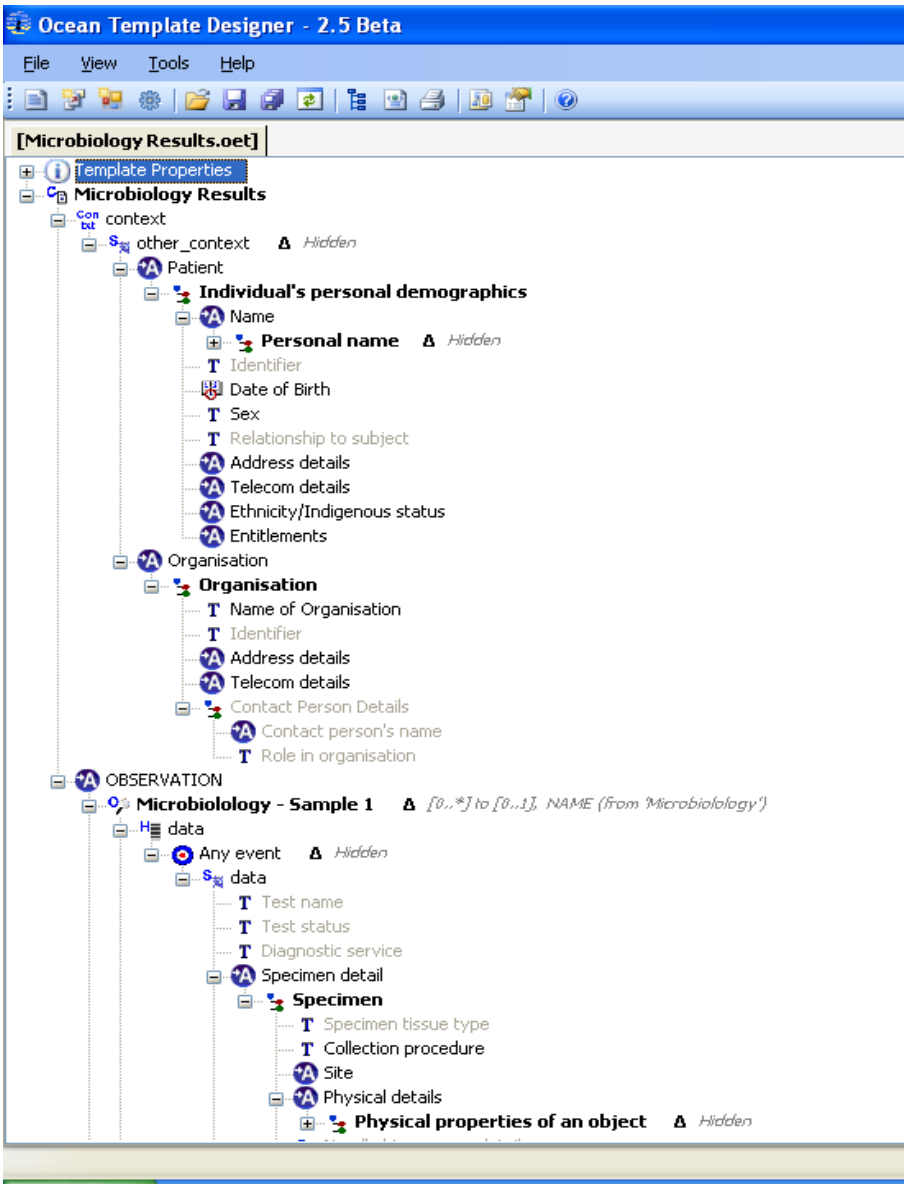
Medication Review Template



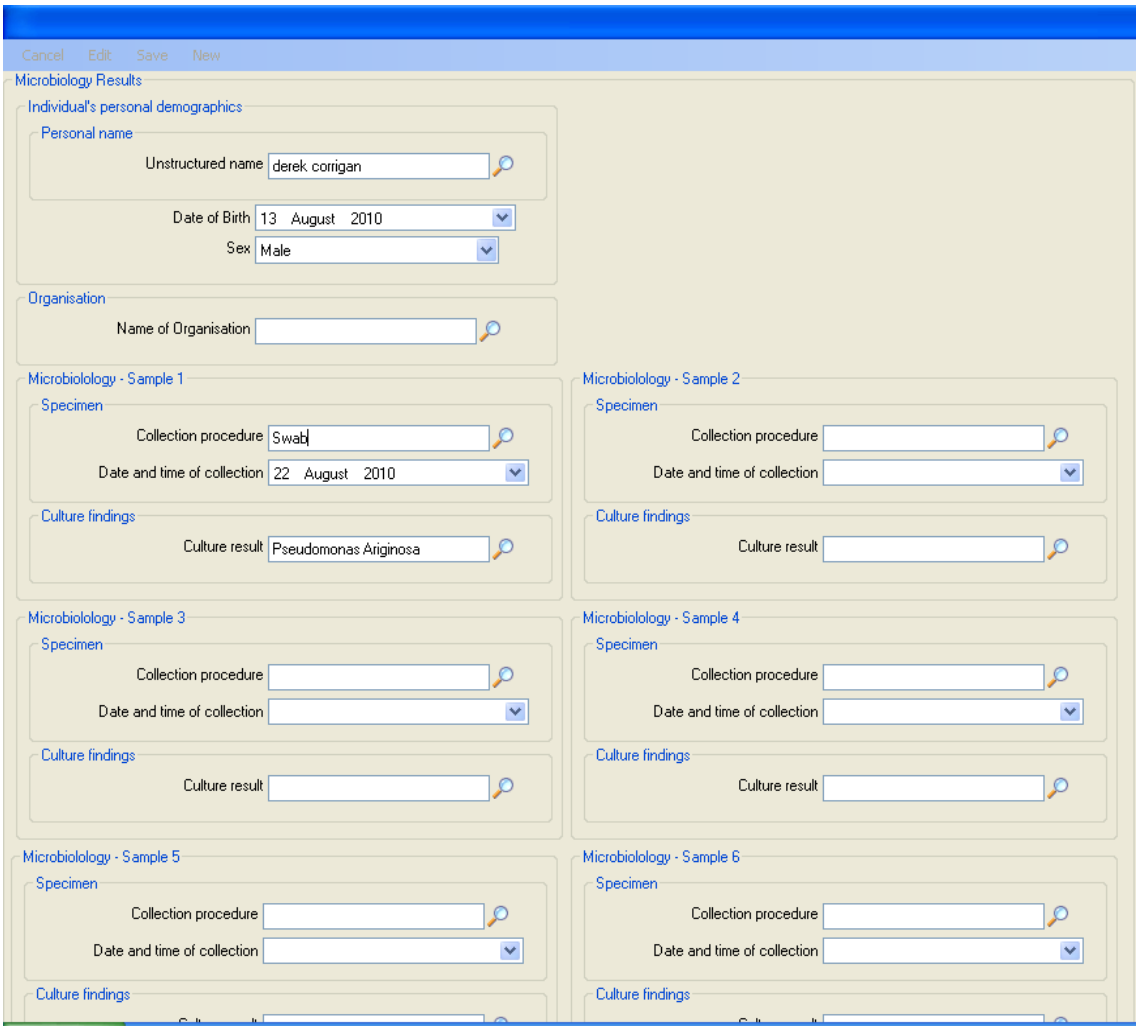
Medication Review Form



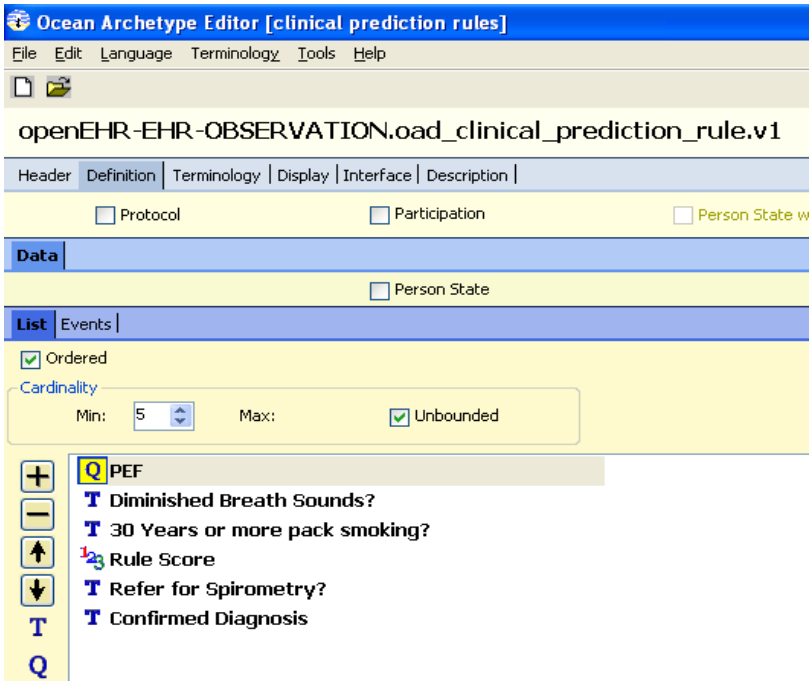
Biochemistry Review Template



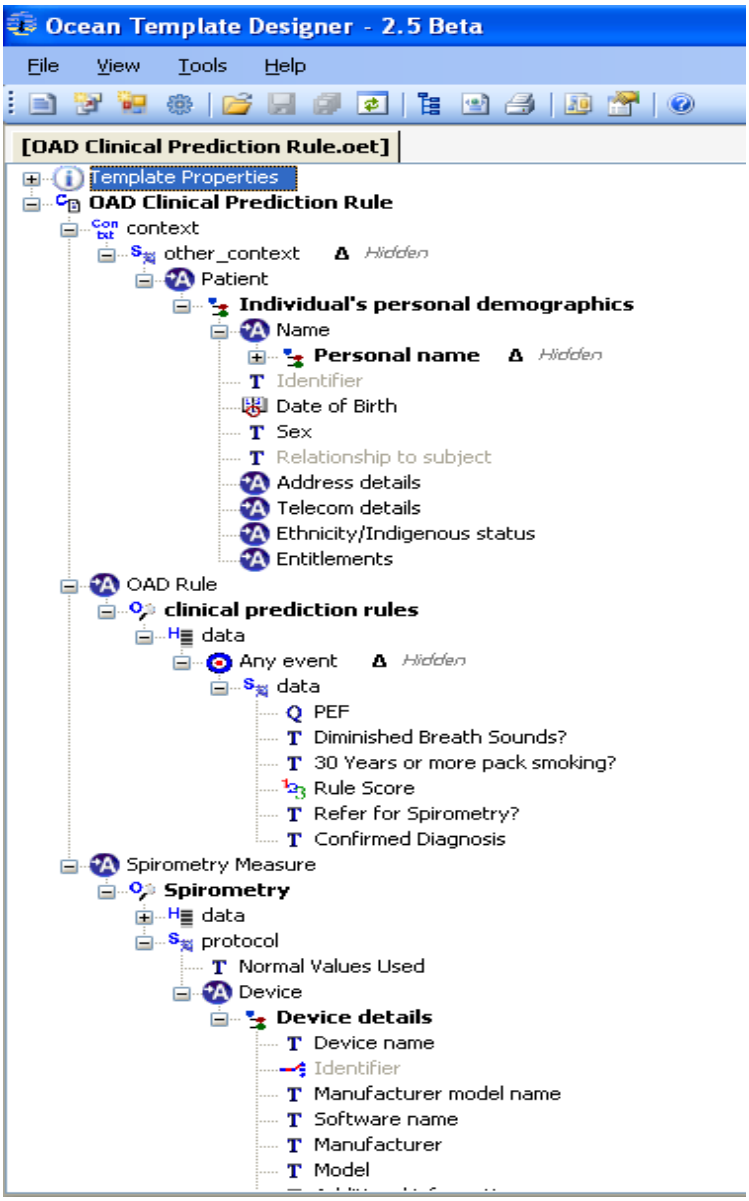
Biochemistry Review Form



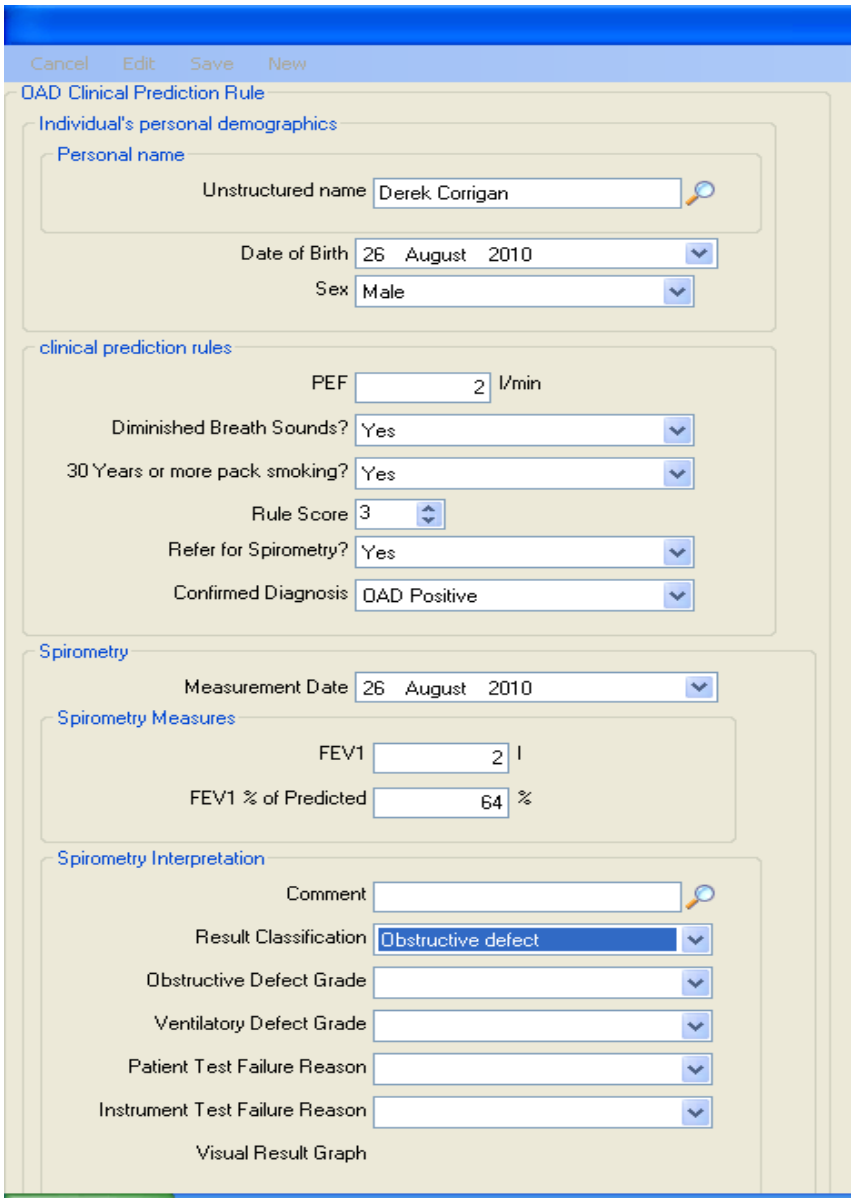
OAD Clinical Prediction Rule Archetype



OAD Clinical Prediction Rule Template



OAD Clinical Prediction Rule Form



Appendix C – Correspondence and Feedback on Spirometry Archetype from OpenEHR Archetype Editorial Group

From: Heather Leslie
Sent: 17 August 2010 10:17
To: Derek Corrigan
Cc: Ian McNicoll
Subject: Re: Spirometry Archetype

Hi Derek,

Looks like you've been archetyping for ages - impressed.

Few issues that we can discuss.

I'm cc'ing Ian McNicoll - one of my colleagues who has just developed a pulmonary function archetype for a new project we are working on - he has just sent the draft through and I've attached it.

Would love to see us all collaborate and see how we can bring these together as part of the maximal dataset.

Ian is in your time zone, so may be easier for you two to tictac together.

Regards

Heather

On 17/08/2010 6:09 PM, Derek Corrigan wrote:

Hi Heather,

As discussed please find the following attached :

Spirometry Measurement Archetype

Also, it may be of interest, one of our research topics in the HRB centre here is Clinical Prediction Rules. I was investigating how archetypes might be used to capture CPR's as a potential form of clinical guideline. The attached paper from Badgett et al details a simple clinical prediction rule to determine whether or not to refer a patient for a full Spirometry check to confirm obstructive airways disease (OAD). It's a simple set of criteria that can be carried out by a GP.

Based on the paper I created an archetype to represent the clinical prediction rule (attached) and then combined that in a template with the Spirometry Measurement archetype as a means of recording the actual spirometry result (if referred) to either confirm the diagnosis or not which could then be used to assess how well the CPR functioned in practice. It's all rather rough but hopefully you get the idea. If you've any thoughts on that I would appreciate it.

I also have archetypes relating to physiotherapy reviews and nutritional reviews but these are not maximal datasets and were designed just for local use.

I also have designed a number of templates to capture the CF Ireland Registry data according to the form and database layouts that they use. Basically I was looking at how templates and archetypes could be used to satisfy the requirements of multi-disciplinary teams for an illness like Cystic Fibrosis. The CF registry aren't actually using these but I used them as the basis of my masters thesis.

If you have any comments or would like to see more I would delighted to discuss.

Many Thanks

Derek

From: Ian McNicoll
Sent: 24 August 2010 13:51
To: Derek Corrigan
Cc: Heather Leslie
Subject: Re: Spirometry Archetype

Hi Derek,

Timely email!! I was just about to send you my updated version, intended for CKM use.

You will see that it has quite a different structure, which is to try and incorporate some of the more unusual tests within the same archetype, and part of the 'maximal dataset' approach we try to use. In practice we would tease out the common tests PEF, FFVC and FEV1 in a template for common usage. This lets is match different reporting styles and mixes of parameters without using multiple archetypes Your work was really helpful in adding to the content and I have added you as a contributor.

I have added a multiple occurrences text element to capture any of the findings you have listed under Result classification, Obstructive and Ventilatory defects. It is always difficult to understand the extent to which these terms are standardised norms , or just local/instrument specific, so for the moment I would expect such termsets to be completed at template level. e.g looking at http://www.nationalasthma.org.au/content/view/332/419/ it looks as if the definition of mild/moderate/severe etc , is dependent on the condition being assessed - as thma or COPD. This is always a difficult area which I would expect ultimately to be resolved by agred international terms in e.g. Snomed , but these are currently very lacking.

There are a couple of technical/design issues with your spirometry archetype, that you may want to look at:

1. You do not need to define Measurement date - this is automatically provided for you by the openEHR reference model as part of the OBSERVATION class on which the archetype is based. This is a very common misunderstanding and can be quite tricky to grasp at first, particularly as the timing model is pretty complex. Let me know if this needs further explanation.

2. The ratios/percentages should use the Proportion data type, rather than quantity.

3. The Test failure reasons should probably be moved to the protocol section.

4. I wasn't quite sure what was meant by FVC1 in this context. I have seen that term used but seems to be synonymous with FEV1 - should your use of FVC1 not really be just FVC? This may reflect my own ignorance, if so , please educate!!

5. We tend to leave the upper limits of the ranges very wide in archetypes, really at the level of 'reality check' rather than at sensible clinical limits, as these are often very dependent on the context e.g paediatric use, ICU etc. On of the disadvantages of my approach is that I would have to set these limits across broad groups of tests, which is less than ideal.

Other than that, an excellent job, which forced me to completely re-design the official version, as I had clearly missed out a great deal of content!!

Please feel free to come back to me if further discussion would be helpful. Thanks for your help and good luck with the MSc - I only just finished mine this year

Regards,

Ian

Dr Ian McNicoll

Clinical Analyst Ocean Informatics
Honorary Senior Research Associate, CHIME, University College London
openEHR Archetype Editorial Group
Member BCS Primary Health Care SG Group www.phcsg.org / BCS Health Scotland