Towards the development of a clinically effective interoperable epilepsy electronic patient record

A Thesis Submitted to University of Dublin, Trinity College for the Degree of Doctor of Philosophy

Louise Mc Quaid PhD, MSc, BSc.
School of Computer Science and Statistics (SCSS)
Trinity College Dublin

Declaration

I, Louise Mc Quaid, 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. I further declare that this research has been carried out in full compliance with the ethical research requirements of the School of Computer Science and Statistics.

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Abstract

eHealth including Electronic Patient Records[1](EPRs), is a key enabler to effectively support the coordinated approach to chronic disease management (CDM), including epilepsy, by improving information flow between patients and providers and among providers themselves. The potential for eHealth applications to reduce medical error, improve patient outcomes and reduce healthcare costs is recognised.(1) However, it has been proven that eHealth projects have failed to meet end-users requirements or are considered incomplete and not fit for purpose.(2) eHealth can benefit from employing a sociotechnical ethos that views the human, organisational and technical components of a system as a network that must be managed collectively in order to realise improved healthcare. Enabling interoperability, the ability to safely share and communicate information between eHealth applications across multiple healthcare providers regardless of geographical location, is also an important consideration for successful eHealth applications.

This research, conducted using a qualitative case study, examines how a sociotechnical approach to EPR requirements, design and deployment can be used to meet clinical requirements. The findings suggest that an EPR based on an STS ethos results in a workable and usable system for end-users.This thesis also considers how existing EPRs can share and communicate information to support interoperability between eHealth applications. It provides a methodology, which was validated using a case study, for mapping from an existing relational EPR to the Health Level Seven (HL7) Clinical Documents Architecture Standard (CDA). It also found that it is possible to map from an existing relational EPR to the HL7 CDA standard to enable interoperability subject to certain constraints such as involving both clinical and technical expertise.

This research has made a theoretical contribution to health informatics research and also has relevance to practice. Specifically, the study improved understanding in the area of design and deployment of EPRs using sociotechnical perspectives in a real world setting and contributes to the literature on healthcare interoperability standards.

[1] An **electronic patient record (EPR)** is a longitudinal record of patient health information within a single institution e.g. a GP practice or a single hospital, or confined to a single domain/disease e.g. an epilepsy patient record

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List of Abbreviations

AED	Anti-Epileptic Drug
ATC	Anatomical Therapeutic Chemical
BA	Business Analyst
BHIS	Beaumont Hospital Information System
CCM	Chronic Care Model
CDA	Clinical Document Architecture
CDC	Center for Disease Control
CDM	Chronic Disease Management
CDSS	Clinical Decision Support System
CEN	Comité Européen de Normalisation - European Committee for Standardisation
CLOB	Character Large Object
CNS	Clinical Nurse Specialist
DTR	Draft Technical Report
EEG	Electroencephalography
EHR	Electronic Health Record
EMU	Epilepsy Monitoring Unit
EPR	Electronic Patient Record
ESTI	European Telecommunications Standards Institute
GPMS	General Practice Management System
HL7	Health Level Seven
HOT	Human, Organisation and Technology
HSE	Health Service Executive
ICT	Information and Communication Technology
IG	implementation Guide

IHE Integrating the HealthCare Enterprise

IHTSDO International Health Terminology Standards Development Organisation

ILAE International League Against Epilepsy

ISO International Standards Organisation

LOINC Logical Observation Identifiers Names and Codes

OID Object Identifier

OO Object Oriented

OPD Out-Patient Department

PACS Picture Archiving and Communication System

PHR Personal Health Record

PIPE Patient Information Profile Explorer

RE Requirements Engineering

RIM Reference Information Model

RMIM Refined Message Information Model

RUP Rational Unified Process

SDO Standards Development Organisation

SNOMED CT Systematized Nomenclature of Medicine - Clinical Terms

STS Sociotechnical System

STSD Sociotechnical System Design

SR Senior Registrar

UCUM Unified Code for Units of Measure

URS User Requirements Specification

UAT User Acceptance Testing

VNS Vagal Nerve Stimulator

WHO World Health Organisation

XML Extensible Mark-up Langua

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Part I

The Design and Deployment of an epilepsy EPR using a sociotechnical approach

Chapter 1 Introduction

1.1 Thesis Introduction

The use of Information and Communication Technology (ICT) in healthcare, or as it is commonly referred to in Europe, eHealth, is a key enabler to effectively support the coordinated approach to chronic disease management (CDM) and improve information flow between the patient and providers and among providers themselves. Over the years, there has been an international effort to more effectively manage chronic disease [3-5] using the chronic care model (CCM) which importantly promotes the use of ICT as one of its core recommendations.[6-8] There is strong evidence to suggest that eHealth, including Electronic Health Records[2] (EHRs) and Electronic Patient Records[3] (EPRs), can greatly support and positively impact on chronic disease management [9-11] promising greater benefits for patients.

The potential for eHealth applications to reduce medical error, improve patient outcomes and reduce healthcare costs is recognised.[1] It is well documented that EHRs/EPRs can potentially add significant value to patient care in terms of improving quality, safety and efficiency.[12] Given the CCM recommendation and the evidence from literature, this thesis assumes that CDM, in this case epilepsy, can benefit from the introduction of an EPR. However, adopting eHealth should not be seen as the solution to fixing all the problems of modern medicine.[13] The evidence suggesting that EPRs may more effectively manage CDM is convincing. However, it has been proven that many eHealth projects have failed to meet end-users requirements or are considered incomplete and not fit for purpose.[2] The difficulty in deploying eHealth initiatives may be attributed to the complexity of the healthcare environment. It is well documented that the business of healthcare is complex and unstable, information intensive, highly unpredictable, not routine and often involves ad hoc tasks and interruptions to workflow.[14] A further difficulty is the management of requirements and system design and deployment of EPRs. Traditional requirements development that focuses heavily on what technical features should be included in systems without considerations of users and organisational issues is not well-suited to the business

[2] An **electronic health record (EHR)** is a longitudinal record of patient health information across multiple care settings
[3] An **electronic patient record (EPR)** is a longitudinal record of patient health information within a single institution e.g. a GP practice or a single hospital, or confined to a single domain/disease e.g. an epilepsy patient record

of healthcare most notably because 'the underlying assumptions of traditional RE practice is that the domain the application is designed for is stable'.[2] A solution is to view EPR development (including requirements, system design and deployment) from a broader sociotechnical perspective. A sociotechnical system (STS) includes dynamic networks of people and technologies and has three key components including social, organisational and technology that must be managed collectively in order to realise the promise of improved healthcare.[15] A sociotechnical approach was used in the requirements, design and deployment stages of the epilepsy EPR development. This means considering the interrelatedness of human, organisational and technical components when designing and building a system and not just focusing on the technology.

This thesis concentrates on how a sociotechnical approach to EPR requirements, design and deployment can be used to meet clinical requirements. The thesis also considers how EPRs can share and communicate information to support interoperability between EPRs across multiple healthcare providers regardless of geographical location. The epilepsy EPR was based on bespoke software rather than on any international eHealth standards or commercial product.

1.2 Background and Context

The Health Research Board (HRB) in Ireland funded a five year (2005-2010) research and development (R&D) programme to examine challenges to epilepsy management in both primary and specialist sectors and to consider how epilepsy management could be supported by the introduction of an epilepsy EPR.[16-18] This R&D programme was undertaken by the epilepsy programme at Beaumont Hospital Dublin, of which the development of the epilepsy EPR forms a part. A partnership was established between the Centre for Health Informatics and the Centre for Health Policy and Management at Trinity College Dublin together with Beaumont Hospital's I.T. department. The research was approved by the Medical Research Ethics Committee at Beaumont Hospital. The broad objectives were to:

- Manage and provide safe and quality patient care through improved health information facilitated by the design, development, deployment and evaluation of a bespoke epilepsy EPR

- Produce quality patient data by facilitating easier interrogation and reporting, updating, analysis and auditing of epilepsy information for the purposes of epilepsy research
- Enable the integration of data from multiple sources to facilitate access to authorised users at multiple locations within and external to Beaumont Hospital (this is addressed in part two of this research).

1.2.1 The epilepsy EPR and Role of the Business Analyst (BA)

This research is primarily based on the epilepsy electronic patient record (EPR), currently used routinely in a live clinical setting by a multidisciplinary team of healthcare professionals at one of the main teaching hospitals in Dublin. The epilepsy programme at Beaumont Hospital is the main referral centre for patients with epilepsy and related disorders in Ireland. It integrates clinical care and research through the work of a multidisciplinary team who provide services including an epilepsy out-patient department (OPD), a nurse specialist telephone advice service, the epilepsy pregnancy register, community services, and a long term monitoring unit. This work was conducted through a multidisciplinary team of 15 staff comprising administrative, clinical, researchers and healthcare professionals who are referred to as the end-users throughout this thesis. The aim of the epilepsy programme is to continuously manage the care of patients with epilepsy. The diagnosis and treatment of epilepsy depends
on accurate integration and correlation of clinical data from multiple heterogeneous sources. The secure web-based epilepsy EPR was designed developed and deployed incrementally over 4 years to include clinic administration, demographics, social history, epilepsy history, anti-epileptic drugs (AED), allergies, OPD plan and clinical investigations modules.

The author played the role of business analyst (BA) in the analysis, requirements, design and deployment of the epilepsy EPR. A BA's role is crucial in the software development lifecycle as they perform a liaison role between the business and technical team in order to effectively communicate the end-user requirements (see chapter 4).

1.3 Scope of Study, Research Questions and Objectives

There are two separate but closely related areas that are being investigated in this research: firstly, the sociotechnical approach to the design and deployment of the epilepsy EPR and

secondly, the methodology for mapping from existing databases to enable standards compliant EPRs. The research questions are:

- Part One: How can a sociotechnical approach be used to ensure that the design and deployment of an EPR meets clinical requirements?

- Part Two: What methodology is required to map an extract (in this case a discharge summary) from a pre-existing relational EPR (in this case epilepsy) to make it conform to a corresponding template (for a discharge summary) defined according to the Health Level Seven Clinical Document Architecture (CDA)

There are two parts to this research. The first part describes the design and deployment of an EPR using a sociotechnical approach. The second part examines the feasibility of mapping an extract of data from an existing EPR to make it comply with the HL7 CDA standard. The research questions are related because there is a lot of investment locked up in existing EPRs and it is important to be able to share meaningful information with other systems. If an existing EPR is non-standards compliant, it is necessary to introduce standards to make the EPR interoperable with other systems.

In order to address these two related research questions, the following research objectives have been derived. Part one is covered by objectives A-D and part two is addressed by objectives E-F.

A. Research relevant academic and grey literature concerned with the condition of epilepsy and STS philosophy in requirements engineering, system design and deployment.
B. Examine the practicalities of how to design and deploy an epilepsy EPR using an STS perspective in a real world clinical environment.
C. Identify the sociotechnical clinical requirements needed to satisfy the design and deployment of the epilepsy EPR.
D. Evaluate the use and usability of the EPR using the anti-epileptic drug (AED) module, a complex and core component of the EPR, as an exemplar.

E. Research relevant academic and grey literature concerned with eHealth standards, specifically the HL7 CDA standard and literature on mapping from relational EPR data models to object oriented models.
F. Develop and validate a process for mapping an existing relational EPR extract to the HL7 CDA standard based on an internationally recognised CDA implementation guide and literature on mapping data models for interoperability.

1.4 Methodology

Part 1 of this study used a qualitative case study approach in order to address the research questions and objectives. It drew on a broad range of literature. Data collection for part 1, the sociotechnical design and deployment of the epilepsy EPR, was gathered through qualitative research methods such as, notes and memos from feedback meetings and workshops, interviews and informal conversations with end-users and analysis of existing documentation and participant observation. The author validated interviews and observations that were captured in very busy interview and fieldwork settings through follow-up meetings and informal conversations. Part 2 of this study also used a case study approach to validate a mapping methodology from existing relational EPRs to the HL7 CDA document standard. This involved following the steps of the methodology by understanding, analysing and interpreting existing documentation for CDA implementation guides (IG), the CDA model called the RMIM and an epilepsy EPR relational database. It also involved the author liaising with the epilepsy technical team lead to gather information about the epilepsy EPR and feedback was documented as notes and meeting minutes.

1.5 Outcomes and Contributions of the Research

This research adds an important contribution to the field of computer science. At a broad level, it focuses on health informatics with particular attention given to the areas of EPRs, and eHealth interoperability standards to enable the safe sharing of health information. In addition, it benefits the clinical problem of epilepsy, a common neurological condition by examining how it can be more effectively managed using eHealth applications such as EPRs based on a sociotechnical philosophy. This research has made a theoretical contribution to health informatics research and also has relevance to practice. Specifically, the study improves understanding in the following areas:

1. Demonstrates that the design and deployment of an EPR using an STS perspective in a real world clinical environment resulted in a workable and usable system.

2. Presents rich descriptions on how to design and deploy an EPR using an STS perspective and ethnography.

3. Provides a methodology which was validated on the same case study (a medication section of discharge summary) for mapping from a relational EPR data model to the HL7 CDA RMIM.

4. Identifies that the mapping from a relational EPR database model to the HL7 CDA RMIM requires input from both clinical and technical expertise.

1.6 Thesis Outline

This thesis consists of eight chapters. Table 1-1 below outlines the association between each chapter and the research objectives alongside a summary of what each chapter entails.

Table 1-1 Summary of the Thesis Structure

Title	Research Objectives	Overview of Chapters
Chapter 1 Introduction		Chapter 1 provides an introduction to the study and indicates the research questions, objectives and the scope. A brief overview of the research findings and contributions are also given.
Chapter 2 The role of the EPR in the management of epilepsy	A. Research relevant academic and grey literature concerned with the condition of epilepsy and STS philosophy in requirements engineering, system design and deployment.	Chapter 2 describes the literature on the role of the EPR to facilitate the management of chronic disease such as epilepsy. There is evidence to suggest that EPRs can facilitate and enhance the management of chronic diseases such as diabetes or epilepsy. This chapter describes the organisation and operation of a clinical out-patient department (case study) which provides context for the study.
Chapter 3 Sociotechnical Requirements engineering in Healthcare	A. Research relevant academic and grey literature concerned with the condition of epilepsy and STS philosophy in requirements engineering, system design and deployment.	Given the multiple strands of the literature which had to be drawn on for this research, the literature review in Chapter 3 is wide-ranging. Chapter 3 covers literature on requirements engineering, sociotechnical systems (STS) theory and design methods. It

		also reviews the field of ethnography, a qualitative research method that is strongly aligned with sociotechnical thinking. The literature suggests that STS principles and design and ethnographic techniques are well suited to system design in healthcare.
Chapter 4 **Design of an epilepsy EPR using a sociotechnical perspective**	B. Examine the practicalities of how to design and deploy an epilepsy EPR using an STS perspective in a real world clinical environment. C. Identify the sociotechnical clinical requirements needed to satisfy the design and deployment of the epilepsy EPR.	Chapter 4 gives a detailed account of the sociotechnical principles that were used to guide the EPR design. It also outlines the data collection methods used including observational studies of the clinic environment and people who worked there and interviews with end-users. The data collected provides rich descriptions to help design the EPR. This chapter concludes with a description of the Anti-Epileptic Drug (AED) module.
Chapter 5 **Evaluation of the epilepsy EPR deployment**	D. Evaluate the use and usability of the EPR using the AED module, a complex and core component of the EPR, as an exemplar.	Chapter 5 examines the use and usability of the AED module of an epilepsy EPR deployed in a *live* epilepsy clinic and categorises the findings under key sociotechnical components: human, organisational and technology. The findings suggested that end-users were able to use the EPR in a clinical environment and that it met their clinical requirements.
Chapter 6 HL7 Clinical Document Architecture (CDA)	E. Research relevant academic and grey literature concerned with eHealth standards, specifically the HL7 CDA standard and literature on mapping from relational physical data models to object oriented models.	The second part of this research was concerned with mapping extracts from an existing database to an international eHealth interoperability standard called HL7 CDA. This provides an important step towards facilitating interoperability from relational non-standards compliant EPRs to a standards based EPR in order to share patient information. Chapter 6 emphasises the importance of interoperability to achieve safe electronic communication between eHealth systems such as EPRs alongside a comprehensive overview of health information standards and mapping from relational to OO models.
Chapter 7 **Mapping from an existing relational EPR database to the HL7 CDA Standard**	F. Develop and validate a methodology for mapping an existing relational EPR extract to the HL7 CDA standard based on an internationally recognised CDA implementation guide and literature on mapping data models for interoperability.	Chapter 7 describes a methodology that was developed and validated for mapping an existing epilepsy relational database to the CDA document standard based on an internationally recognised CDA implementation guide and literature around mapping.
Chapter 8		The final chapter highlights the key aspects of the thesis. Sections 8.2

Discussion and Conclusions	returns to the research questions and objectives. Section 8.3 identifies and discusses the main findings and presents conclusions. Section 8.4 considers how the findings could be generalisable to other areas. The limitations of the study are outlined in section 8.5 and suggestions for future research are discussed. The contributions that were achieved from the study are outlined in Section 8.6 and finally the final conclusion is presented in Section 8.7.

1.7 Publications and Presentations

The publications and presentations related to this thesis are outlined below:

Publications

- Mc Quaid L, Breen, P, Grimson, J, Normand C, Dunne M, Delanty N, Kalra D, Fitzsimons M. Socio-technical considerations in epilepsy electronic patient record implementation. International Journal of Medical Informatics (2010);79:349–60.

- Varley J, Delanty N, Normand C, Coyne I, McQuaid L, Collins C et al. Epilepsy in Ireland: Towards the primary–tertiary care continuum. Seizure. (2009);19 (1):47-52

- Breen P, Mc Quaid L, Grimson, J, Delanty, N, Dunne M,Dunleavy B, Normand C, Fitzsimons M. Integrating clinical theory and practice in an epilepsy-specific electronic patient record. Stud Health Technol Inform. (2009);150(6):145.

- Fahey P, Harney C, Kesava S, McMahon A, Mc Quaid L, and Kane B. Human computer interaction issues in eliciting user requirements for an Electronic Patient Record with multiple users. Proceedings of the 24th International Symposium on Computer-Based Medical Systems 2011; Bristol, UK: IEEE.

Presentations

- Presentation to the Health Research Board (HRB) Programme Grant Mid-Term Review (2008) on "*a consideration of sociotechnical challenges in EPR implementation".*

- Presentation to the annual Irish Neurological Association meeting (2006) on "*embedding the e in neurology: the epilepsy EPR"*.

- Poster presentation at the Health Informatics Society of Ireland Annual Conference (2006) called "*The Role of the Electronic Patient Record (EPR) in Epilepsy Research*"

- Demonstration of the epilepsy EPR (2006) at the annual American epilepsy society conference, San Diego.

Chapter 2 The role of the EPR in the management of epilepsy

2.1 Introduction

This thesis uses epilepsy as an example of a chronic disease that can benefit from the use of eHealth. There are multiple types of epilepsy syndromes and seizure types. The diagnosis and treatment of epilepsy is complex involving input and the integration of information from multiple clinical disciplines such as neurology, neurosurgery, neuropsychology and pharmacy and non-clinical disciplines such as administration.

The evidence suggests that it is necessary to improve on the delivery of healthcare services by enhancing efficiency, access to services, and providing continuity of care.[19] Like other chronic conditions, to optimally manage epilepsy, interoperability of clinical information is needed. This typically requires the integration of clinical information from various healthcare disciplines who are located in different healthcare settings such as general practice, community based services and secondary and tertiary care.[20-24] The management of chronic disease including epilepsy can improve with the use of eHealth and the secure exchange of standardised information between different healthcare providers and services such as the HL7 CDA standard as discussed in part two of this thesis.

Part one of this thesis (chapter 2 to chapter 5) is concerned with understanding how a sociotechnical approach can be used for the design and deployment of an EPR to meet clinical requirements. The epilepsy EPR at Beaumont Hospital was used as the case study for this research. Literature on eHealth, in particular EPRs, was reviewed and how it can facilitate the management of health information for chronic illness such as epilepsy. Section 2.2 of this chapter outlines the clinical care model for chronic disease management and section 2.3 describes the role of EPRs in the management of chronic diseases. In order to provide context for this research, section 2.4 of this chapter describes the condition of epilepsy, as an exemplar of a chronic illness. The characteristics of epilepsy are presented with a particular focus on drug therapy for epilepsy as this is the main method of treatment for patients with epilepsy to control their seizures. The literature describing the management of epilepsy clinics is outlined in section 2.4.4. It was important for the author to understand the particulars about how staff worked in an epilepsy service, the role they had managing patients, the environment that they worked in, what processes they adhered to and what type of information was captured during patient-clinician encounters.

2.2 Chronic Disease Management and eHealth

Chronic diseases are a high priority for health services internationally and nationally as they are common, complex and costly to manage.[25, 26] In developed countries, they are the leading cause of death and morbidity.[3] They are characterised as long term or recurrent illnesses, non-communicable, difficult to cure and can lead to some form of functional impairment or disability.[27] Some of the most common chronic diseases include epilepsy, asthma, cardiovascular disease, mental disorders and diabetes. An individual's health outcome can be optimised through effective management of the condition.[28] This involves a systematic approach from a diversity of healthcare disciplines including: medical, nursing, psychology, physiotherapy, laboratory and administration across a variety of healthcare settings (e.g. primary, secondary and community).

Advances in medical science, the use of more preventative care measures, improvement in treatments, better nursing and medical care and better socio-economic circumstances for individuals have led to a dramatic increase in life expectancy. These factors have contributed to a significant rise in the number of people living with comorbidity (multiple chronic diseases) and polypharmacy (patient takes multiple medications).[10, 29] The financial costs associated with chronic disease management (CDM) are a significant strain on health services with expenditure estimated at approximately 75% to 80% of total healthcare costs (US figures).[9] There is a similar situation in Ireland where the management of chronic disease is difficult because of the current healthcare delivery model used in Ireland. This typically consists of fragmented services within hospitals and across organisational boundaries. A document published in 2008 by the Department of Health and Children set out the "*policy requirements for the future prevention and care of chronic disease in Ireland*" and among the recommendations was the introduction of a shared chronic care model to support a more collaborative approach to CDM and the development of clinical information systems to support CDM.[30]

The prevalence of chronic diseases is predicted to rise and will place even greater demands on health services in the future.[31] There has been an international effort to more effectively manage chronic disease using the international recognised chronic care model (CCM) developed in the 1990s by Wagner et al. (1998) at the MacColl Institute for Healthcare Innovation (MacColl Institute).[3] This widely used shared care model aims to promote better collaboration with patients, who should be well informed about their condition, and involves

the development of proactive multidisciplinary care teams. Varley et al.,(2010)[18] conducted research into the primary–tertiary care continuum for epilepsy in Ireland which "explained the need to shift from the current fragmented approach to a shared care model for the benefit of the patient with epilepsy and their families". In addition to team based clinical care management, CDM models recommend the use of evidence-based treatments and the integration of clinical information through the use of ICT.[6, 8] The use of ICT in healthcare, eHealth, is a key enabler to effectively support the coordinated approach to CDM and improve information flow between the patient and providers and among providers themselves. A comprehensive definition of eHealth is as follows:

> *"e-health is an emerging field in the intersection of medical informatics, public health and business, referring to health services and information delivered or enhanced through the Internet and related technologies…. the term characterizes not only a technical development, but also a state-of-mind, a way of thinking, an attitude, and a commitment for networked, global thinking, to improve health care locally, regionally, and worldwide by using information and communication technology".*[32]

eHealth has the potential to provide timely, quality information at the point of care to all those involved including patients and the multiple providers delivering care in many different settings.[11, 33-35] Dorr et al.,(2007)[9] conducted a comprehensive systematic literature review of clinical information systems for CDM. They concluded that 67% of systems reviewed were successfully implemented and associated with positive changes in outcomes.

As mentioned in chapter 1, there is evidence to suggest that eHealth, including EPRs, can support and positively impact on CDM [9-11] promising greater benefits for patients with chronic disease. It is generally accepted that there is potential for eHealth applications such as EPRs to reduce medical error, improve patient outcomes and reduce healthcare costs.[1]

Ongoing research and development is required to effectively design and deploy eHealth applications such as EPRs to enhance patient care. Good evaluation around the delivery of eHealth systems such as EPRs is needed and the sociotechnical aspects of eHealth applications must be understood and managed to achieve improved healthcare.[15] It is recognised that there is a need for greater research to evaluate the impact of the use of eHealth in CDM. A systematic review of the impact of eHealth on the quality and safety of

healthcare[36] concluded that *'despite support from policy makers, there was relatively little empirical evidence to substantiate many of the claims made in relation to eHealth technologies'.* They observed that eHealth applications contribute to the improvements in the quality and safety of healthcare but more rigorous evaluation of the impact of eHealth applications is required.

2.3 Electronic Health Records (EHRs) and Electronic Patient Records (EPRs)

The use of eHealth solutions and in particular EPRs/EHRs, has the potential to greatly improve the quality and safety of healthcare.[37-39] There are many different terms and definitions used throughout the literature to describe EPRs/EHRs.[40] This is possibly because of the variation in EPRs/EHRs and the unavailability of standards and guidelines in the past. Hence, it has been difficult to develop an agreed comprehensive definition for the EHR and the EPR. A simple definition of an EHR is 'a repository of information regarding the health status of a subject of care, in computer processable format' [41] but this is considered out-of-date as EHRs are viewed as more of an active record linked to knowledge such as clinical guidelines, protocols and alarms.[42]

The International Organisation of Standardisation (ISO) has proposed that records are differentiated according to whether they are shareable and interoperable, supporting integrated and continuity of care within and across organisation boundaries such as institutions and healthcare providers or are confined to single domain or speciality and are local to the facility e.g. detailed health information on the subject collected over a period of time and used typically within an institution. The ISO Technical Report ISO DTR 20514 Health Informatics: Electronic Health Record: Definition Scope and Context (ISO/DTR 20514) has provided an authorative definition of the shared-EHR or Integrated Care EHR (ICEHR), which is suitable for this research:

> *'The Integrated Care EHR is defined as a repository of information regarding the health of a subject of care in computer processable form, stored and transmitted securely, and accessible by multiple authorised users. It has a commonly agreed logical information model which is independent of EHR systems. Its primary purpose is the support of continuing, efficient and quality*

integrated health care and it contains information which is retrospective, concurrent and prospective'.[41]

The definition and differentiation between the different types of health records are defined as follows:

- 'An **electronic health record (EHR)** is a longitudinal record of patient health information across multiple care settings
- An **electronic patient record (EPR)** is a longitudinal record of patient health information within a single institution e.g. a GP practice or a single hospital, or confined to a single domain/disease
- A **personal health record (PHR)** is a patient-held record owned and managed by the patient; it may include information provided by a healthcare provider as well as information provided by the patient' (Taken directly from HIQA, 2011).[43]

It is widely believed that EPRs/EHRs may improve patient care by providing timely, secure access to better quality health information by multiple healthcare providers and patients in different locations. EPRs/EHRs have the capacity to reduce some of the financial costs associated with healthcare by enabling better coordination of treatment and elimination of duplicate tests.[37] The perceived benefits of EPRs/EHRs have been well documented including:

- Improved patient safety through eHealth initiatives such as ePrescribing solutions that are linked to an EPR/EHR.[44]
- Improved effectiveness by enabling access to data at the right time and place to the right person, providing evidence-based care and improving adherence to clinical guidelines.[45]
- Better management of chronic conditions which requires the ability to share information across different settings such as the community, primary and acute settings in order to facilitate an integrated service.[35]
- Reduced costs as a result of the benefits from savings associated with unnecessary repetition of tests and the inability to access paper charts housed at multiple locations.[46]
- Enabling and empowering patient self-management through an EPR/EHR.[11]

However, alongside the perceived benefits are risks associated with the introduction of EPRs/EHRs such as the unknown consequences of changing from paper to electronic systems, privacy and confidentiality issues, network security issues and socio-technical issues. For example, a potential barrier to successful EPR implementation is the dependency on the traditional paper based chart. The paper chart is often characterised by its disorganised, ambiguous, incomplete, illegible and inaccessible nature.[47] However, it remains the principal tool to support shared communication between different healthcare professionals at different locations. The paper chart, often in tandem with an EPR/EHR and other disparate electronic clinical systems, must cater for complex clinical data. Data types include unstructured text, structured text, alphanumeric, diagnostic image data, sound and video. Working with both paper and electronic systems in parallel can pose significant challenges for healthcare professionals. Elicitation of clinical notes from two sources can lead to inconsistencies, missing documentation and ultimately lead to medical error.[48, 49] Hence, the transition from paper to electronic should be awarded careful consideration.

At the most basic level, EPRs/EHRs can be used for data entry, storage, display, reporting and exchange of patient's health information. They can support a diverse group of end-users such as clinicians, other healthcare professionals, administrators, managers and patients themselves and can interface to other systems such as Picture Archiving Communication Systems (PACS), ePrescribing, Clinical Decision Support Systems (CDDS) and electronic ordering systems. However, they vary greatly in terms of their functionality, intended use and degree of sophistication including the extent to which they integrate with other systems.

2.4 The Epilepsy Exemplar

Epilepsy is a common chronic disease. Its diagnosis and optimal treatment is complex involving input and the integration of information from multiple clinical and non-clinical disciplines. In the Irish context, for a patient with complicated epilepsy who has attended an epilepsy service over a long period of time, there is often a large volume of data which can be fragmented and located on disparate paper and electronic systems.

2.4.1 An overview of epilepsy

Epilepsy is one of the most common (prevalence 0.75–1%) chronic neurological conditions worldwide.[25] The condition is characterised by recurrent epileptic seizures and a diagnosis is partly based on a person having suffered from two or more unprovoked epileptic seizures within a two year timeframe. The brain is the control centre for the body and is made up of neurons which are constantly transmitting and receiving messages which enable the body to work properly. A seizure may occur should there be a change in neurological functions triggered by abnormal electrical activity in the brain.[50]

Different epilepsy syndromes and seizure types have been identified and are classified according to the International League against Epilepsy (ILAE).[23] For an individual with epilepsy and their families and carers, the condition is more complicated than solely managing seizures. Epilepsy can have a profound effect on an individual's psychological, economic and social life.[24] Also, it is notable that a high proportion of people with epilepsy may also have co-morbidities and suffer with one or more other chronic diseases compounding the challenge that is involved with epilepsy management.[51]

The treatment of epilepsy involves various methods including pharmacotherapy, neurosurgery as well as psychological and social support.[23] The goal of epilepsy management is to achieve seizure remission, while minimising side-effects of drug therapy, and to enable patients to maintain a good quality of life.[21] It is important to establish the correct diagnosis of epilepsy in order to provide the most effective treatment. Treatment of epilepsy, taking account of quality of life issues, involves the selection of the most appropriate drug therapy.[23] In some individuals, who continue to have frequent seizures and remain refractory to medication, surgical management is considered.[52] An alternative to surgery is the implantation of electrical stimulation devices such as a vagal nerve stimulator (VNS).[20, 24]

For the majority of people who develop epilepsy, the prognosis can be good whereby the condition remits and its clinical manifestations may be short-lived. Long term remission is possible for two thirds of patients with epilepsy which decreases the chance of the patient experiencing subsequent relapses.[53] Non-compliance with AEDs or if a patient remains untreated for their seizures increases the likelihood of the patient having another seizure.[54]

The most important predictors for control and remission of seizures are based on a correct diagnosis and the patient's response to the first prescribed AED.

2.4.2 Classification of epilepsy

An early and accurate diagnosis of epilepsy is fundamental to improve a patient's prognosis.[55] Patients who have recent-onset seizure activity (or where there is a clinical suspicion of epilepsy) who experience multiple seizures before they receive a diagnosis and specialist treatment tend to have a worse outcome than patients who are reviewed and treated promptly.[56, 57] There is no gold standard for the diagnosis of epilepsy[58] and it can be difficult to reach a confident, conclusive diagnosis. The diagnosis of epilepsy should be carried out by a clinical professional with expertise in epilepsy namely an epileptologist who can safely and proficiently determine the diagnosis. [58] The diagnosis of epilepsy involves the epileptologist recording a detailed medical history from the patient and ideally obtaining an account of the seizure descriptions from a reliable witness to corroborate the patient's account. Various diagnostic services are used in conjunction with recording a clinical history including computerized axial tomography (CAT), magnetic resonance imaging (MRI), electroencephalography (EEG) and long-term video/EEG monitoring, therapeutic drug monitoring and neuropsychological services.[59]

Epilepsy is often misdiagnosed and therefore can at times be inappropriately treated.[60, 61] There are various issues that may contribute to the misdiagnosis of the condition. It can be difficult to differentiate between certain types of seizures and other conditions, most notably cardiac syncope which is recognised as one of the main differentials for epilepsy.[62, 63]

People are often diagnosed with epilepsy after they have a major seizure but may have previously experienced seizures that were subtle and it may go unreported.[22] Finally, the key symptoms and signs of epilepsy can be intermittent and brief and it is therefore possible that a patient will display no neurological signs associated with epilepsy at a particular point in time.[64] This can further complicate the process of achieving a correct diagnosis as clinical and EEG examinations may not show up any abnormalities but had they been obtained at a different time, abnormalities may have been identified.

The issues above demonstrate the importance of recording the clinical history for the diagnosis of epilepsy.[65] Optimum use of eHealth such as the epilepsy EPR can support epileptologists in making clinical decisions to inform as accurate a diagnosis of epilepsy as possible. For example, it is paramount for clinicians to have access to timely and up-to-date clinical information for the patient to ensure a diagnosis and treatment plan can be initiated and maintained for the patient. A patient with epilepsy relies on a multidisciplinary team of clinicians in diverse geographical healthcare settings including emergency care, primary care and tertiary specialist epilepsy services. There needs to be meaningful exchange of information gathered at each site that can be consistently understood by the patient's primary care givers. This can be achieved through the optimum use of standards-based epilepsy EPR.

The classification of epilepsy syndromes and seizures underpins the treatment of epilepsy. The classification of a patient's seizure type is dependent on key criteria such as a patient's age, the accuracy of the recording of their history and the quality of the investigations used. Seizures can be classified as partial, generalized, and unclassified. Partial seizures initiate in a specific or discrete region of the brain locally and then may or may not spread. Generalised seizures affect the whole brain at onset.[66] Epilepsy is considered a condition that has many aetiologies and should not be classed as a single disorder.

2.4.3 Selecting the correct anti-epileptic drug (AED)

This section outlines the type of AEDs currently available for administration, drug interactions, the side-effects that specific AEDs have, and the methods used to introduce and taper AED medication. Also the literature highlighted how certain AEDs are more effective for specific seizure types and also more suited to certain types of patient's e.g. new onset epilepsy, the elderly, women of child bearing age.

For several decades, different types of anti-epileptic drugs (AEDs) have been available for the treatment of epilepsy. Although there are surgical options for the management of epilepsy, administering AEDs remains the primary basis of treatment.[67] The principal aim of AED treatment is to attempt to reduce and stabilise seizure activity for the patient and to ultimately achieve freedom from seizures. To succeed with this objective, an ideal AED for a patient should demonstrate sustained efficacy and provide good tolerance for the patient

with limited side-effects.[68] There are several pharmacological treatments available providing good opportunities for patients to receive tailored drug therapy. There is some debate around the effectiveness of newer AEDs that have become available over the last few decades and whether they are more or less toxic than the more established reliable drugs such as Phenytoin and Phenobarbital.[59] There is uncertainty around the effects the drugs have on seizure frequency and whether they suppress seizures or "arrest" epilepsy over the long term. However, although the availability of newer AEDs may complicate management choices, it may also provide a new opportunity to better manage individual patients more effectively.[69]

The management of epilepsy using pharmacotherapy is complex. To achieve optimum management of epilepsy (e.g. seizure freedom), the clinician must choose the most appropriate AED or in some cases a combination of AEDs to suit the patient. It has been suggested that up to 70% of patients with epilepsy could live a life free from seizures assuming they are prescribed an appropriate selection of anti-epileptic drugs (AEDs) and that the patient medicates correctly i.e. is fully compliant.[70] Treatment selection should reflect the patient's syndrome/seizure type, lifestyle and their own unique clinical characteristics, including, for example, whether they have co-morbidities, their cause of epilepsy or mood disorders. The clinician will most likely consider the following factors when deciding on an appropriate drug for the patient: evidence around the efficacy and effectiveness of the AED for the individual's "seizure type, the patient's age, sex childbearing potential, history of adverse-effects, comorbidities and associated medications".[71] Ultimately the clinician will aim to get a balance between the correct AEDs for optimum seizure control with minimum adverse side effects for the patient. They also need to choose AEDs that help mitigate the consequences of long term treatment with AEDs.[72, 73]

Although a patient may have received appropriate medical treatment, it is estimated that 40% of patients with epilepsy do not attain seizure freedom.[74] It is suggested that more than 30% of patients with epilepsy have a drug-resistance to seizures, also known as, pharmacoresistance, which impacts negatively on both the patient and the health service they interact with. It is important to identify early on if a patient is at risk of pharmacoresistant epilepsy to minimise a patient's risk of disability, morbidity and mortality.[75]

It is recommended to start patients with new onset epilepsy on a single drug also known as monotherapy. Combination or polytherapy (more than one AED combined) should only be initiated should a patient fail to respond to monotherapy. Drug interactions (e.g. a substance usually another drug that affects the activity of a drug when both are administered together) are a common phenomenon observed during combined therapy. It is common for patients with epilepsy to have comorbidities making polypharmacy and therefore drug interaction more likely.[71] Drug interactions are a major concern in the clinical use of AEDS mainly because AEDs are prescribed over a long period of time and possibly over a patient's lifetime.

One of the most important considerations in selecting a medication for a patient is to consider how well a patient will tolerate the medication to try to avoid adverse effects. The main adverse effects or side-effects to AEDs can be classified as reversible or dose dependent, chronic and idiosyncratic. Examples of reversible side-effects include ataxia, sedation, cognitive dysfunction, chronic side effects that are not easily reversible include changes in body weight, hirsutism and idiosyncratic reactions such as skin rashes and liver toxicity. More serious side effects such as fatal liver toxicity (associated with an AED called Felbamate) and irreversible visual field defects (associated with Vigabitrin) are also possible and these AEDs are typically used only as a last resort in treatment[76].

It is imperative to try and control the symptoms of epilepsy and to minimise toxicity and the side effects of a medication.[77] Effective management is possible by gradually introducing a medication in order to attenuate certain side effects and by carefully tapering the withdrawal of the medication.[78] There is no standard way of withdrawing an AED for patients who are in remission as prognosis following withdrawal is different for each individual patient.[79]

2.4.4 Epilepsy Outpatient Clinics

The management of an epilepsy outpatient department is complex and challenging. A multidisciplinary team of epilepsy specialists including clinicians, nurses, neuropsychologists and neurosurgeons are devoted to providing comprehensive care for people with epilepsy. Clinicians play a key role in diagnosing, ordering and interpreting investigations such as EEG and telemetry, and provide review and follow-up services and treatment in the outpatient clinics. They are also responsible for providing support, supervision and educating other

primary healthcare providers in epilepsy. Sometimes other neurological conditions can mimic seizures. The main differential diagnosis for epilepsy is cardiac syncope.[22] Epilepsy specialists collaborate with cardiologists to differentiate between the two conditions. Specialist epilepsy nurses in the OPD setting tend to focus on providing advice on the treatment and the condition of epilepsy alongside education services and counselling for patients with epilepsy to help mitigate the sociocultural issues that patients face which can contribute to inadequate treatment and recovery.[22]

The two main types of patients who attend an epilepsy OPD include: patients who return for review with an existing diagnosis of epilepsy (not necessarily a correct one) and new onset patients with a clinical suspicion of epilepsy or initial diagnosis of epilepsy. For patients who have a long history of epilepsy, the paper chart can contain hundreds of pages. This makes it difficult and time-consuming for a clinician to access the information that they require as locating the chart and sifting through the paper chart can be a tedious task.[80]

As with other chronic disease, good practice suggests that patients with epilepsy receive an annual review, access to nurse led clinics and optimum clinical management in the community.[65]

Hadjikoutis et al. (2005)[22] discuss an approach to the patient with epilepsy in the outpatient department. They aptly define the service that an epilepsy clinic delivers and describe in detail the routine events that take place in an epilepsy clinic including the type of patients reviewed, tasks performed and information recorded. In particular they outline the clinical history that is recorded for a patient with epilepsy. The type of information and the flow of information captured throughout a patient-clinician encounter at an epilepsy clinic, should include the following: history of seizures, drug treatment history, medical history, family history, social history, physical examinations, investigations, management, surgery, details about vagus nerve stimulation, information for patients on lifestyle and questions from patients.

2.5 Conclusions

This chapter described the condition of epilepsy as an exemplar of a chronic illness in order to provide context for the thesis. It also provided background on eHealth and EHRs which are relevant to the research aims in this thesis. Gaining an understanding of epilepsy and

what is involved in an epilepsy OPD was also relevant because it was important for the author to understand the details of how staff worked in an epilepsy service, the role they had managing patients, the environment that they worked in, what processes they adhered to and what type of information was captured during patient-clinician encounters. Chapter 3 will give a literature review of the traditional and sociotechnical requirements engineering processes and sociotechnical principles and techniques that exist. Chapter 3 also presents an overview of the field of ethnography as the author in her role as BA in the epilepsy EPR programme, conducted observational studies as part of this research

Chapter 3 Sociotechnical Requirements Engineering in Healthcare

3.1 Introduction

As outlined in chapter 1, the aim of part one of this thesis was to understand how to design and deploy an EPR to meet clinical requirements using a sociotechnical perspective. It is widely recognised that there is a need to manage the social and organisational aspects of technology in order to contribute to successful IT systems, including EPRs.[81, 82] EPRs are designed, developed and used by people who work within organisations. People inevitably have different perspectives and expectations on what the EPR should do and how it should connect and share information with other systems (as discussed in part two of this research). People also have to work within a wider organisation that has its own culture and way of working with defined goals and rules. To help bridge the gap between technology and how people integrate technology into their work, a broader sociotechnical perspective is needed i.e. developing an EPR from a social, organisational and technical perspective.[83, 84] This research adopted sociotechnical thinking, that is, a holistic approach to the design and deployment of the epilepsy EPR ensuring that the social and organisational issues were given equal attention alongside technology concerns.

This chapter is concerned with the literature on sociotechnical system (STS) to inform the design and deployment of the epilepsy EPR in a real world clinical environment. The requirements, design and deployment of the EPR were based on broad STS principles (see section 3.3.4) which were used to guide and influence the EPR design. Traditional requirements engineering (RE) and ethnography were also used as methods for the design and deployment of the epilepsy EPR. This chapter describes sociotechnical systems, the theory behind STS and gives an overview of common sociotechnical principles. Literature on traditional requirements engineering is outlined in section 3.2. Section 3.3 describes sociotechnical requirements engineering including the theory behind it, the role of STS in healthcare and the definition of STS including its components and dimensions. Given that the RE process used in this thesis was conducted from an STS perspective, ethnography through observational studies (See section 3.4) was used to achieve this. Ethnography is a qualitative methodology that is aligned with STS philosophy and enables the researcher to

capture requirements that are richer in context, and therefore provides evidence to support how an STS approach can be used. This combined approach of sociotechnical requirements engineering and ethnography seeks to understand human beings and the nature of their transactions with each other (e.g. relationships) and their work environment alongside the technology that is used.

3.1.1 Business Analyst (BA) role in Sociotechnical Requirements Engineering

The business analyst (BA) plays an important role acting as a mediator in STS RE and may undertake tasks such as observations of the end-users work and interpreting this work which helps to inform and enhance requirements by providing rich descriptions about the requirements. Coiera and Tomb (1998) define observational studies as "an effective method for understanding clinical needs of users and to accommodate analysis of communication behaviour amongst healthcare workers".[85] The BA records the results in a user requirements specification or a series of analysis models.[86] It is important for business analysts to gain a clear understanding of the user requirements and have the capability to communicate them effectively to ensure that a system fits with the end-users' needs and expectations and to ensure a system is fit for purpose. The BA must explore the environment that the system will be used in by observing the end-users' work practices. It is well recognised that the likelihood of delivering requirements that match the end-users' needs and expectations may only be realised when a system has been designed and is operational and evaluated from a socio-technical perspective.[87]

3.2 Traditional Requirements Engineering

The ultimate aim of any eHealth project, including EPRs, is to build a system that will do what the user expects and needs, to deploy the system on time and within budget. RE is a critical stage of the overall software development process[88] with several of the most common reasons for failures in system development relating to inadequate requirements engineering.[89] Traditional requirements engineering has a clear and structured process. The purpose of RE is to outline in an unambiguous and complete way the user requirements associated with the system, to capture what the user wants from the system and to bridge the communication gap between the intended end-users and the software developers. A complete RE process typically includes a set of activities such as requirements elicitation, analysis, negotiation, documentation and validation of requirements with corresponding

methods and techniques for each activity.[90] RE aims to reduce ambiguity about what is required by the end-user and help to produce clear and concise user requirement specifications (URS), a blueprint that enables software developers to build a system which meets the expectations and needs of end-users.[91, 92]

3.2.1 Requirements Engineering Process

Requirements engineering (RE) outlines the processes involved in the requirements lifecycle and aims to certify that requirements are developed, managed and tested in an effective way.[83, 91] A requirement is "something that the system must do or a quality that the product must have. Usually a requirement exists either because the type of system demands certain functions or qualities, or the client wants that requirement to be part of the delivered system".[86] RE aims to specify what systems should accomplish rather than how they should be accomplished.[93] Software engineering involves the process of how a system is built. According to Boehm (1981)[94] RE is defined as "designing the right thing" as opposed to software engineering which is "designing the thing right".

A typical generic RE lifecycle is comprised of two core components namely requirements development and requirements management. The development stage of RE should include definitions of the business, user and system requirements. Requirements development activities occur in the early stages of the software development lifecycle. However, requirements can evolve throughout the entire software lifecycle given that RE is an iterative process.

It is well recognised that there is no standard requirements engineering process that will fit all organisations. A complete requirements development process could include a set of activities such as elicitation, modelling and analysis, negotiation and validation of requirements with corresponding methods and techniques for each activity. The following sections will describe each of the activities and any corresponding techniques commonly used for a generic RE development process including: requirements elicitation, analysis, negotiation and validation.

3.2.1.1 Requirements elicitation

Requirements elicitation is the first and possibly the most important step in requirements development and is closely linked to the other RE activities as specified requirements need to be interpreted, analysed, modelled and validated.[95] It is particularly important when designing complex, sociotechnical systems such as clinical information systems .The word elicitation is often used rather than to "record" requirements as there is more to capturing requirements than simply asking the right questions. The purpose of requirements elicitation is to collect requirements from a variety of stakeholders and sources such as end-users.

There is no best fit model for eliciting requirements and various elicitation techniques exist and are often used in conjunction with each other. Requirements of systems are rarely static and it is the role of the BA to decide on what the best techniques to use dependent on the domain and the software system that needs to be developed. As stated by Gougen and Linde(2003)[96] every method or technique has some limitation and a combination of various methods can be useful and applied to particular problems. There are a number of reasons for using an assortment of elicitation techniques such as different stakeholders holding different viewpoints, dependent on the size, scope, complexity and amount of stakeholders involved in the software project.[97]

Some common elicitation techniques include interviews, questionnaires, analysis of existing documentation, scenario analysis, observation and analysis and prototyping.[96] Davis et al. (2006)[98] conducted a systematic review on elicitation techniques and their effectiveness which cited interviewing as one of the most valuable techniques for gathering requirements. Gougen (1993)[96] outlines some criticisms on certain requirements elicitation techniques including how interviews, particularly questionnaires, are inconsistent as they have different meanings and are interpreted differently by the various people conducting them.

Gougen (1993)[99] believes requirements elicitation cannot be solved in a purely technical way. Nytro, Sorby and Karpati (2009)[100] suggest that observation is a suitable approach to requirements gathering and can be used repeatedly in iterative design. Observations are useful to elicit early requirements that are not well understood and can inform domain modelling and stakeholder identification and it can also be used in other stages of the RE lifecycle given the iterative nature of the RE process. The use of ethnography is a proven

qualitative method in the fields of human computer interfacing, computer supported cooperative work and requirements engineering.[96] Savage (2000)[101] calls for there to be more of an uptake for its use in healthcare. There are some good examples of where ethnographic studies have been used to describe the communication, information needs and behaviour of healthcare staff and Berg in particular has published extensively in this area and has performed several ethnographic studies.[14, 102-104]

3.2.1.2 Requirements analysis

Requirements analysis aims to evaluate the quality of the requirements that were recorded during the elicitation stage of the RE process. The key objectives of requirements analysis are to examine requirements individually, identify and highlight any issues and discuss the issues and risks with end-users to agree solutions. Criteria used to analyse individual requirements are analysed using a check-list to identify any potential errors include checking that the requirement is necessary, unambiguous, consistent, complete and feasible.

3.2.1.3 Requirements Negotiation

This negotiation usually between the BA and the end-users is an integral part of the analysis stage and helps to confirm that the correct requirements have been gathered and any changes that need to be made are agreed with the end-users helping to manage their expectations. Requirements analysis and negotiation combined is also known as validating the requirements. End-user meetings and wider stakeholder meetings if necessary are organised to discuss and negotiate on requirements. Difficulties arise in the negotiation process when stakeholders are not willing to compromise and have extreme viewpoints on a particular requirement. To overcome this, requirements are prioritised to help highlight what is the most critical. Elicitation, analysis and negotiation are very closely aligned, is a complex process and will involve numerous iterations.

3.2.1.4 Requirements Documentation

The output of the requirements analysis is a requirements document which once approved and signed off by relevant stakeholders is an important document with an overall objective to act as a contract between the software supplier/developers and the customer. Undoubtedly it needs to be an unambiguous, transparent, complete, maintainable and

concisely written document that will provide a clear picture of the software product to be developed.

3.2.1.5 Requirements Validation

The validation phase is usually conducted after the requirements analysis. It ensures that any requirements documentation including specifications and models are accurately recorded and meet the end-users expectations and needs. Requirements are checked to ensure they are complete, relevant, traceable, testable and feasible. Each requirement must be testable making the user requirements a useful tool in the testing phase of the overall software development lifecycle. User acceptance test (UAT) cases should be written up with the requirements. UAT can facilitate the validation of the software systems' functionality to ensure the software design and development meets the users' requirements. The validation process demands the direct involvement of end-users in reviewing the requirements.[105] Prototyping of requirements (functions and features of the software) can be useful at this stage of the RE process as it can assist users in visualising or experience with working a system, particularly if the system did not previously exist (e.g. bespoke).

3.2.1.6 Requirements Management

Requirements management may be applied to all activities from elicitation to validation and is used to trace requirements throughout the software development process to maintain consistency between deliverables and the project plan. It covers tasks such as the unique identification of requirements, change management of requirements and the generation of a user requirements document (URS). It is an ongoing activity and will feature through the entire software development lifecycle.

Section 3.3 below will describe requirements engineering using a sociotechnical perspective including the theory of STS, definitions of STS including the definition that is used for STS throughout this research, the most commonly defined STS principles and STS dimensions and finally issues around transposing STS design principles into practice.

3.3 Sociotechnical Requirements Engineering

Traditional RE is not always suitable for developing intricate systems such as an EPR that needs to function in a complex healthcare environment. Traditional RE focuses more on

what should be achieved, what technical features should be included without considerations for the user's social and organisational issues e.g. considerations about how an EPR should be incorporated into workflow. It is necessary to develop the requirements from a broader sociotechnical perspective that takes into account the highly collaborative, diverse work typical in healthcare.

Managing requirements from a sociotechnical perspective allows designers to gather requirements and elicit rich descriptions of the environment surrounding the EPR.[2] The value of the traditional requirements engineering process is acknowledged and its continued use in the design and development of complex systems is recommended as it is a proven process that adds significant value to the end product. However, Baxter and Sommerville (2011)[106] endorse that requirements should reflect socio-technical processes suggesting that

"*We need to develop guidance for requirements writers that allows them to express a richer picture of the socio-technical systems to engineers responsible for system development".*

According to Cheng and Atlee (2007)[105] requirements descriptions are written in terms of the user's environment and describe the impact that the system may have. Requirements descriptions tend to offer a more simplistic explanation of the requirements over the technical specification by precisely defining the problem area that the proposed solution should solve. This method is important given that a core problem with designing software systems is that various players involved in the software development process such as analysts, developers and the end-users can have very different interpretations about what a solution should be and what is truly needed.

3.3.1 Sociotechnical Systems Theory

In early studies of STS theory, a negative impact on productivity was demonstrated when changes were made to the technical component of work without equal attention to the social structure and human requirements.[15] Grounded in the social sciences, STS can be attributed to the longstanding efforts of psychologists Emery, Trist, and the Tavistock Institute of Human Relations (London) in the 1950s. Their seminal work introduced novel methods such as ethnographic studies.[107] The evolution of STS theory was borne out of

the perceived dehumanising effect that the introduction of new technology had on workers. Trist and Bramforth (1951) conducted studies on the effects of mechanisation (i.e. automation replaces human workers by machines) of British coal mines. They concluded that mechanisation had actually decreased worker productivity instead of producing an expected increase in productivity. Mechanisation affected how teams worked together and divided the teams who had previously provided the complete coal mining process. Also, the equipment from the machines was so loud that it interfered with how people communicated and hindered teamwork. The findings suggest that the problems with the introduction of the new technology (machinery) were due to lack of investment in the social and human requirements rather than the automation of new machinery. By not considering the social aspects, the overall result for the English mining industry was decreased productivity and labour strife. Hence, the principal goal of sociotechnical design was aimed at improving the quality of employees working life and job satisfaction.[107, 108]

3.3.2 STS in Healthcare

Healthcare is an example of a highly complex STS and is composed of many interdependent social, technical and organisational elements.[109] Greenhalgh et al (2008)[110] make a strong case for using a sociotechnical approach in healthcare based on an evaluation of the Summary Care Record Programme, part of the UK NPFIT project. They advocate the use of a 'user pull model of change' as opposed to a 'technology push' method and highlight the need for changes in the working practices and job roles of users, that is, the wider social systems. A STS philosophy is acknowledged as being a suitable approach for developing eHealth applications within health informatics.[111] This is echoed by Berg and Toussaint (2003)[112] who recommend that it is necessary to gain a complete understanding of a user's work structure in order to develop health IT systems that are acceptable to the user and STS complements this.

In healthcare a hospital could be considered an organisation that has its own culture, politics, processes, policies and procedures (both internal and externally at a national and international level). Each hospital can have many departments covering different domains and specialities both clinical and administrative. The people (hierarchical with different levels of users) within the organisation and the departments they belong to develop their own culture and business processes to carry out their work. Various IT systems within a hospital need to integrate effortlessly to support people's work practices and cater for different

business processes. All components belonging to the hospital system need to connect and communicate effectively to allow it to function appropriately.

An EPR rooted at local level e.g. at a hospital department level can be significantly impacted by processes carried out at other departments within that hospital and by hospital management.[113] It can also be greatly influenced by its external environment such as government policies and regulators and broader economic, political and cultural systems. [111] This is echoed by Brown and Vergragt (2008)[114] who state 'it has become increasingly clear that human-IT micro systems are themselves embedded within larger systemic contexts, and that both these contexts, as well as the interactions and change processes both between and among them, need to be clearly conceptualized and explored in greater detail'. [114]

The introduction of an EPR within a hospital may result in altered clinical roles, work processes (patterns, behaviours and routines) and the culture of a clinical department.[115, 116] To help to accommodate this change, an EPR should be viewed as an active component of the clinical environment that should seamlessly integrate with clinical staff work processes and behaviours and any organisational considerations that need to be adhered to. An EPR should not be viewed in isolation in its intended clinical environment.[117, 118] The human, organisational and technological elements of an EPR should be viewed and managed as a network rather than separate entities.[102] Any new change that impacts a business such as the introduction of an EPR will affect all three components of a STS.[118]

3.3.3 Defining STS

The term 'sociotechnical systems' (STS) is loosely used to describe many complex systems, including healthcare, as outlined above. As suggested by Greenhalgh et al. (2008)[29] 'in socio-technical systems (dynamic networks of people and technologies), both people and technologies 'act' (i.e. do things) but not in the same way. For example, people have feelings, motives and ideas whereas technologies do not'. Badham et al (2007)[119] summarise five key aspects that constitute a sociotechnical system, namely that the system: "has interdependent parts, adapts to and pursues goals in external environments, has an internal environment comprising separate but interdependent technical and social subsystems provides choice, i.e. system goals achievable by more than one means

performances depend on jointly optimising the technical and social aspects of the system".[119] (Taken directly from Badham et al, 2007).

The literature suggests that employing a sociotechnical approach to IT system development and implementation can lead to better user acceptability and is more likely to deliver better value to all stakeholders involved.[120] This can only be achieved when the sub-systems are optimised and working seamlessly together as a network in order to deliver a system that satisfies end-users.

At a high level, Mills (2006)[121] defines a sociotechnical approach as an "integration of two essentially different sub-systems, the socio (people-related) sub-system and the technical (equipment) sub-system". Harrison et al (2007)[122] expand on the definition describing how early sociotechnical systems research 'documents dynamic, mutual influences among the social subsystem (people, tasks, relationships), the technical subsystem (technologies, techniques, task performance methods, work settings), and their social and organizational environments'. [123, 124] In this research, STS is defined as dynamic networks of people and technologies that has three components: social, organisational and technology. These STS components and their dimensions are defined in figure 3-1 below.

- **Social component** describes the human factors related to the people who work within and across an organisation and focuses on their behaviour and attributes (skills, attributes, values).
- **Technology component** describes the type of technology that people use including hardware, software, data, physical surroundings and machines. The technological aspects can incorporate system processes, tasks and quality dimensions of that technology.
- **Organisational component** is used to describe the business of an organisation in terms of its environment and structure. It includes dimensions such as the organisational culture that people work in, including the politics, procedures, laws and regulations that surround them.

Based on Yusof (2008)[125], Harrison et al (2007)[122]

Figure 3-1 Definition of STS including components and dimensions

3.3.4 STS Principles

There is no single, universal standard method for using a sociotechnical approach for system design. This section will outline some the most common STS principles which underpin the sociotechnical philosophy. Various sociotechnical principles have been articulated and are well researched. However, STS principles provide advice to designers rather than a detailed methodology. Table 3-1 below summarises some of those most common STS principles. The most popular principles were devised by Cherns (1976)[126] and later revised by Clegg (2000)[127]. STS principles feed into discussions about design relating to organisational and social aspects of a system. They falter in not providing the implementers of the systems with any practical guidance. Clegg (2000) updated and extended Chern's principles by adding more principles for STS design and to reflect more modern developments (in terms of ways of working). They are also pitched at a high level of design, offering guidelines similar to Cherns. Both Cherns' (1976), Chern's (1987)[128] and Clegg's principles strongly outline that design needs to reflect the needs of the stakeholders.

Table 3-1 Common sociotechnical principles
(directly taken from Peltu et al. 2008)

Principle	Description
A systems view	Identify and address goals for organisation (e.g. aims and objectives), human (e.g. motivation) and technology dimensions.
Social shaping	Understand that system design, implementation and use are extended, socially-shaped and political processes.
Core process integration	View organisations as a number of core service-delivery and other processes that typically cut laterally across different functions.
Local adaptability	Meet planned and unpredicted change through as much local shaping as possible, with variances controlled at their local source using the combination of system elements most appropriate to a given context.
Boundary management	Organisational and work boundaries are crucial and frequently highly political, so should be managed carefully to promote the sharing of knowledge and experience.
System incompleteness	Ensure design and adaptation is ongoing, as requirements are likely to be continuously evolving.
Holistic evaluations	Regularly review progress and adjust course as necessary, bearing in mind the 'system incompleteness' principle.
Multi-stakeholder needs	Take account of the needs of the enterprise, the system's users and those affected by its use.
User ownership	Build strong ownership of systems and their design by those who use and manage them in their working environments.

User participation	Support meaningful, not token, inputs to system design and implementation from all users and other key stakeholders.
Social support	Establish systems in an environment that supports and encourages desired behaviours.
Resource support	Provide education and financial resources to underpin effective design, implementation, review and ongoing evolution.

3.3.5 Defining STS Dimensions

In their evaluation of the summary care record programme in the UK, Greenhalgh et al (2008)[110] emphasise the need for, and difficulty of, adopting a sociotechnical approach to eHealth. They defined multiple levels as a way of analysing the dimensions of a sociotechnical network as illustrated in table 3-2 below. The different levels include the macro level or analysis at a national or regional level, the meso level or organisational level, and finally the micro level which means conducting analysis at the clinical encounter. The dimensions that they included are also highlighted in table 3-2 below.

Table 3-2 Socio-technical network showing multiple levels of analysis
(directly taken from Greenhalgh et al., 2008)[29]

Level	Dimension
Macro Level e.g. National and Regional Level	National and Regional Policies and Priorities Economic Climate Legal constraints Technological Developments Social Movements (e.g. civil liberties) Professional Norms and Standards.
Meso Level e.g. Organisational level	Hard elements such as: Job descriptions Training and work routine IT systems and in-house knowledge Culture and support for innovation and risk-taking skill sets and resource allocation Soft elements such as: Organisational culture and level of support for innovation and risk-taking
Micro Level e.g. Clinical Encounter	Knowledge (explicit/formal and tacit/embodied) which humans possess; the meanings they assign to technologies and to their

	own and others' behaviour; and how these are affected by wider social structures including: ▪ What we think other people know? ▪ How we expect them to behave? ▪ How trust plays out in different circumstances? ▪ What is 'inscribed' in technologies (e.g. as decision models or security protocols)? ▪ What technologies can and cannot do in particular conditions of use?

3.3.5.1 STS Dimensions for evaluating the epilepsy EPR in a real world practical setting

The STS dimensions that were used to evaluate the deployment of the epilepsy EPR (in the epilepsy clinic) were based on Yusof et al. (2008)[125] evaluation framework for health information systems. Yusof et al. (2008) developed an evaluation framework which aligns with the STS components of human, organisation and technology (HOT-fit). They conducted critical appraisal of other HIS evaluation frameworks and they analysed other models on information system evaluation. The HOT-fit evaluation framework was built on two different models, the first called the Information Success Model developed by DeLone and McLean (2003)[129] and an IT Organization Fit Model (Scott-Morton,1991). Yusof et al. (2008) evaluation framework was tested using a case study on a fundus imaging system used in a primary care organisation in the UK and they found that "comprehensive, specific evaluation factors, dimensions and measures in the new framework (HOT-fit) are applicable in HIS evaluation". They argue that their HOT-fit evaluation framework can be applied to any Health Information System in general. Examples of evaluation measures according to their corresponding dimension and factor are listed in Figure 3-2.

3.3.6 From Design Principles to Practice

There is extensive research conducted on transposing STS theory into practice. Scott and Briggs (2010)[130] and Li (2010)[109] highlight the importance of closing the gap between STS research work in academia and its implementation in practice. However, there is little evidence of good working examples to demonstrate that the STS approach has been successful in translating from the research world into practice.[131]

Historically there has been a lack of uptake of STSD in general for healthcare IT systems (Reddy et al., (2003)[2], however some work has been carried out on how to use a sociotechnical approach for RE particularly around requirements elicitation and anaylsis.[102], [14],[132] Baxter and Sommeville's (2011)[84] concern is that introducing STS into practice is challenging because aligning STS with existing software engineering system methodologies is cumbersome particularly in relation to changing processes and in persuading developers of its benefit. Some efforts have been made in health informatics to drive the STS agenda into practice. Whetton and Georgiou (2010)[111] propose that 'academics and professionals need to engage in a critical dialogue to identify, discuss, and question different perspectives and understandings' of STS in healthcare in order to fully exploit its potential. Li's (2010)[109] publication outlines a model to help link theory and practice of STS in health informatics.

Mumford (2006)[107] carried out an extensive review of STS design approaches and findings from various projects carried out in the 1960's and 1970's which led to a methodology based on sociotechnical principles called the Effective Technical and Human Implementation of Computer-based Systems (ETHICS). [133] ETHICS combined design from both an IT and work (job satisfaction and worker's quality of life) perspective and how personal achievements matched organisational goals.

In summary, there is no single method for conducting a sociotechnical approach to system design. The STS principles that exist are used for guidance and are not concrete methods. The sociotechnical dimensions, as outlined in table 3-2 and Yusof's evaluation framework provide an appropriate way of using a sociotechnical approach in practice. Section 3.4 will outline how ethnography, a qualitative methodology, aligns with sociotechnical thinking.

Technology			Human		Organization		Net benefits
System quality	Information quality	Service quality	System use	User satisfaction	Structure	Environment	
Data accuracy, data currency, Database contents, ease of use, ease of learning, availability, usefulness of system features and functions, flexibility, reliability, technical support, security, efficiency, resource utilization, response time, turnaround time	Importance, relevance, usefulness, legibility, format, accuracy, conciseness, completeness, reliability, timeliness, data entry methods	Quick responsiveness, assurance, empathy, follow up service, technical support	Amount/duration:(number of inquiries, amount of connect time, number of functions used, number of records accessed, frequency of access, frequency of report requests, number of reports generated), use by whom? (direct vs. chauffeured use,) actual vs. reported use, nature of use (use for intended purpose, appropriate use, type of information used,) purpose of use, level of use (general vs. specific,) recurring use, report acceptance, percentage used, voluntaries of use, motivation to use, attitude, expectations/belief, knowledge/expertise, acceptance, resistance/reluctance, training	Satisfaction with specific functions, overall satisfaction, perceived usefulness, enjoyment, software satisfaction, decision making satisfaction	Nature, (type, size) culture, planning, strategy, management, clinical process, autonomy, communication, leadership, top management support, medical sponsorship, champion, mediator, teamwork	Financing source, government, politics, localization, competition, inter-organizational relationship, population served, external communication	Clinical practice (Job effects, task performance, productivity, work volume, morale,) efficiency, effectiveness (goal achievement, service), decision making quality (analysis, accuracy, time, confidence, participation), error reduction, communication, clinical outcomes (patient care, morbidity, mortality,) cost

(Taken directly from Yusof et al. 2008)

Figure 3-2 Yusof's Evaluation Framework

3.4 Ethnographic Methods in Clinical Setting for Requirements Elicitation and System Design

Ethnographic analysis is a method that allows designers to examine and understand individuals in their own work environment which is a non-trivial exercise. Ethnography is a qualitative methodology that is aligned with the sociotechnical philosophy. The author used ethnography, through observational studies, to elicit requirements in the requirements elicitation phase of the design of the epilepsy EPR (see chapter 4). Observational studies were also used at the evaluation stage to understand how the EPR was being used, how useful the EPR system design was in the epilepsy service (see chapter 5). The findings from the observations were fed back into the requirements. Ethnography was chosen because it is a qualitative way to capture rich content about the end-user's expectations, needs and work environment. Often there is a need to employ alternative methods that go beyond the traditional data collection methods of questionnaires and surveys. Because ethnography is a qualitative research method, it is an effective means to understand the nuances and intricacies of a complex healthcare organisation.[134]

Ethnography is used across many disciplines, principally in anthropology and sociology, but also in the areas of education and medicine, making it difficult to find a standard definition as interpretations and views vary. However, Kearney (2004)[135] provides a comprehensive description of ethnography describing it as a method for "direct, largely informal interaction with the people being studied so as to provide the opportunity to learn about their society and culture as naturally as possible". Lambert et al (2011)[136] have collated a broad list of definitions for ethnography but assert that given the diversity it is easier to state the role of the ethnographer than to define it. Part of the ethnographer's role is to conduct direct observations of participant's routine behaviour, their work tasks and their natural environment over a sustained period of time by questioning everyday practices that are often taken for granted by the participant.[137, 138]

An ethnographic inquiry can incorporate both qualitative and quantitative methods (Savage, 2000).[101] Ethnography does not favour any particular method of data collection. Dixon and Woods (2003)[139] describe ethnography as the "closest to a gold standard" in qualitative research and is one of the central data collection method used, alongside interviews.[140]

Authors Holy (1984)[141] and Lambert et al.(2011)[136] concur that the most defining feature of ethnography is the use of prolonged fieldwork using observation.

Observational studies are a valuable technique for gaining an understanding of clinical need and to analyse how healthcare workers communicate among themselves.[85, 142] There is a premise that when people are familiar with each other and interact routinely in their own familiar setting they start to create their own realities.[137] Observation is an ideal way to distinguish between what people "say they do and what they actually do".[143] Other data collection techniques can be used to enhance observational studies such as conducting informal interviews, audio or video recordings and analysing relevant materials such as posters, memos, forms etc.[139] Depending on the objectives of the study, Merriam (1988)[144] suggests structuring observations using criteria such as the participants, the setting that the observations take place in, activities and interactions, frequency, duration and non-verbal interactions.

Ethnography allows the researcher to understand how clinicians and other healthcare staff behave by observing how they practice their work. Importantly, the researcher can view the participants' beliefs and practices as they occur and in the context in which they occur.[134, 145] It gives the ethnographer a nuanced and intricate understanding of the cultural context and the relationships between people.[137] This helps to generate a thick or rich description of the people and their environments.[146] The benefit of generating such a rich description is that it allows the ethnographer to interpret descriptions by looking for repeatable thoughts and behaviours with various participants and in different situations.[136] It is important to describe the observation by recording the most relevant and noteworthy detail that is meaningful rather than recording data in isolation[147] as is the 'Taylorist' research approach.[148] The Taylorist method is non-interpretive and the ethnographer typically engages in counting instances such as examining how often a person performs a specific task or captures the time taken by observing how long a task takes.

Although there are no prescribed rules or guidance to practice ethnography, it is well established that ethnographers should be reflexive.[143, 149] Reflexivity is described as the "sensitivity to the ways the researcher and the research process have shaped the collection of data, including the role of prior assumptions and experience".[143] The researcher should aim to provide an unbiased interpretation of what a participant is saying or doing and needs

to demonstrate evidence around how they produced their interpretation.[150] Recordings should not simply provide a description of the event or scene but need to include a specific context. The success of an ethnographic study and how recordings are interpreted are dependent on the researcher's skills and ability to be objective, their interpersonal skills[151] and prior professional and academic (theoretical) experience influencing how rich descriptions are gathered and interpreted.[152, 153]

Both the social characteristics of current work practice and the technical features of the system should be considered when performing requirements gathering and analysis.[2]

Criticisms do exist regarding ethnography and its role in the elicitation of requirements. The paradox that surrounds ethnography is that it provides rich observational data that is invaluable for eliciting information around the cultural context in which a technical system will reside. But in practice ethnography such as observational studies can be difficult to conduct as summarised by Viller and Sommerville (2000).[154] The results from an ethnographic inquiry are difficult to communicate to a design team as the unstructured notes with rich descriptions are highly qualitative. Therefore there needs to be a mechanism to transform them into a format that is more appropriate for software developers to clearly understand (i.e. there are cultural and language barriers between sociologists and technologists). Sorby et al. (2007)[95] suggest that this can be overcome by carrying out more focused ethnographic studies whereby the researcher has designed predefined or closed questions prior to entering the research field.

Ethnography like all research methodologies has its limitations which are well documented in the literature.[155] Campbell (1995)[156] lists some risks that need to be considered when performing ethnography. They include:

- Difficulty with gaining access to the research field where the observation will take place,
- Establishing relationships between the researcher and the participants as difficulty can arise when there is a conflict between the "bias of the researcher over the voice of the researched!"
- The possibility of becoming so immersed in the culture "going native" whereby you lose sight of the research focus.[157]

A possible risk is the Hawthorne effect where the participant may change their behavior or be more motivated to please the observer as they are conscious of being under scrutiny (i.e. the demand effect).[156] Ethical issues are particularly prevalent in relation to direct participant observation which raises issues around informed consent.[101] Ethical issues need to be clearly confirmed and negotiated with study participants prior to observations and continuously throughout the study. A further criticism is that ethnography as a qualitative method does not produce generalisable results. They are specific to the study it is being performed in; however many authors suggest that this is also the case for other qualitative methods.

3.4.1 Prior research in usage of ethnography within software development process

Sociotechnical design (STSD) approaches are advocated for systems development. STSD may not always be explicitly referred to as such and STS philosophy underpins areas such as participatory design methods, computer supported cooperative work (CSCW) which is concerned with the social nature of work and the need to develop support systems and ethnographic approaches to design. STSD methods can be categorised based on the how well they align with three key stages of the systems engineering lifecycle analysis, design and evaluation. Baxter and Sommerville (2011)[106] indicate how a range of STS approaches relate to the different phases of the software engineering life cycle. All of the STSD approaches align strongly with one particular phase of the software lifecycle.

A key philosophy of STSD is a focus on participatory methods where end users are involved in the design process. User participation is utilised in software development using agile methods such as extreme programming (XP), Dynamic Systems Development Method (DSDM), and Scrum.[158] The ETHICS framework (1983, 1995), was mentioned in section 3.3.6 of this thesis and is an example of where an STS project was paired with agile methods of software development. Although the concept of user participation is at the essence of STSD, the uptake and use of user-centred methods has been inadequate. For example, Eason (2001)[159] outlines that when participatory design methods have been used, user involvement was still largely to assist in the development of a techno-centric

system and participants were not involved directly with an integrated systems development process that incorporated both social and organisational requirements.

As discussed in section 3.4, ethnography which is influenced by the sociotechnical ethos is a methodology that highlighted the relevance of STS in the design (phase) of software systems.[160] The use of ethnography for requirements elicitation is a proven qualitative method particularly in the fields of human computer interfacing, CSCW and requirements engineering.[161]

The field of CSCW has implicit roots in a sociotechnical philosophy. [162] The benefit that ethnographic studies have brought to the field of CSCW has largely taken the form of improved understanding of the way in which work is socially organized, and how seemingly mundane tasks can play a vital role in the successful accomplishment of the work. An example is the work in the COMIC project which examined how the role of ethnography could be modified to make it more suitable for use in the software design process. This led to a number of different scenarios of ethnography in systems design which are all aimed at integrating the process of ethnographic study into the systems design process.[154] There are other proposed similar models for integrating ethnographic analysis both into conventional waterfall-based development approaches and also iterative methods.

The emergence of lean production and business process re-engineering largely dominated the software design industry in the 1980's and 90's and overshadowed the STSD approach. There is a disconnect between STSD and traditional systems development methods. Baxter and Sommerville (2011) advocate for a pragmatic approach to the integration of sociotechnical considerations into software procurement and development processes. They have a long-term research goal to develop the field of socio-technical systems engineering (STSE). This involves the "systematic and constructive use of socio-technical principles and methods in the procurement, specification, design, testing, evaluation, operation and evolution of complex systems".

3.5 Conclusions

The literature provides evidence that using an STS philosophy combined with traditional RE and ethnography for EPR design and deployment is highly valuable and suitable in a healthcare environment. The literature provided STS principles and dimensions that can be used as guidelines to inform EPR design and deployment. This research is concerned with

how an EPR can be designed and deployed using an STS perspective. For example, how can an STS EPR design be implemented in practice? Chapter 4 of this research will outline the STS approach that was used for system design. It also includes the findings that emerged from using an STS philosophy and what was involved e.g. what are the nuances when implementing an STS project? Chapter 5 describes an evaluation of the EPR in terms of its usefulness and usability in the epilepsy service. An evaluation framework was used which includes various STS dimensions that were used for this research and is outlined in section 3.3.4 above.

Chapter 4 Design of an epilepsy EPR using a sociotechnical perspective

4.1 Introduction

Chapter 3 of this thesis provided evidence to suggest that a successful EPR must be viewed from a sociotechnical perspective in order to design the right system in the right way in a healthcare setting. Medical work is a social process and work activity takes place in a highly collaborative work environment.[2] Therefore, it is important to understand not only the requirements but also the work context which can be facilitated using a sociotechnical viewpoint.

This chapter describes the process that was used in the analysis, requirements engineering and design stages of the epilepsy EPR development lifecycle emphasising how the sociotechnical ethos was embedded in the EPR development. It also illustrates the outcomes of the sociotechnical requirements and design stages. Some examples of rich sociotechnical requirements and a detailed description of the anti-epileptic drugs (AED) module of the epilepsy EPR are provided which demonstrates the sociotechnical system design. Chapter 8 also provides discussion on the sociotechnical aspects of the analysis, requirements and design. This chapter will first describe sociotechnical philosophy, including sociotechnical principles, which were used to inform aspects of the analysis, requirements and design of the epilepsy EPR. Section 4.2 describes the epilepsy EPR pre and post-implementation followed by section 4.3 which outlines the epilepsy EPR development lifecycle. Section 4.4 and 4.5 outline the requirements and system design respectively. The AED module, which was designed using the sociotechnical approach, is described in section 4.6.

4.2 Description of the epilepsy EPR

As part of sociotechnical thinking, it was important to understand the end-user environment and work setting where the epilepsy EPR would be in practical use. Section 4.2.1 describes the preliminary research that was completed by the author as part of an MSc in Health Informatics prior to this research, including business analysis that was completed and which is useful to revisit including business process mapping and use cases.[163] Section 4.2.2 illustrates the epilepsy clinic environment prior to the design and deployment of the epilepsy EPR and also how information was managed in the epilepsy clinic before the epilepsy EPR

was initiated. Finally a description of the epilepsy EPR post-implementation and what functionality is currently used in practice is outlined in section 4.2.2.3.

4.2.1 Preliminary Research

Some preliminary work was completed by the BA prior to this research. An MSc on requirements engineering[163] was awarded to the author in 2004 and the findings influenced this research in terms of the process used for requirements engineering and system design. Part of the MSc was to research potential vendors and software products that may have been able to meet the needs of the epilepsy service; however no suitable product was identified that matched the end-users needs. This was one of the factors that led to the decision to develop the epilepsy EPR in-house as a bespoke development. In addition, a postal questionnaire was sent to other epilepsy centres internationally (2003) to inform the MSc research how other epilepsy services managed their data on epilepsy and if they used and maintained an EPR or clinical information system. The findings suggested that there was very little activity around managing epilepsy information at that time. Two key pieces of information from the MSc are applicable to this research and are useful to revisit to provide clarity: (1) a business process map of a patient's journey through the epilepsy EPR (see figure 4.1) and (2) a use case map which identified 30 use cases for the epilepsy EPR (see Appendix A).

4.2.1.1 Process Flow Diagram of epilepsy clinic

The process map illustrates the patient's journey through the epilepsy clinic. Actors identified in the process include the patient, the secretary, the nurse specialist, junior medical, and the senior registrars and consultant. The diagram tracks a patient from their arrival to the epilepsy clinic to their departure. It demonstrates decision points that may affect the patient's route through the clinic. For instance, is the patient on the clinic schedule list? If yes, an associated paper chart is pulled and placed on the existing pile of charts on the secretary's desk indicating that the patient is in the queue to be seen by a nurse specialist. The importance of this map was to capture the "AS IS" state of the epilepsy clinic process before the introduction of an EPR and to capture the information flow and key decision points made by the end-users.

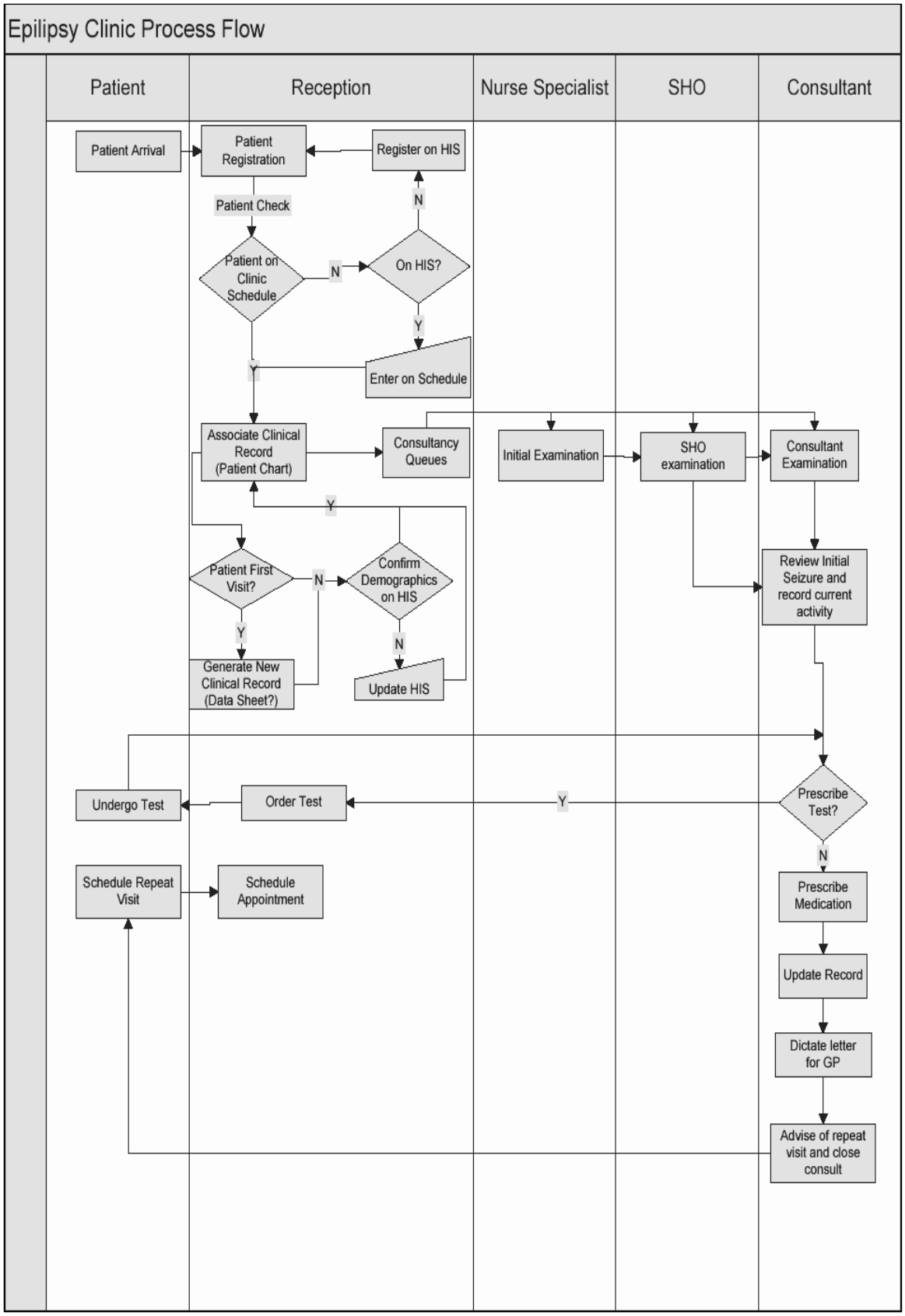

Figure 4-1 Process Flow through Epilepsy OPD

4.2.1.2 Use Cases

Use cases capture who (actor) does what (interaction) with the system to fulfil a particular goal.[164] There were 30 use cases identified for the epilepsy EPR (See Appendix A). The use case diagram for the epilepsy EPR illustrates all potential interactions between actors and the EPR system to satisfy a particular goal and was modelled using the unified modelling language (UML). Each of the 30 use cases were elaborated during the MSc. The BA worked with the champion users to flesh out what was required for each use case. A template was designed and both the use case diagram and the use case descriptions were communicated to the software developers.

- **Scenarios**

The use cases were elaborated during the MSc research using narrative descriptions elicited from end-users during formal interviews. Scenarios represented real life examples of how the epilepsy EPR could facilitate the management of patient care. Scenarios were also used to capture the social aspects of end-user's workflow.

This thesis used as input the use cases outlined above in section 4.2.1.2 and the scenarios that were agreed during the MSc. The following section 4.2.2 will provide a description of the epilepsy EPR and relates to the work of this thesis.

4.2.2 Epilepsy clinic setting (Pre-implementation)

Approximately 40,000 people in Ireland have epilepsy.[165] The epilepsy programme integrates clinical care and research through the work of a multidisciplinary team which provide services including an epilepsy out-patient clinic, a nurse specialist telephone advice service, the epilepsy pregnancy register, community services and a long term epilepsy monitoring unit. The care of an individual with epilepsy is the responsibility of a wider team of healthcare professionals whose roles include clinical neurologists, nurses, neurosurgeons, neurophysiologists, technical personnel, psychologists, neuro-pathologists and physical scientists. A number of tasks were associated with epilepsy care including diagnosis, recommendations for therapy and outcome measures such as efficacy and complications of treatment.[166] These tasks depended on accurate integration of clinical data from multiple heterogeneous sources.

It was agreed that the epilepsy EPR would be deployed in the first instance in the epilepsy out-patient department (OPD), as opposed to the in-patient epilepsy monitoring unit (EMU) or the telephone advice line service. This was because the epilepsy OPD was the hub of the epilepsy service and there was a cross section of staff of varying disciplines who delivered care to patients with epilepsy. The epilepsy OPD provided care for approximately 60 patients with epilepsy or suspected epilepsy at the weekly clinic. At the time this research took place, approximately 35 return-patients and 10 first-visit patients attended the weekly epilepsy OPD and the remainder consisted of patients with other neurological disorders.

4.2.2.1 Staff of the epilepsy service

There were 15 staff committed to delivering the overall epilepsy service (at the time of this research). They included 2 senior medics (1 consultant epileptologist and 1 senior epilepsy registrar), 3 junior medical doctors, 2 epilepsy nurse specialists, 2 epilepsy monitoring unit (EMU) nurses, 1 epilepsy pregnancy nurse, 1 epilepsy community nurse, 1 administrator, 2 medical physicists and 1 researchers (genetics of epilepsy). The end-users that are defined throughout this research are the staff described above who were expected to use the proposed epilepsy EPR.

End-users were familiar with health informatics but not with the concept of using a sociotechnical approach for the design of the epilepsy EPR. The BA provided end-users with educational sessions at two consecutive 1-hour weekly meetings using a Microsoft PowerPoint presentation describing the role of health information in medicine, EPRs, STS and their benefits. All of the multidisciplinary team particularly the senior management were very open to participating in the design of an EPR.

4.2.2.2 Information management at the epilepsy OPD (Pre-Implementation)

At the time this research was conducted, the paper chart was (and remains) the legal chart for recording patient information. Clinicians traditionally rely on the paper chart to carry out clinical tasks at the clinic for recording and reviewing patient information and to decide on diagnosis, treatment plans etc. At the epilepsy OPD either a paper proforma or blank continuation sheet was used by the clinicians during clinical encounters to handwrite the following information about epilepsy management: epilepsy syndrome diagnosis; current AEDs including dosage and frequency; list of prior AEDs; seizure description and

classification; change in seizure frequency; results of investigations and investigations pending; clinical observations; driving status; note on specific health and lifestyle topics discussed; and care plan. These handwritten notes were contained in the patient's paper chart. Over the course of the epilepsy EPR development (see section 4.3 below) this method of capturing and recording information on paper continued in the usual way.

In addition to the paper chart, electronic systems were available to authorised users throughout the hospital which the epilepsy EPR integrated with. There were two main electronic systems deployed throughout the hospital that was important for the epilepsy EPR to interface with including the Beaumont Hospital Information System (BHIS) and the Patient Information Profile Explorer (PIPE) described below. Another system that was used by the epilepsy programme at the OPD was the Vagal Nerve Stimulator (VNS) software. This software was supplied by an external company to Beaumont hospital and was accessed by end-users via an application using a laptop. The Beaumont hospital Information System (BHIS) is an electronic patient administration system. BHIS is the master source of demographic, admissions and clinic administration information for Beaumont Hospital patients. The Patient Information Profile Explorer (PIPE) is an electronic system which facilitates users to order and review patient's laboratory information and investigative procedures. Both the BHIS and PIPE systems were available for use on personal computers or thin clients at the OPD.

4.2.2.3 The Epilepsy EPR (Post-Implementation)

The epilepsy EPR is in daily use at Beaumont Hospital and has been operational since 2010 and approximately 5500 epilepsy patients have a validated electronic record.[80] Since this study took place some of the updates to the epilepsy EPR are outlined as follows: 'The modules of functionality that have been further developed include social history, clinical investigations, a vagus nerve stimulation (VNS) clinic, nurse telephone advice line, care-plan and a multidisciplinary meeting template. Current users of the EPR include consultant epileptologists, non-consultant hospital doctors, clinical nurse specialists, community epilepsy nurses, researchers, clinical management personnel as well as external users. An out-patient clinic, nurse-led telephone advice line, VNS clinic as well as clinical research projects are the type of epilepsy services that are currently supported by the EPR. The epilepsy EPR has a comprehensive audit trail that tracks system use. It incorporates clinical archetypes for representing a patient's clinical description and also provides the flexibility to

capture patient-specific nuances. The EPR architecture was designed to improve medical vocabulary and record keeping, to support the delivery of clinical services as well as clinical research and health services monitoring and planning. A reporting tool allows efficient interrogation and analysis of data about individuals or populations of patients. Clinicians managing epilepsy have more timely access to the same information thus advancing a model of shared epilepsy care'.[165]

The remainder of this chapter describes how the EPR was developed including the software development lifecycle with a focus on the sociotechnical analysis, requirements engineering and sociotechnical system design.

4.3 Epilepsy EPR Development lifecycle

This section outlines the overall software development lifecycle incorporating six stages: the planning, analysis and requirements, design, development, deployment and evaluation of the epilepsy EPR as illustrated in figure 4-2 and figure 4-3. This chapter is concerned with the analysis, requirements and design stages. The evaluation of the deployment stage is outlined in chapter five. The BA conducted the business analysis, requirements engineering and the design phases of the development lifecycle using a sociotechnical ethos. According to Clegg's (2000)[127] sociotechnical principles, it is advocated that a sociotechnical ethos is applied throughout the entire development lifecycle (Clegg's principle 5: Design is an extended social process).

4.3.1 Overview of the development lifecycle of the epilepsy EPR

The software development lifecycle was loosely based on the Rational Unified Process (RUP) which is an iterative software development lifecycle approach. This type of agile development aimed to deliver benefits such as early mitigation of risks, early visible progress and a system that more closely meets the needs of the users. A phased approach was used to deliver the different modules of the epilepsy EPR and iterative refinement of each stage of the epilepsy EPR development from system design to evaluation was carried out. Iterations were restricted to approximately eight week intervals (depending on the user requirements for that module) in an attempt to get user feedback as quickly as possible so functionality could be developed that more closely matched the end-user's needs.

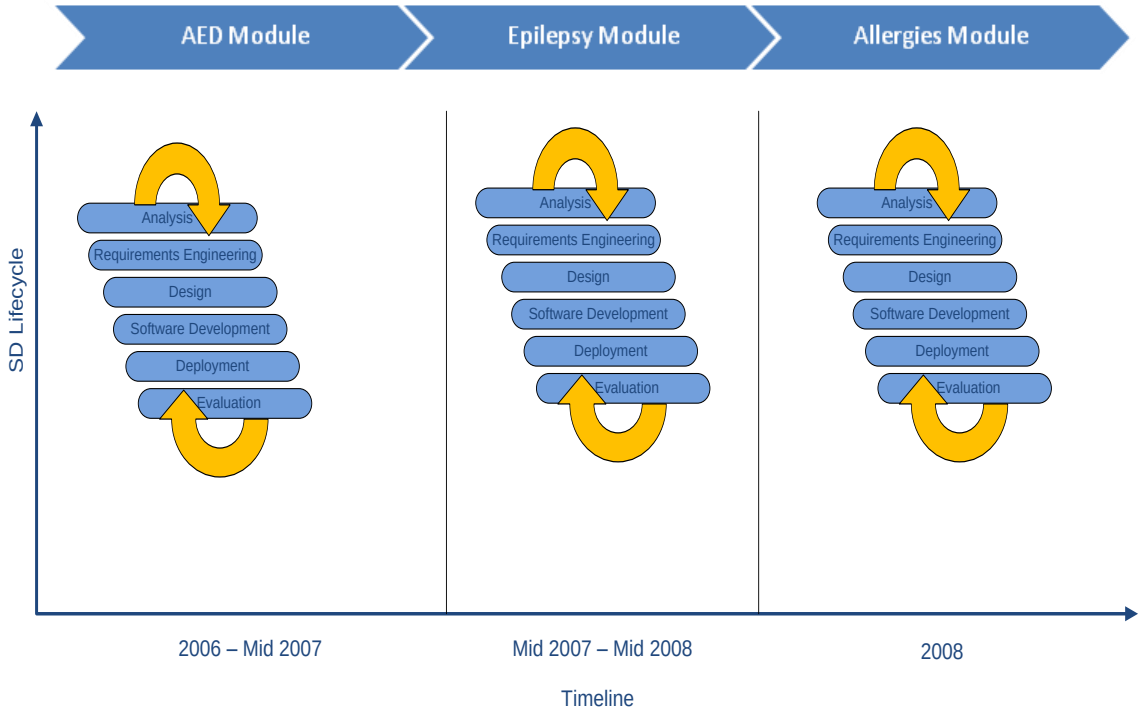

Figure 4-2 the iterative stages of the epilepsy EPR development lifecycle

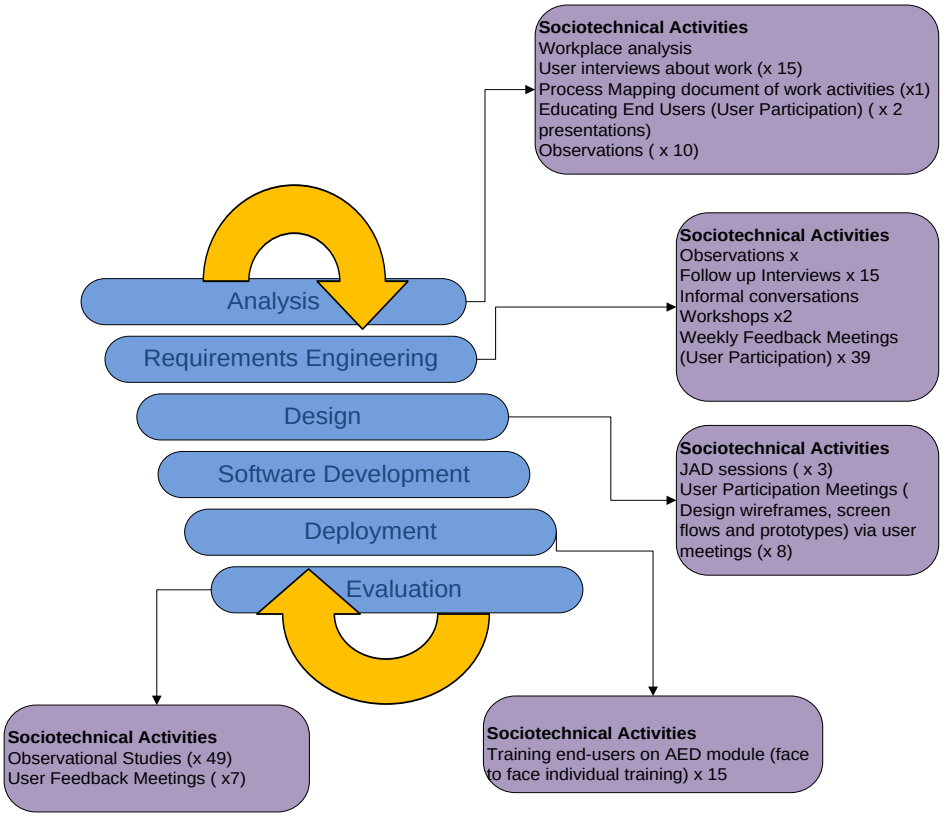

Figure 4-3 Sociotechnical activities associated with the stages for the development AED module of the epilepsy EPR

An overview of each stage of the epilepsy EPR development lifecycle is described below:

- **Planning phase** of the epilepsy EPR project was well documented and provided a comprehensive business case, project plan including a project initiation document and project schedule. These documents outlined important details for the EPR including the initial scope, timelines, identification of stakeholders, objectives and milestones.
- **Analysis and requirements engineering phase** (see section 4.4 below)

- **Design** using a ST ethos is described in section 4.5 below

- **Software development** involved software design, software engineering and testing which was undertaken by the in-house development team. The modules of the epilepsy EPR were developed based on the requirements that were supplied to the software developers by the BA. The technical system was designed using a modular, layered and standards-based architecture providing a generic EPR platform for customisation in the epilepsy domain and subsequently potentially in other domains. It leveraged data already available in existing hospital systems. Alongside the functionality documented in the user requirements, an important feature that was included in the EPR development was a comprehensive electronic audit trail to be used when the system was fully implemented and operational. Following the software development of the EPR module, rigorous system and user acceptance testing (UAT) were conducted and provided a measure of usability before the application was deployed into practical use.

- **Deployment** included an implementation plan, developed by the BA, to seamlessly roll out the EPR. This included carrying out end user training on each of the EPR modules released. Written instructions on how to use the EPR modules were given to participants; however it was more usual that the BA was involved in providing hands on support when the participant was using the epilepsy EPR. Individual training needs were assessed to identify gaps between the participant's current computer skills and computer skills required to use the EPR. This was based on interviews, job analysis and observation of the participant's work environment. Training was delivered in a variety of formats: face-to face training, group demonstrations and briefing sessions. The length of time per participant to fulfill training requirements

depended on the individual requirements of the end-users. Participants practiced "hands-on" with various modules of the epilepsy EPR on a test system. Fictitious patients were created on the test system for training purposes. The author provided onsite support at the clinic to reinforce training instructions.

- **Evaluation** of the design of the EPR was carried out at specific stages of the epilepsy EPR lifecycle which is a key sociotechnical principle. This was particularly pertinent at the design stage in relation to eliciting requirements where ethnography was used. Users were involved in all stages of the development lifecycle and their opinions fed directly into the revisions of the EPR design and development. The evaluation used qualitative methods such as ethnography and quantitative methods such as user acceptance testing using test scripts that took place in the user's own environment e.g. telemetry unit of nurse advice line offices, using fictitious patient information. Evaluation was carried out more formally with the AED module pilot implementation as discussed in chapter 5.

Three clinical modules that were designed first included the epilepsy history, anti-epilepsy drugs (AED) and allergies were designed using the development lifecycle. Section 4.4 below gives an overview of the sociotechnical dimensions that were considered when conducting the requirements engineering for the epilepsy EPR modules followed by an overview of the requirements engineering process. Section 4.5 outlines the approach that was taken to design the epilepsy EPR modules using the sociotechnical principles.

4.4 STS approach to requirements engineering

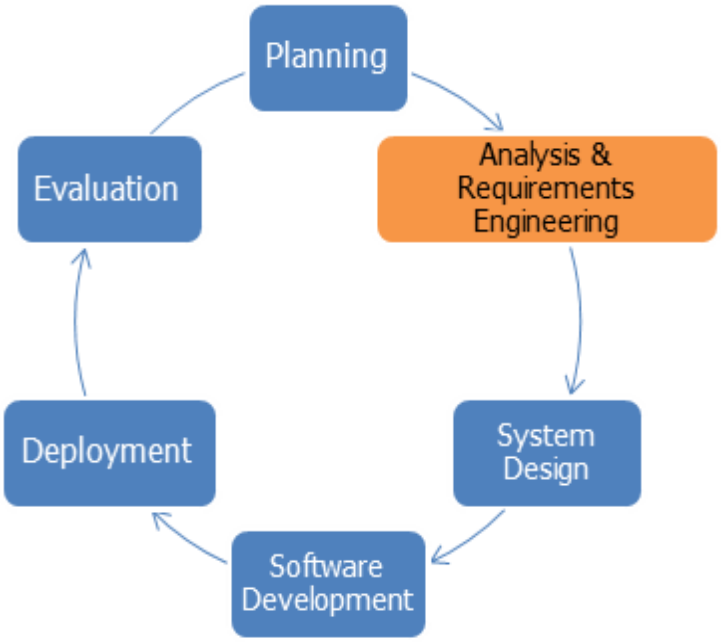

Figure 4-4 Analysis and RE stage of the epilepsy EPR development lifecycle

4.4.1 An approach to sociotechnical requirements engineering

A mixed-method approach was used to elicit requirements from a sociotechnical perspective including using relevant sociotechnical principles to guide requirements engineering as outlined in table 4-1 below and conducting a traditional requirements engineering process as described in section 4.4.4 below.

In this research, a sociotechnical requirements engineering (RE) process was used to elicit user requirements as the evidence suggests that sociotechnical RE results in requirements that are enriched with the social and organisational detail that enables the system to be built to closely match the end-user's needs.[2] The BA conducted sociotechnical requirements engineering by augmenting traditional techniques such as semi-structured interviews and informal conversations with staff about their work with ethnographic observational studies to capture the sociotechnical aspects. Ethnography using observational studies was the main

qualitative method that was used to capture the sociotechnical requirements. Observational studies allow for rich descriptions of the end-users' work tasks and of their environment.

4.4.2 Analysis Stage

As mentioned in section 4.2.1, some preliminary work was already conducted by the BA on the business processes of the epilepsy clinic including some observational studies to develop a business process map of a patient's journey through the clinic (The BA reused the business process map of the epilepsy OPD (see figure 4-1) and reviewed it with end-users and updated it where appropriate.

4.4.3 Data Collection for sociotechnical requirements

Following on from the analysis stage, the BA, as a participatory observer[4], observed the end-users carrying out their actual work in the epilepsy clinic. Ethnography through observational studies was used to uncover some basic characteristics of the social aspects of the epilepsy clinic as it is important to integrate the social and organisational processes into how the system is designed alongside the technology. The BA defined STS dimensions based on STS principles that were outlined in chapter three. The STS dimensions for this research are defined in table 4-1 and provided guidance for engineering requirements.

Table 4-1 Sociotechnical dimensions to guide RE and design

Component	Dimension
Social	Work activities and tasks
	Roles and responsibilities
	Explicit and tacit knowledge
	Behaviour
	Skills
	Group functioning
	Values
Organisational	Organisational structure hierarchical v flat
	Social organisation e.g. the relationships between functions/department

[4] Participatory Observer - Participant observation means watching the events or situation or activities from inside by taking part in the group to be observed. The participant observer freely interacts with the other group members, participates in various activities of the group, acquires the way of life of the observed group or his own, and studies their behaviour or other activities not as an outsider but by becoming a member of that group.

	and the organisation Job descriptions Training and work routine Culture and support for innovation and risk-taking
Technology	IT systems and in-house knowledge Skill sets and resource allocation

As outlined in section 4.2.1, the BA had exposure to how the epilepsy OPD operated as preliminary work was previously conducted in this area. For the purposes of this thesis, the BA conducted observational studies over a period of 6 weeks at the epilepsy OPD visits which operated for approximately six hours. This included collecting data by recording field notes through observational studies at 10 patient-clinician encounters. A patient-clinician encounter was held in a clinic room and consisted of one doctor reviewing one patient. The consultation differed in length of time depending on whether the patient was a first time patient or a return patient. For example, a first time patient with complicated epilepsy could require a consultation of approximately 1 hour whereas a return well controlled patient with epilepsy could have a consultation completed in 20 minutes[5]. Patients were often accompanied by a family member or a carer. The BA observed how the clinicians conducted the activities of the patient-clinical encounter and the interactions that happened between the clinicians and the patients and sometimes with other clinicians who may have interrupted the consultation to collaborate or seek advice.

The BA also recorded, through observations, the type and flow of administrative and clinical information that was generated during the patient visits which included: the type of questions asked by the clinician, the responses of the patient and vice versa, the order of the information communicated between the patient and clinicians, the tools used by the clinicians and the source of this information e.g. who and where information was coming from. The BA cross-checked the fieldnotes made during observations with the administrative and clinical information recorded in the paper chart. Besides attending and observing the patient-clinician encounters, the BA also observed how a range of clinic staff carried out their tasks and their interactions and communication with each other and with patients. The staff that were observed included the clinic secretary, nursing, junior doctors, senior registrars and the consultant epileptologist. This provided the BA with rich descriptions and

[5] Time does not include review with epilepsy nurse and waiting time in clinic prior to being seen by the nurse/clinician

"nuances" of routines of clinical work which complemented interviews held with end-users about their work activities, roles and responsibilities and skillsets that are difficult (if not impossible) to capture when documenting formal user requirements using traditional methods such as structured interviews away from the participants natural environment (in this case the epilepsy OPD).

The BA also had brief informal conversations with the end-users during the course of the epilepsy OPD sessions and sometimes conversations were followed up with longer conversations away from the epilepsy OPD setting. For example, at other epilepsy meetings such as the monthly multidisciplinary team meetings, the BA had opportunities to informally chat with clinicians and discuss events that happened previously in the epilepsy OPD or ask informally about their view on the epilepsy EPR progress or their work tasks at the OPD. The BA found that recording observational field notes illustrated the interaction between staff and patients and highlighted nuances and intricacies about what occurred in the clinics. The BA acted as a participatory observer and was aware of being unobtrusive to staff when carrying out observations. The fieldnotes were written as descriptive as possible during a fast paced clinic.

4.4.4 Requirements Engineering Process

An overview of the traditional requirements engineering process that was used for engineering requirements for the epilepsy EPR is outlined below. The requirements elicitation activity is described in detail in 4.4.4.1. Examples of the sociotechnical aspects of RE are presented in 4.4.5 below.

A detailed overview of the requirements engineering literature is described in chapter 3 of this thesis. The BA undertook a two-day workshop in Dublin City University in Dublin on requirements engineering. The aim of engineering requirements for the epilepsy EPR was to accurately elicit what the users required in order to deliver unambiguous user requirements specifications (URS). A URS facilitates software developers to build a more successful system that meets the end-users needs. An overarching requirements engineering process was used by the BA to engineer requirements for all modules of the EPR. The key activities involved in the requirements engineering process included requirements elicitation, analysis, negotiation, documentation, validation and management. The requirements engineering

process was applied to each of the epilepsy EPR modules and each activity has corresponding techniques as described below.

4.4.4.1 Requirements elicitation

Requirements elicitation is the task of communicating with the end-users to determine what their requirements are. The requirements elicitation stage is considered the most important step in the requirements engineering process as ensuring the requirements are as accurate as possible upfront in the development lifecycle can add significant value and bring about substantial cost savings.[167] For this reason, the BA invested considerable effort in the requirements elicitation activities. Requirements evolved throughout the entire development lifecycle and new requirements and changes to requirements were captured throughout all stages of the epilepsy EPR development. For example, initial baseline requirements were identified at the initial requirements engineering workshops and early stages of design but also new and updates to requirements emerged during other stages such as during user acceptance testing and deployment.

The requirements gathering techniques used by the BA included techniques such as analysis of existing documentation, interviews, workshops, prototyping of initial early requirements and ethnography (observational studies). Each technique is described below:

- End-users provided documentation that they used in their daily work such as proformas, organisational documentation about the epilepsy service such as organisational charts, procedures and protocols and user manuals of existing systems that they used.
- Formal (semi-structured) and informal interviews were held. Initial one to one interviews with end-users were conducted that were refined and modified over time and consisted of a combination of both closed and open interview questions. Open informal discussions were also held with end-users which provided additional, nuanced information regarding their functional requirements. In addition, end-users were interviewed about their work and the main tasks that they undertook in their role alongside the functional requirements needed
- Regular workshops were held with groups of end-users to brainstorm and elicit requirements

- Observation was used to elicit information about domain knowledge that could inform the requirements.

4.4.4.2 Requirements Analysis

A systematic manual analysis of requirements was carried out to determine whether the requirements were unclear, incomplete, ambiguous, inconsistent or contradictory. Each requirement was analysed one by one to ensure it was atomic and then checked against the following list of quality criteria: Completeness, Feasibility, Ambiguity, Testability, Relevance, and Traceability. Any conflicts or dependencies between requirements were identified and resolved and finally they were classified and organised into coherent clusters.

4.4.4.3 Requirements Negotiation

Requirements were negotiated, prioritised signed off and agreed with end-users. If end-users failed to agree on the requirements, a second meeting or subsequent meetings were organised until agreement was met. The penultimate step was to negotiate the requirements with the end-users to get agreement and sign-off on the requirements. However, given that requirements have a tendency to change, this was an opportunity to identify and resolve any conflicts that end-users had with the requirements. Having completed a cycle of the RE process, the final step was to take stock and complete a post-mortem on the iteration to identify what worked well and what did not. Requirements negotation was a continuous, interlinked, iterative lifecycle.

4.4.4.4 Requirements Documentation

Following requirements negotiation, requirements were then formally documented in order to manage them effectively, and to ensure that they were identifiable and traceable. Requirements were documented in various forms, such as using natural-language documents, use case, scenarios, and user requirements specifications.

4.4.4.5 Requirements Validation

Validation of the requirements was conducted to ensure that the requirements accurately expressed the stakeholder's needs. This involved developing prototypes of the requirements

and getting feedback from users. Prototyping the requirements was an apt technique to use for the validation activity. The epilepsy EPR was a bespoke system and it was difficult at times for end-users to visualise what they needed from the EPR which differs from eliciting and validating requirements from an "off the shelf" product which end-users could experience before agreeing to modifications. Hence prototyping was important.

4.4.4.6 Requirements Management

Once the requirements had been developed through steps 4.4.4.1 to 4.4.4.5, there was a need to manage requirements. Managing requirements involved identifying and tracing requirements effectively.[105]

4.4.5 Examples of Sociotechnical Requirements Engineering for the epilepsy EPR

Some examples of requirements that were elicited for the AED, epilepsy history and allergies modules are illustrated below and the sociotechnical aspects are highlighted.

- **Requirements from different viewpoints**

One of Clegg's sociotechnical principle is that design is an extended social process which includes the concept that design is extended over lengthy periods of time and therefore the system gets reconfigured as it goes along. This includes the concept that stakeholders can interpret designs and their meanings in different ways. End-users differing viewpoints on requirements were apparent and were managed at feedback meetings and through informal conversations with the BA. At a high level and depending on their role, end-user's viewed the use of the epilepsy EPR differently. These different viewpoints were important for the BA to be cognisant of when eliciting and managing requirements because it was important that requirement were clear and were agreed by all end-users irrespective of their role and seniority. For example, a junior clinician felt that the epilepsy EPR provided training opportunities in terms of learning about the condition of epilepsy in a systematic way, the consultant epileptologist viewed the EPR as a way for pulling up information quickly and being able to verify clinical information when they were asked to intervene at a consultation during a clinic by another clinician and a nurse specialist viewed the epilepsy summary record as a useful way of retrieving information about the patient in order to give the most appropriate advice to a patient at the epilepsy OPD. At feedback meetings, end-users also

differed on low-level requirements such as data values and it was agreed that the value "other" would be included in all drop down lists with a free text box to capture values that were not on the list.

- **Workflow and sociotechnical requirements engineering**

One of Clegg's sociotechnical principles is that "core processes should be integrated" and he maintains that processes should be simplified to take out unnecessary activities, repetitions and delays. The BA recorded formal workflow but as Berg et al. (2008) outlines there is a difference between requirements that reflect what actually happens as opposed to what happens with very "formal" workflow which usually sets out formal boundaries between clinicians and how formal boundaries or processes such as "a doctor prescribes a medication and a nurse administers a medication" are accurate and do exist but "in reality a nurse will often take the lead and will suggest the right dosage to a clinician". This was evident in the epilepsy OPD where junior SHOs sometimes collaborated and relied on the advice of epilepsy nurse specialists to inform them about the patient's seizure types and medications. Also as Berg outlines "anyone with hands-on insight into medical work knows that getting answers to questions like 'what is this patient's core problem' or 'what is the proper action for this patient at the moment' is often complex , interpretative and an interactive process".[(14)] For example in epilepsy, it may take several encounters before a patient has been given a diagnosis of epilepsy which depends on multiple investigations being ordered and interpreted and are therefore a patient may be given a differential diagnosis.

- **A complex requirement**

An example where managing requirements from a sociotechnical view point was beneficial was in relation to adding a medication. The original high-level requirement was that the end-user was able to "add a medication" from a list of AED values and also that the end-user could include the dosage, frequency, time and route. Through discussions with end-users at feedback meetings and through the BA observation at the OPD, this requirement evolved to include the ability to "Add Existing" and "Add New" medications (see figure 4.5). The reason behind this decision was that "adding a medication" did not cover the relevant scenarios required to add a medication in practice at the OPD. The BA observed that if a clinician wanted to add a new medication to the AED module, it was adequate to automatically use todays date as a default. However, if a clinician wanted to update an

existing medication (see chapter 5 Section for retrospective data entry) and dosage that a patient was on, a date could not be populated. This was because often a patient would not be able to tell a clinician when they started a medication and the BA observed that patients referred to starting a medication "a few years ago" or they "couldn't remember exactly". This example illustrates the complexity around eliciting requirements that on paper may initially appear straightforward.

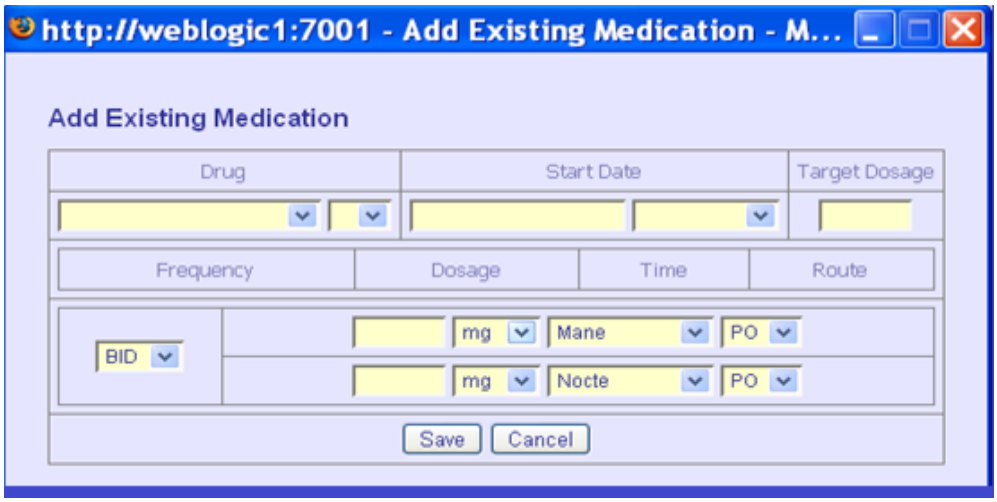

Figure 4-5 Screenshot from a pop-up box of an AED module to add existing medication

- **User Interface (UI) requirements**

The literature suggests that during early pilot testing of a system in a clinical environment, both the user's workflow and the user interface requirements are likely to need revisions.[168] The process of iterative refinement was used to elicit requirements and for system design of the epilepsy EPR which aligns with Clegg's sociotechnical principle on "Evaluation is an essential aspect of design".[127] This meant that requirements evolved for the user interface of the epilepsy EPR and changes needed to be made in order to match the user's clinical workflow. For example, a user requirement that was initially documented from requirements workshops was that: "*A user must be able to change a medication*" (*Medications User Requirements Specification*) and it was further defined as the ability to change a dosage, frequency etc. From a sociotechnical viewpoint, the BA observed at OPD sessions that if a clinician

'wanted to change the dose of a medication, the AED module of the epilepsy EPR required the clinician to discontinue the old medication dosage and enter a new one, but the user interface should hide this complexity' (*Observation Notes, BA)*.

This observation was noted at the early stage of the requirements and design processes and this issue was also identified as a design issue (screenflow) that was addressed in future iterations but from an end-user viewpoint it was identified and relayed to the BA as a user interface issue. Another user-interface requirement that benefitted from a sociotechnical perspective was in relation to how tick-boxes were designed on the page. End-users discussed at feedback meetings how

"*tick boxes were too far away from the drop-down values*" (*Feedback Meetings, End-Users*)

and the end-users agreed that this raised a risk because a user could make a mistake and click on the wrong tick-box. As a result, the requirement evolved to state that it should be positioned next to the values.

4.5 Sociotechnical approach for System Design

System design involved designing the functions and features that were needed to satisfy end-user requirements. System design takes as its initial input the requirements identified in the approved user requirements specification. The epilepsy EPR was co-designed between the BA and end-users and was influenced by the IT development team. Involving end-users in how the EPR was designed helped to elicit the end-users tacit work knowledge to inform system design. By considering the end-users work practices, a more work informed and user-oriented design was achieved. Functional modules were prototyped using mock-up screens and end-users gave feedback which, where relevant, was also incorporated into the end-user requirements. The techniques that were used to design the epilepsy EPR are outlined below.

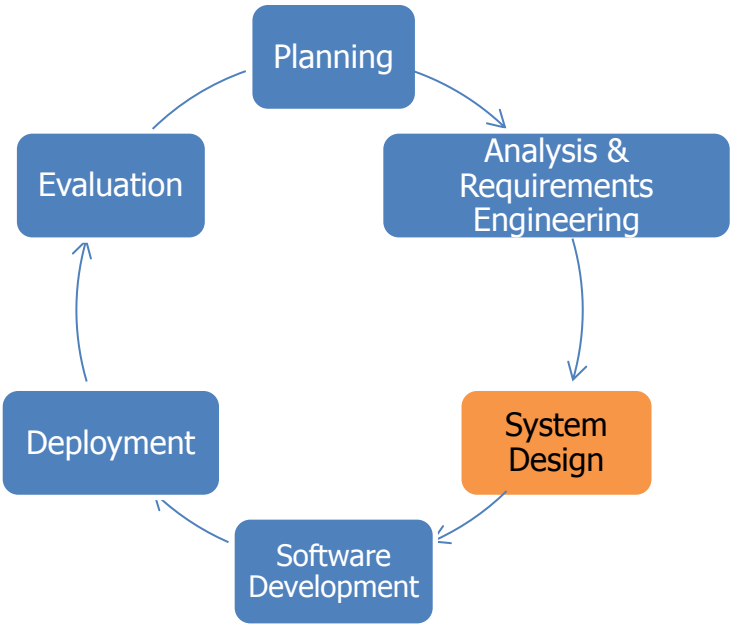

Figure 4-6 System Design stage of the epilepsy EPR development lifecycle

4.5.1 Modelling

The UML modelling tools were used to translate functional requirements into diagrammatical representations to enable the IT development team to better understand the end-users' requirements. The BA worked in collaboration with the IT development team model requirements using the UML and produced class diagrams for the AED module which were a useful method to communicate clear requirements between both parties.

4.5.2 Wireframes

The BA designed wireframes with the end-users which enabled the IT team to mock up a user interface (or more functional prototype). Wireframes were used to illustrate the features and content (at the high level of data fields) and the layout of each function per screen that were required for the epilepsy history module. This was a first step in the evolutionary development of the functioning prototypes. Usually a wireframe does not have any functionality behind it and is therefore easy to change. Wireframes were drawn up on tools such as Microsoft Word or PowerPoint (See example in figure 4-7 below) or with pen and paper depending on how complex the requirements were for the module. Wireframes and initial prototypes with limited amount of functionality were used at the initial stage of requirements elicitation specifically when requirements were poorly

understood. Wireframes evolved into functional prototypes which then evolved further as more features and functions were added.

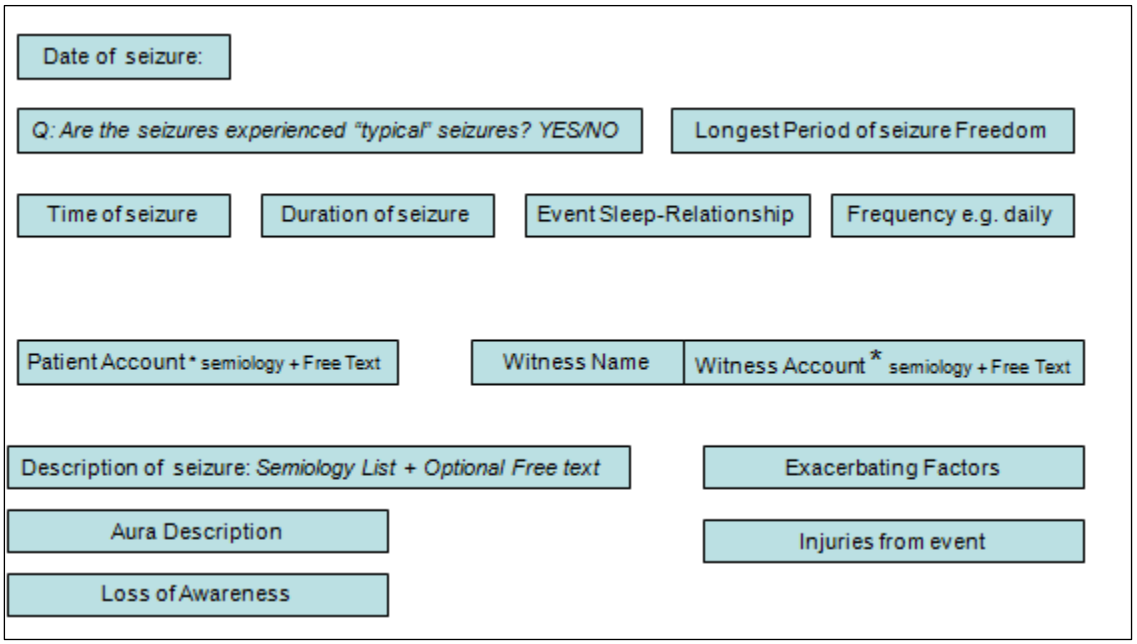

Figure 4-7 Example of wireframe for seizure history

4.5.3 Screenflow

The wireframes that were designed by the BA and the end-users described in section 4.5.2 were then communicated to the IT development team and were enhanced to incorporate how the end-users could interact with the screens and how the screen flow could work. The BA asked the end-users a set of questions in relation to screen flows which further informed the design (in terms of UI and data requirement, flow and structure). An example of a screenflow for the classification or diagnosis of epilepsy is illustrated in figure 4-8 below.
The epilepsy classification describes the diagnosis and aetiology of epilepsy. The type of questions that the BA asked the end-users in relation to the epilepsy syndrome diagnosis and aetiology included:

(1) Is there ever only a single classification which may be revised or is each classification for a patient an independent attestable document?
(2) How are syndrome classification and aetiology related? Whenever a syndrome is revised or added is there usually a corresponding aetiology?
(3) What information needs to be displayed in the classification list?

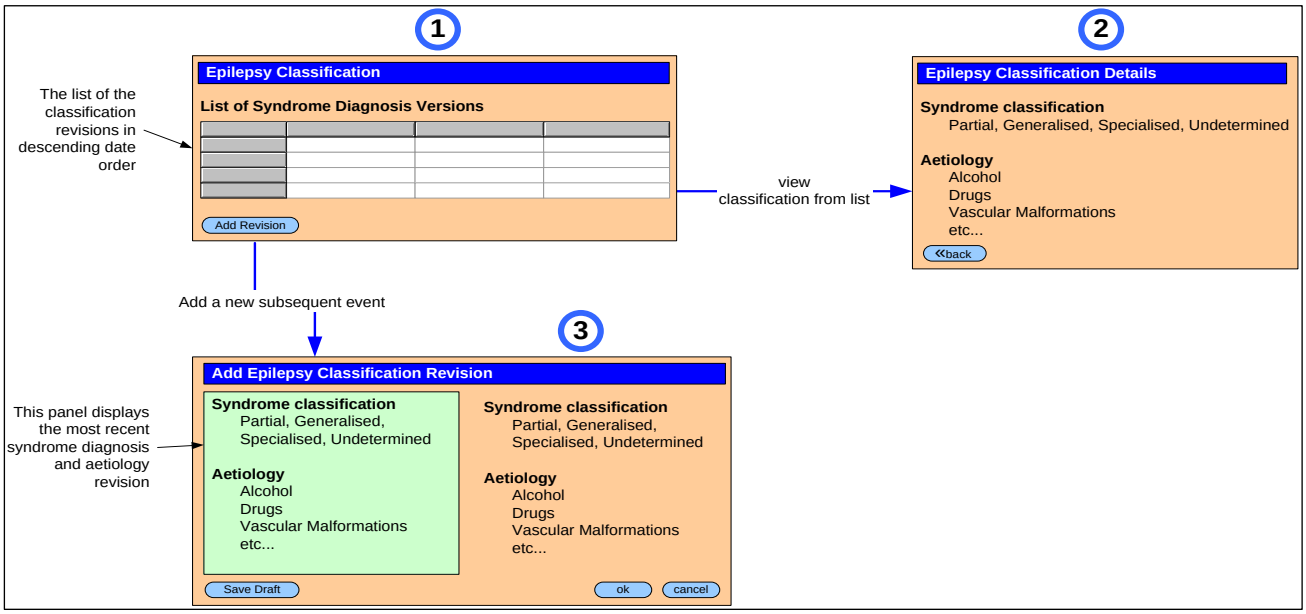

Figure 4-8 Example of a Screenflow for Diagnosis of epilepsy

(Screens developed by Beaumont Hospital IT development team)

4.5.4 Data Structures and Data requirements

Datasets were defined for each module of the epilepsy EPR. Datasets were composed of data fields, data elements and their data values. Combined techniques were used to elicit the dataset requirements from the end-users. They included: face-to-face meetings with different end-users of various disciplines to elicit their requirements for the datasets, extracting information from existing proformas that already had lists of data values defined, using healthcare information standards that are internationally available (such as the data values from the HL7 standard for demographics values) and the International League against Epilepsy (ILAE) classification system that was used for the dataset for the epilepsy history module. Datasets that were defined by individuals were collated and were raised for discussion at workshops or weekly meetings. Data values were modelled using a tool called XMLSpy or were represented in a table using Microsoft Word. The data structure in figure 4.9 below illustrates the classification of epilepsy seizures and syndromes, aetiology and risk factors are illustrated below.

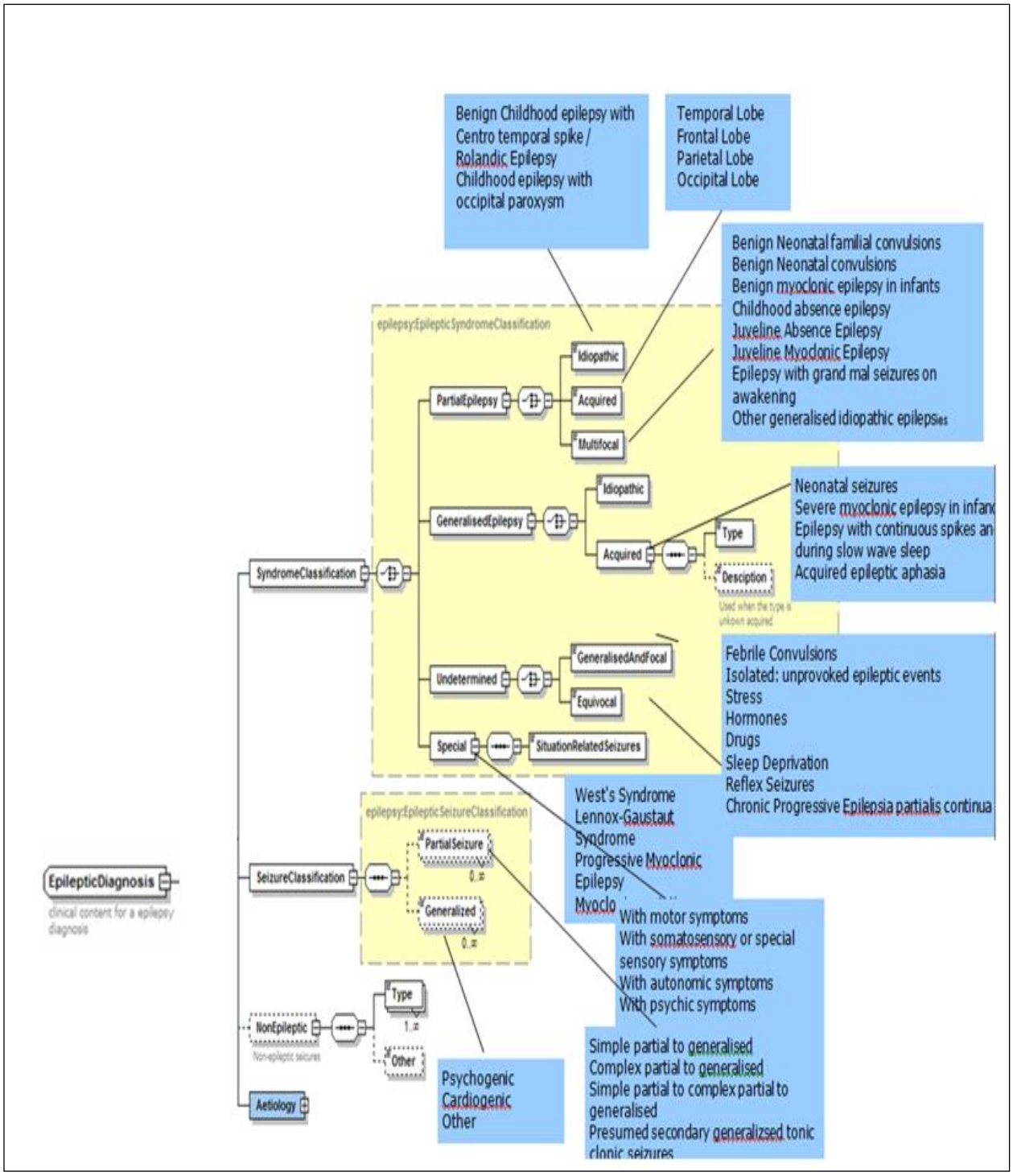

Figure 4-9 Data Structures and Data Values for an Epilepsy Diagnosis

4.5.5 Evolutionary Prototyping

With evolutionary prototyping, use of the system in its intended environment informs a process of iterative refinement from which a more effective system evolves. Users were aware that the first iteration of a module could be enhanced to produce a more

sophisticated application. Prototyping involved creating mock up screens to illustrate diagrammatically the functionality required by users. Prototypes were reviewed and verified at joint application workshop design sessions attended by the BA, software developers and end-users. Prototyping involved regular user feedback which could often result in changing the system functionality and requirements. Over time system design and user requirements evolved and new prototypes were developed. This work fed into the development stage of the EPR lifecycle and software developers engineered a solution. A working prototype of the epilepsy EPR modules was one of the main outputs of the epilepsy design. The functions and features of the epilepsy EPR module that were developed facilitated the access, recording and display of the patient's epilepsy information. There was a mixture of structured, drop down lists that were hardcoded into the application and free text options to enable the end-user to enter information into the EPR.

4.5.6 Working Prototypes

An example of the epilepsy prototypes for the subsequent seizures is illustrated in figure 4-10. The functions and features of the epilepsy history module that were developed facilitated the access, recording and display of the patient's epilepsy history information. There was a mixture of structured, drop down lists that were hardcoded into the application and free text options to enable the end-user to enter information into the epilepsy history module. The module consisted of four main interactive screens including the: events and seizure semiology which included the defining events such as a description of the patients first event, a description of the patients typical events/seizure and descriptions of any other types of events/seizures the patient experiences, seizure classification, syndrome classification and aetiology.

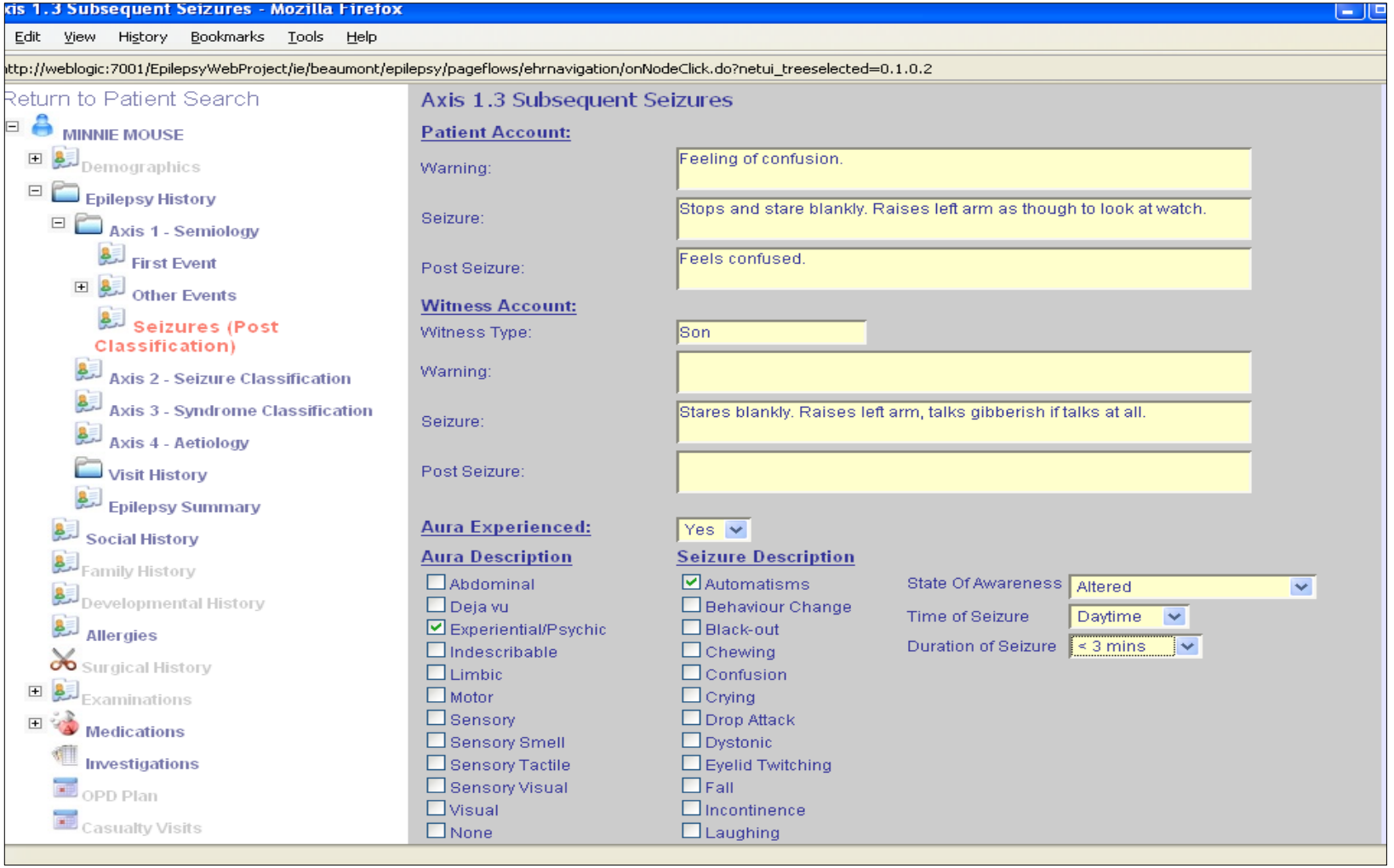

Figure 4-10 Example of final prototype for Seizures (post diagnosis)

4.5.7 Examples of Sociotechnical Design

The BA noted the benefit of employing an iterative design process throughout the epilepsy EPR design. This aligns with Clegg's sociotechnical principal that "design is an extended social process" and that people using the system must "interpret it, amend it, massage it and make such adjustments as they see fit" implying that the system gets reconfigured throughout the development lifecycle. The BA observed the benefits of using an iterative process for system design as the end-users were engaged in the design process. End-users were empowered because they made the decisions about what type of data they wanted to include in the data requirements, what structure and flow of screens they needed and how they wanted their information presented. This was facilitated through undertaking multiple iterations of designing data requirements, data structures, screen design and sreenflows.

- **Different ways of working**

An important user requirement was documented to "create an epilepsy summary page". This would include the most up-to-date and most relevant epilepsy history information about the patient which includes a patient's diagnosis, their current and past medications, their allergy information, investigations, laboratory and pathology results and EEG findings. Figure 4-11 below outlines a sample of requirements (also some change requests and enhancements) that were requested by different end-users for the epilepsy summary page after the initial epilepsy summary page was designed. The user requirements in figure 4-11 below were recorded in a traditional way stating what the user wants and documented clearly and without context. The traditional way of capturing requirements was used as it is important to state what is required by the end-users, however, this research complemented the traditional requirements method with sociotechnical methods such as observations. The traditional requirements do not take into account how the epilepsy summary is used in practice and how it integrates with the end-users work. By observing the use of the epilepsy summary in the clinic, the BA observed that each member of staff had very clear instruction about their role and what their responsibilities were at the clinic. The BA also observed that there was a strong sense of teamwork and collaboration among staff. For example, the epilepsy nurse specialists would often give advice to junior doctors about an AED or a particular seizure type or a doctor would query an epilepsy nurse specialist about a particular patient that the nurse may have reviewed at their telephone advice service

between visits. However, they still had distinct roles in the OPD and this was reflected in how they would use the epilepsy EPR. For example, it was clear that the epilepsy summary page was beneficial for all users. However, it was essential for the consultant as it gave him a synopsis of the patient when the consultant was verifying information about patients with all staff at the clinic and he needed a quick reliable and accurate update on the patient. A junior doctor was able to use the page as a way of understanding more about epilepsy and as a guide and training tool when working in the clinic. Certain sections of the epilepsy summary were more pertinent depending on the role of the end-user and by viewing the requirement from a sociotechnical perspective, a recommendation was made to provide different views of the epilepsy summary depending on the role of the user.

Enhancements for the requirement 'create an epilepsy summary page'	
E0002	Epilepsy Summary Page - The current version of an epilepsy syndrome (Axis 3) must be updated in the epilepsy summary. The current versions include Axis (1.1 -1.3). The summary must display the multiple forms for (Axis 1.2 and Axis 1.3) if they exist.
E0007	Epilepsy Summary: There are too many values pulled into the summary to describe a diagnosis. Do not pull through the heading (Level 1). For example: Localisation Related Epilepsy in to the epilepsy summary. Only pull through the label (Level 2) Localisation Related Epilepsy Cause Known & cause unknown. Pull through the values (Level 3) and sub-indent the values.
E0008	Epilepsy Summary: Axis 2: Do not pull through heading (Level 1) Generalised Seizures to the epilepsy summary. Condition: This should only happen if the user clicks on the heading 2 and / or heading 3.
E0011	UI: Epilepsy Summary – Change grey writing to black. For example see Course of epilepsy.
E0012	UI: Epilepsy Summary – Insert Comma's after wording that does not have another word following it.
E0021, M0034	Epilepsy Summary: Pull target dose into the epilepsy summary. Target dose is in Medications module. Same as Requirement M0034.
E0025	Epilepsy Summary: Change wording of Heading "Event Type" to "Event"
E0027	Epilepsy Summary: Display "Target/ New Dosage" on Medications section of epilepsy summary

Figure 4-11 Requirements to create an epilepsy summary page

- **Structure versus free text**

Berg et al. (1998)[14] describe how free text enables communication among clinicians and it is important to get a balance between structured and free text when designing forms. Berg et al. (1998) discuss how "an overdose of isolated entries to fill in might detract users of their core work, especially when users have to visit different windows to accomplish a task.

Reddy et al.(2003)[2] also recognise the importance of combining free text and structured data noting that clinicians need to capture nuances about the patient and not just tick boxes. An example of where this was applied was the epilepsy history module of the epilepsy EPR which used a combination of free text and structure (see figure 4-10 above) to capture the patient's seizures and syndromes. For example, this design enabled the clinicians to capture clinical information about the patient's seizure accounts which was a narrative and they could then qualify the narrative information with keywords. By ticking keywords, the information could then be used for reporting purposes. This was achieved by endorsing user participation, which is central, to the sociotechnical ethos through a joint application workshop which involved end-users (x4), software developers (x3) and the BA.

- **Values and mind-sets are central to design**

A sociotechnical ethos that was used throughout the design stage was that "Values and mind-sets are central to design" (Clegg's principle 2). This promotes the concept that humans and machines complement each other and it highlights that humans are the experts in the work they carry out. It was recognised that the end-users were the experts to inform the content and design of the structure and screen flows of the epilepsy EPR so it would integrate with their work. End-users were domain experts in delivering epilepsy care and were capable of being able to "interpret and intelligently add" information to the forms that they designed.[169] For example, the BA observed (at the design stage and pre-deployment) that clinicians were the decision makers in managing medication decisions, such as what new medication they would administer or discontinue for a patient and the design and technology needed to support them in this role. The BA observed that the clinician's behaviour in the clinic was to spend considerable amount of time flicking through a paper chart in order to retrieve relevant information that they may not have been able to gather from a patient. It was important for the clinician to find out if a patient was on a particular medication in the past, that is if they had discontinued a medication. This observation was recorded in the medication user requirements specification.

Use Case #	Use Case	UR-ID	Requirement
9.2	View Prior Medications	M0043	The system must display prior medications. Prior medication (s) must be displayed as a list. The list must be in alphabetical order.

Figure 4-12 A traditional requirement for viewing prior medications

The epilepsy EPR supported the user in providing a list of all medication that had been discontinued by the patient but it is the clinician's decision making around how to utilise the discontinued list to make an informed decision about medication management that is important.

- **Data Requirements**

An important requirement that emerged following observations in the OPD was to include a medication value for "folic acid" for all child bearing women with epilepsy. The initial scope of the AED module was to include AED medication only which stated that 'The system must capture basic anti-epileptic medication data' and the initial scope of the AED module, which was agreed by end-users was described specifically in the medications user requirements specification in figure 4-13 below as:

5.2 The medications module <u>does not</u> currently include the following capability:

5.2.1 Non epilepsy medication are not included e.g. medication for other medical conditions

Figure 4-13 an excerpt from the medications user requirement specification

However, by using a sociotechnical approach to design, an important requirement was unearthed. The BA observed that all clinicians asked women of child-bearing age if they were taking appropriate folic acid given that they had epilepsy which meant that the amount of folic acid has to be increased. Following discussions with end-users, it was agreed to include the value folic acid as a new requirement.

There was a significant amount of effort and time invested to design data requirements and sometimes one-hour feedback meetings were spent on reviewing values. For end-users the terminology and how the lists were ordered were particularly important. The following section will describe the design of the AED module of the epilepsy EPR and provides some context for the evaluation study around the AED module deployment that is described in chapter five.

4.6 The AED Module based on sociotechnical design

The following section is an example of the AED module (see figure 4-14 below) that adhered to the sociotechnical design described in section 4.5. The AED use case was chosen as one of the key modules for design in the early stages of the research project as treating a patient with epilepsy depends on a timely and accurate drug treatment which is crucial to ensure the best possible outcome for the patient. The accurate treatment of epilepsy requires considerable expertise by clinicians and is fundamental to the clinical management of patients with epilepsy. Clinicians need to know the type of seizures and syndromes that a patient has in order to treat them effectively with appropriate medications or potentially surgery. It is imperative to achieve the appropriate AED or combination of AED's to optimally control a patient's seizures. The AED module was a challenging module to design given the complexity of managing medications.

4.6.1 Design of the AED module

The purpose of the AED module was brainstormed at workshops facilitated by the BA and was attended by the end-users comprising the nursing and medical team involved in the delivery of Beaumont Hospital epilepsy services. The AED module was designed according to the same requirements and design process described in 4.4 and 4.5. The AED module was designed using a combination of methods including requirements engineering workshops, clinical scenarios, ethnographic analysis, joint application design sessions and evolutionary prototyping. Follow-up one-to-one informal interviews were conducted where the BA further clarified and refined requirements with individual users. Clinical scenarios and observation supplemented the gathered requirements. A class model and use case lists were established and used to aid the development of the AED module. Initial prototypes were reviewed and verified at joint application design sessions attended by IT developers and end-users. Following development of the AED module, system and user acceptance testing (UAT) were conducted and provided a measure of usability before the application was put into practical use (i.e. live clinic).

4.6.2 Description of the AED Module of the EPR

The AED module aimed to track a patient's epilepsy medication over time and provided access to the most-up to date epilepsy medications when and where needed to better

inform clinical decision making. The scope of the AED module was limited to the administration of epilepsy-specific medication only and did not cater for non-epilepsy medications. Medications are often the primary and preferred choice of treatment for patients with epilepsy. Medications for patients with epilepsy are frequently reviewed and changed until the patient is well controlled. To facilitate this, timely access to medication information such as lists of current and prior medications are required.

The user interface of the AED module facilitated the access, recording and display of the patient's medication information. Standard epilepsy EPR screens consisted of a tree structure called the patient tree and clinical forms for data entry. A patient tree acts as a navigation tool, guiding the end-user through different screens. It displays an expandable list of patient information or modules including medications, examinations, epilepsy history. Each module of patient information was represented by a node on the tree. Nodes can be expanded by clicking into further sub-nodes or sub-categories of information e.g. all medications, prescriptions. Each sub-node linked to a unique clinical form.

The type of information entered into the AED module was in a structured format. For example, drop down lists were designed and updated by users such as lists of AED names, dose and frequency details, alongside side-effects experienced, responses to medications and reasons for discontinuing the medication. The structure of data helped to decrease the risk of data entry error and improved the quality of information and reporting results. When a current medication was discontinued by a user, the EPR could automatically change the medication status from "current" to "prior" which improved the safety of how the AED module is used. Free text was facilitated where necessary.

Some challenges of eliciting requirements and designing the AED module were in relation to user resistance from end-users who were not permanent staff at the clinic and who may have had no long-term investment or interest in the area of epilepsy. Also, it was a busy service so the BA understandably experienced some resistance from end-users when they were under time constraints and were at times under resourced and did not view the design of the EPR as their priority.

4.7 Conclusions

Three clinical modules of the epilepsy EPR were developed over the course of this thesis. They included the patient's epilepsy history, AED's and allergies. The BA alongside the end-users co-designed each module of the epilepsy EPR using an iterative design approach and incorporated socio-technical principles into the requirements engineering and system design processes. Each module passed user acceptance testing in a test environment and each module was deemed suitable to be integrated into *live* clinical practice at the epilepsy clinic. However, observation and user feedback highlighted factors that would require attention in order to seamlessly integrate the epilepsy EPR in clinical practice to support end-users in their work. Further discussion and examples of the sociotechnical aspects of the EPR requirements and design are described in chapter 8.

Chapter 5 describes the evaluation for the deployment of the AED module in the epilepsy clinic using a sociotechnical perspective and examines the AED module from a sociotechnical perspective when deployed in a real world clinical environment and used by clinicians at the point of patient care.

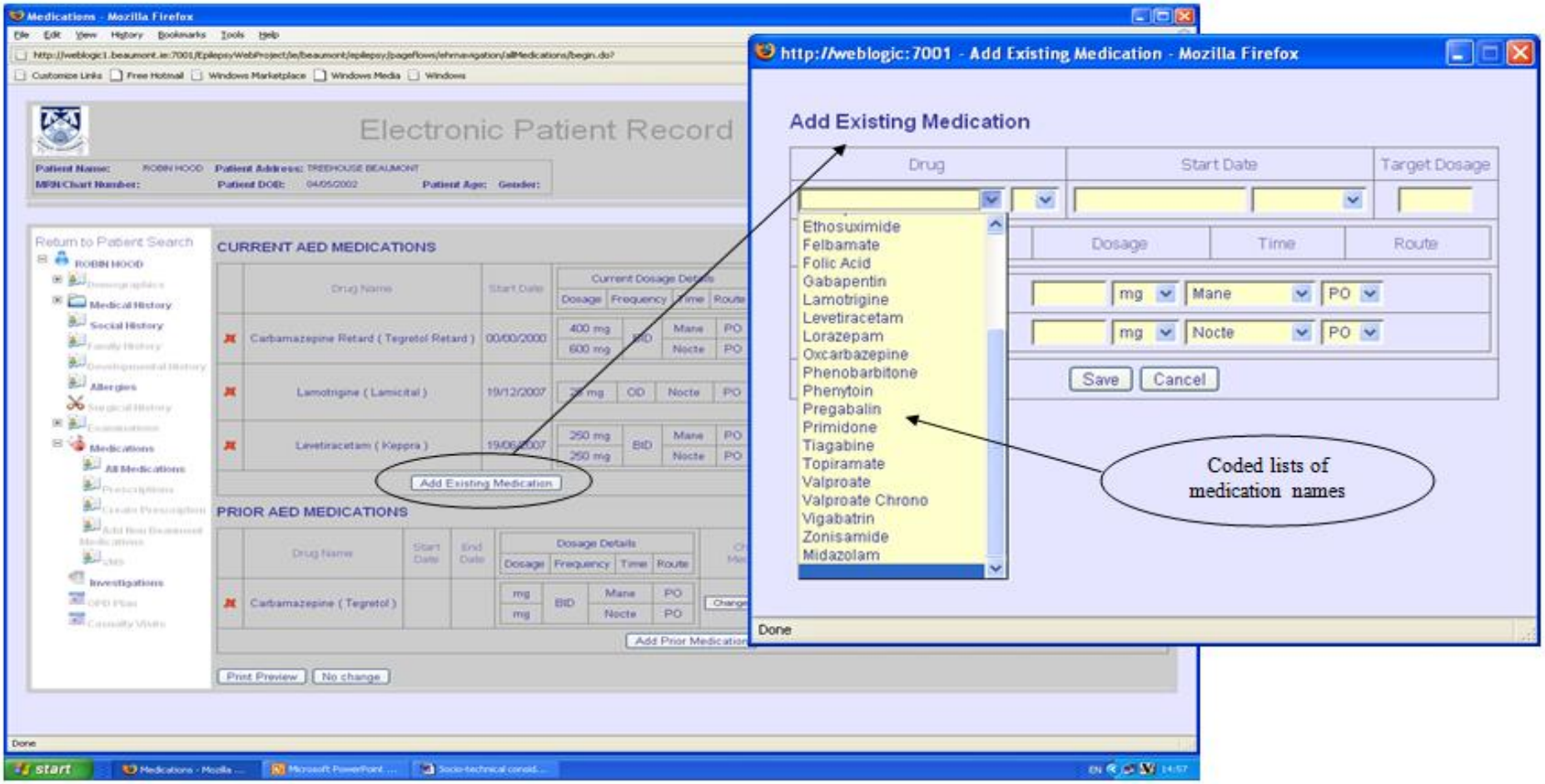

Figure 4-14 Medication AED User Interface

Chapter 5 Evaluation of the epilepsy EPR deployment

5.1 Introduction

Chapter 4 of this research outlined the iterative approach that was used to design a bespoke epilepsy EPR based on a sociotechnical philosophy. Chapter 4 also gave an example of how the AED module was designed using a sociotechnical approach and the challenges that were involved. A key sociotechnical principle is that evaluation should take place throughout all stages of the development lifecycle (see figure 5-1). This chapter evaluates the deployment of an AED module of the epilepsy EPR in the live clinical setting. The scope of the deployment and evaluation stages of the epilepsy EPR development lifecycle and the sociotechnical methods that were used at each stage are described in detail in chapter 4 in section 4.3.1. Section 5.2 will outline the study design followed by the study setting in section 5.3. The remainder of the chapter concentrates on the evaluation methods in section 5.4 and finally the outcomes of the study in section 5.5.

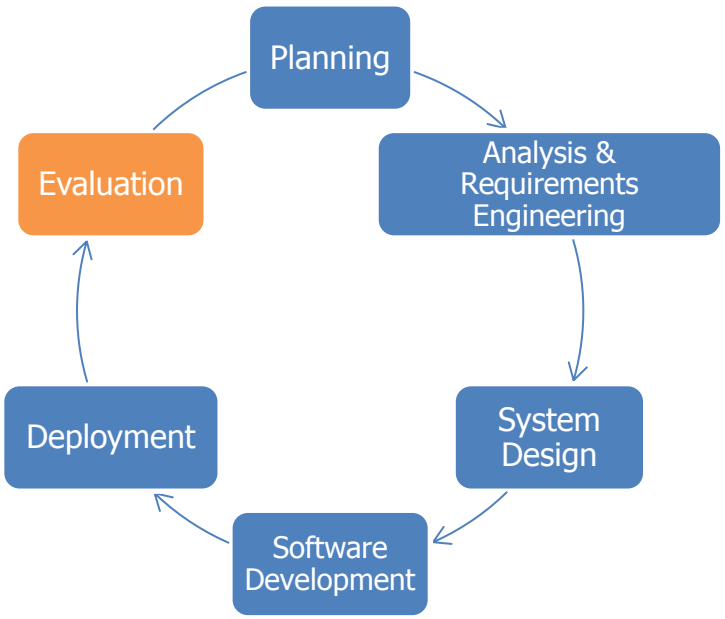

Figure 5-1: Evaluation stage: evaluating the deployment of the epilepsy EPR

5.2 Study Design

The aim of the study is to evaluate the deployment of an AED module of the epilepsy EPR in a *live* clinical environment having been designed using an STS approach. This involved examining the challenges around the AED deployment from a sociotechnical perspective. Specifically, the usability and usefulness of the AED module of the epilepsy EPR was evaluated. Qualitative and quantitative methods were employed in an observational field study. The outcome measures of interest in this study include user's perception of usefulness and ease of use of the AED module, observations of the impact of the technology on work processes in the epilepsy OPD and accuracy of use of the AED module use. The evaluation methods used for each of the outcome measures are outlined in table 5-1 below and 5.2.1 outlines the operationalisation of the HOT-fit framework for the evaluation of the AED module. Section 5.4 will describe the four evaluation methods in detail and the data analysis undertaken. Emerging issues from the study were grouped into three key themes based on sociotechnical factors human, organisational and technological based on the HOT-fit framework as described in chapter 4.

Table 5-1 Outcome measures and methods for pilot of AED deployment

Outcome Measures	Methods	HOT-fit Evaluation Framework
Usefulness	Feedback meetings, Ethnography	Human (User Satisfaction) – Usefulness
Ease of use	Feedback meetings, Ethnography	Technology (System Quality) – Ease of Use
Impact of AED module on work processes	Ethnography	Organisational (Environment) - Clinical Processes
Accuracy of use	Data Validation	Technology (Information Quality) Accuracy and Completeness

Given the iterative nature of the EPR development lifecycle as described in chapter 4, the outcome of this study could also inform requirements and facilitate wider adoption of the AED module and ultimately larger scale implementation of additional EPR modules.

5.2.1 Operationalisation of the HOT-fit model for the evaluation of the AED module

The HOT-fit framework was outlined in chapter 3 and the framework provides comprehensive criteria to evaluate health information technology systems including EPRs.

The model is comprised of three factors including human, organisational and technology and each factor has a range of dimensions associated with it. There are eight dimensions in total and each dimension is associated with a number of evaluation measures. Examples of evaluation measures according to their corresponding dimension and factor are listed in figure 3-2. The impacts of health information systems are assessed in the net benefits of the HOT-fit framework.

The goal of the evaluation study in this thesis was to evaluate the usability and usefulness of the AED module of the epilepsy EPR. The outcome measures that were defined for this study are illustrated in table 5-2 below and include the HOT-fit dimensions: User satisfaction, System Quality, Information Quality and Environment.

- **Context**

It was not feasible to select all evaluation measures in the HOT-fit model given the scope of the study which consisted of one researcher (the author) and one module for evaluation. The goal of the study was clear from the outset and the author selected the measures based on how to evaluate the usability and usefulness of the AED module. The author also considered that the study was conducted at the evaluation stage of the development lifecycle. Staff already had some exposure to using the AED module through user acceptance testing before the AED module was deployed in the epilepsy clinic, Therefore, some staff already had preconceived opinions based on their experience of using the EPR in one-to-one training prior to the deployment stage. Some staff may have had a positive experience or difficulty with the performance or instability of the EPR i.e. bugs. This may have influenced their attitude and behaviour towards using the EPR. Therefore, the measure "Intention to use" was not investigated as the assumption was that the evaluation was on how the end-users would actually use the AED module in the clinic. Also, the "Net benefits" of the HOT-fit framework were excluded as the assumption is that they are not they would not be realised at the time of evaluation. The author aimed to determine if the AED module was (1) useful enough to meet the needs of the end-user and was considered useful by them (2) convenient and easy to use and (3) integrates with the work patterns of the end-users.

- **Measures**

The measure that was selected from the HOT-fit model to best represent the usefulness (user satisfaction) of the EPR was from the Human factor under the 'User Satisfaction' dimension called Perceived Usefulness. According to Yusof*, "User Satisfaction" is "often used to measure system success.* User satisfaction is defined as the overall evaluation of a user's experience in using the system and the potential impact of the system. User Satisfaction can be related to user's perceived usefulness and attitudes towards HIS which are influenced by his/her personal characteristics". The author selected the "ease of use" dimension to assess whether healthcare professionals regarded the AED module of the EPR as satisfactory, convenient and pleasant to use i.e. the usability of the AED module. Problems in using the system can be categorized under of technology factors (ease of use). The ease of use measure was defined as a system that is user friendly, has a simple to use interface and facilitates straightforward data entry. The organisational factor was used to measure Organisational (Environment) - Clinical Processes measure was selected to evaluate the impact of the AED module on work processes which examines how IT systems and the work processes and organizations of which they are a part are complex and continuously changing. The accuracy of use was the final measure that was used and was selected from the Technology (Information Quality) Accuracy and Completeness measure of the HOT-fit framework. Information quality concerns whether the data in the AED module was relevant, comprehensive, precise and accurate. Since clinicians themselves enter data, the focus was not on how precise or complete the data that was entered was as this was presumed on the basis of the clinicians' professionalism. Instead, given the dual use of electronic and paper systems, the focus was on of whether the information that was entered in the AED module was an accurate representation of what was written in the paper chart.

- **Exclusions**

The study was an evaluation of the first time deployment of the AED module in a live clinic and therefore it was not reasonable to use some of the measures such as frequency of reports or number of reports generated as the EPR was not fully operational and there was not enough data available. The study was confined to the epilepsy clinic service and the author did not use measures that related to a broader scope such as financing source, government and inter-organisational relationships. This was the first evaluation study conducted on the AED module in the epilepsy clinic and if it was repeated again it would have been possible to use further measures such as response time and turnaround time.

However, given that the end-users were satisfied with system performance throughout the testing phase, the author did not include it. It was not constructive to look at the 'database contents' measure as again the evaluation was conducted as an early initial stage of deployment and this measure would be more relevant when the AED module was more operationalised. The 'availability' measure was not necessary as the EPR was available at set times for the purposes of this study and tested for availability and accessibility prior to trial use.

5.3 Study Setting

This research was based on the tasks that end-users carried out in the OPD and the data recorded in the AED module of the epilepsy EPR during patient-clinician encounters. The study was conducted over 20 OPD clinics held at Beaumont Hospital, Dublin. On average, 35 return-patients and 10 first-time patients attended the OPD. Two senior medics (1 consultant epileptologist and 1 senior epilepsy registrar), 3 junior medical doctors, 2 epilepsy nurse specialists, 1 epilepsy pregnancy nurse and 1 administrator delivered the epilepsy OPD service.

A purposeful sample of 4 clinicians were recruited to participate in the study: two senior medical doctors (1×consultant epileptologist and 1×senior epilepsy registrar) and two epilepsy nurses specialising in epilepsy care. These participants were senior staff involved in the delivery of the epilepsy service. They were selected as they were considered subject matter experts in the delivery of healthcare services for epilepsy and their knowledge of the service was an important factor in conducting an effective evaluation which would inform how the AED module could be deployed in their clinical environment.

Prior to the evaluation, the BA trained the participants on using the AED module and each participant was given an average of two 1-hour sessions to fulfill training requirements. Participants also practiced "hands-on" training with the medication module on a test system. Fictitious patients were created on the test system for training purposes. The author provided onsite support at the clinic to reinforce training instructions. A user help manual was provided as an additional resource for end-users to reference.

During the planning stage of the evaluation exercise, the two doctors were asked to use the AED module of the EPR over a 20 week period for a convenient sample of patient consultations at weekly out-patient sessions. Both doctors agreed to use the EPR for 2

patient consultations per clinic. Therefore the aim was for both doctors to interact with the AED module for 80 patient encounters over the 20 weeks. Given the nature of the busy epilepsy clinic, the doctors opted to use the AED module when it was convenient for them to do so and to feedback their reasons why it was appropriate to use at a certain time in order to inform future deployment of the EPR.

In advance of an OPD, the two epilepsy specialist nurses pre-populated the EPR for a subset of the patients due to attend an OPD so that the doctors could then interact with this electronic record during their consultation with the patient. The subset of patients was based on return patients who had previously attended the epilepsy OPD, who held a patient chart with the hospital and who already had a diagnosis of epilepsy.

At the epilepsy OPD, a paper template was designed by the epilepsy OPD staff and was called a "continuation sheet" that was used by the clinicians to handwrite clinical information about epilepsy (see section 4.2.2.2) and was used alongside the paper chart. These handwritten notes were contained in the patient's paper chart. Over the course of the AED module pilot study, this method of capturing and recording information on paper continued in the usual way. There were two methods used for data entry. This included data entry at the point of patient care recorded at the epilepsy clinic and retrospective data entry from the paper chart. AED information such as AED name, dosage details, and reasons for discontinuation pertaining to both first time and return patients who attended the weekly epilepsy clinic was recorded and entered into the AED module by the study participants. "First time" patients were defined as patient's who had not previously attended the Beaumont Hospital epilepsy OPD although they may have attended other clinicians for treatment of their epilepsy.

The following section 5.3.1 discusses how the clinician interacted with the AED module and the protocol that clinicians were asked to follow in order to record medications in the AED module.

5.3.1 Clinician Interaction with the AED module

Authorised users were able to log-in to the EPR using an individual username and password. In order to retrieve an individual patient record, an end-user could search the EPR using a patient search facility. Also there was a clinic list that was ordered by date and an end-user

was able to click on a date and view a list of patients and then click onto the patient name that they required to retrieve their details. As described in chapter 4, the BHIS or the patient administration system for the hospital contains the registration and administration details for what was known as the OPD download. At the time of scheduling a patient's OPD appointment, their demographic details, date and time of appointment, and the particular clinic they are due to attend are recorded in the BHIS. The epilepsy EPR interfaced with the BHIS, so that on the day of the OPD, patient details were downloaded to the EPR. For first time patients, no medication information existed in the AED module of the EPR prior to their attendance at the OPD. Therefore, the first time the patient's medications data was entered coincided with their first visit to the OPD. For a return patient, medication history was pre-recorded in the AED module by the participating epilepsy nurse specialists who transcribed information previously recorded in the patient's paper chart into the AED module. This was then available for review and update at the clinic. If medications were changed at the OPD, this pre-recorded information could be updated directly in the AED module. Entry of first time patient data and updating return patient data was conducted by the consultant epileptologist or the senior registrar participating in this study.

Study participants were instructed that they were responsible for verifying the reliability of the data entered into the AED module. The BA observed that data verification procedures already existed regardless the EPR and included: cross-checking current and prior medications with the patient or caregiver, and authorisation from the consultant neurologist that any changes made to the patient's medication or new medication prescribed were appropriate. In addition to this normal practice of verifying data, the participants were asked to corroborate the AED information that they entered with information recorded in the paper chart.

5.3.2 Protocol - Hardcopy record of AED module use

Once medication data had been entered electronically to the AED module, a "print preview" or medication printout option, which displayed the most recent summary of the patient's medication, was selected. The user checked the data entry on the print preview, printed a hardcopy and signed it and placed the hardcopy into the patient's paper chart. For later evaluation by way of a data validation exercise (see section 5.4.4), a second copy of this medication summary was filed by the BA. Therefore, the step of replicating a hardcopy of the AED record which had already been written on the paper chart continuation sheet was

taken in order to evaluate the reliability of the AED module printout for replacing the handwritten medication record.

In order to ensure that end-users understood and adhered to the process, a protocol was devised by the author. Study participants were asked to adhere to the protocol when interacting with the AED module in the epilepsy clinic as illustrated in figure 5-2 and outlined below. Participants were asked to follow the protocol outlined below:

- Access paper chart
- Handwrite information in paper chart and on continuation sheet
- Record signature in the paper chart
- Access the AED module and retrieve record
- Update AED module with the patient's medication information
- Verify the medications information entered on the AED screen for accuracy
- Print the AED information from EPR on pink paper and sign off on printout
- Place the signed copy of the AED printout in the paper chart.

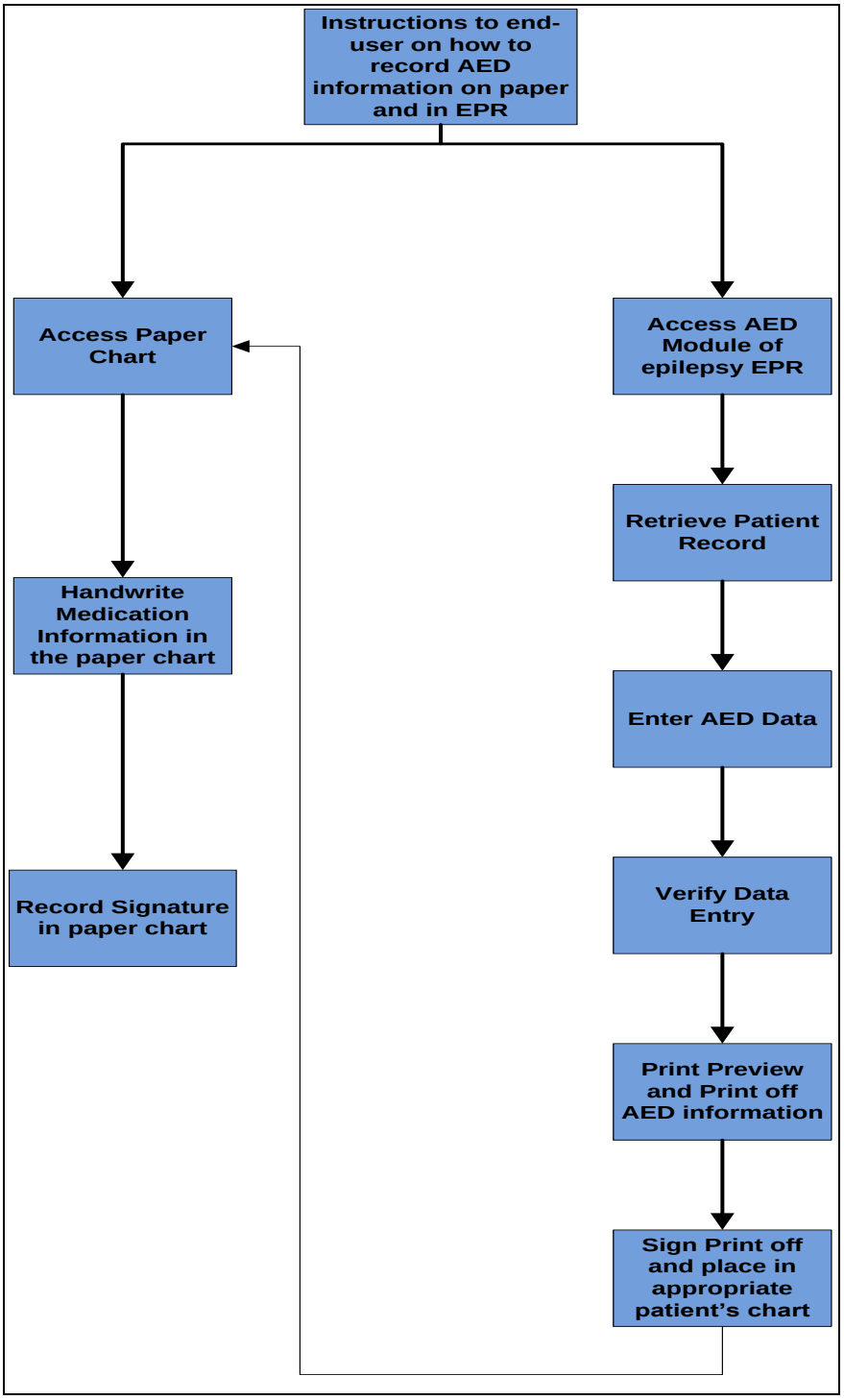

Figure 5-2 Protocol for capturing medications on paper and electronically

5.4 Evaluation Methods of the AED module

Qualitative and quantitative methods were employed in an observational field study i.e. the author observed the end users in their work environments when they used the EPR during patient-clinician encounters. This allowed the author to observe how users interacted with the EPR at the point of patient care and to record the challenges and enablers the end-users faced with using the EPR not just from a technical viewpoint but also in terms of a human (attitudes, behaviour) and organisational viewpoints (work processes and environment). As mentioned in section 5.2, the study design was based on the HOT-fit evaluation framework for HIT and incorporated factors of usefulness and ease of use of information technology. Three key approaches to the evaluation were taken and are listed below. Two methods were qualitative in nature including the ethnographic analysis and feedback group meetings while the third, the data validation exercise, was a quantitative method. Each evaluation method is described in sections 5.4.1 to sections 5.4.4 below.

5.4.1 Ethnography

Data was recorded during observational studies at the epilepsy clinic at 18 of the planned 20 OPD clinics, both during patient-clinician encounters, as well as during informal conversations between participants and other members of the epilepsy team. The author, in the role of BA, was familiar with the operations of the OPD having carried out observational studies for the design of the overall epilepsy EPR (see chapter 4). In the context of this study, the BA used ethnography through observational studies to record field notes to inform the measures of outcome as defined in section 5.2 above. In particular, this involved observing the:

- Technical viewpoint – observe the clinician's interaction with the AED module to examine the usefulness of system features and functions and ease of use of the AED module
- Human viewpoint - the participants' behaviour and attitudes in terms of their attitudes to system use
- Organisational viewpoint – clinical processes by examining communication, collaboration and staff interactions and the ergonomics of clinic environment.

Below are some of the questions that the BA used as prompts to help to deduce contextual information from the observations:

- Who does what tasks and where?
- What are they trying to accomplish?
- What routines are there in this setting? For instance, when are patients called into the clinic rooms? When do people break for lunch? When do they enter information in the chart? Is there a pattern?
- How do staff relate to patients?
- What are the staff dynamics?
- How do staff talk about and understand what is going on?
- How do staff relay information? For example, nuances can be picked up or a tone of voice can explain or put a completely different interpretation on what is being communicated.
- What did I learn from these notes?
- Why did I include them?

Having completed the observations and taken field notes, it was routine for the BA to check the patient's charts for concordance with the field notes and informally ask the staff about particular patient records that were entered into the AED module at that clinic.

An example of an observational study is illustrated in figure 5-3 below and is an excerpt from the field notes that were captured by the author. It is representative of a typical clinician-patient encounter in the epilepsy clinic for a well-controlled patient with epilepsy.

The following example is representative of the conversation between the clinician and the patient for this encounter.

Observation Notes

- *Date of observation:* Tuesday 24/04/2007
- *Duration:* The observation took place for 15 minutes (9:07am -9.22am).

Reflections and Context (the consultant was floating in the clinic and seeing patients where possible as the senior registrar was not at the clinic. There is a feeling of urgency about the length of time spent per patient given that the clinic is so full).

It is the morning of the weekly epilepsy clinic. The consultant epileptologist is preparing for the clinic. The consultant (CT) is looking over documentation including a list of patients who are due to attend

the clini today. He is also using the EPR to review pertinent summary patient information and information about the patient's medications.

The researcher is positioned to the left of the consultant on a chair out of direct view of the patient. The researcher can see the information on the EPR but cannot see the information in the paper chart (however, this information can be checked at a later stage when carrying out the data validation exercise).

Informally, the consultant tells the researcher that it is easier to look at summary information for patients on the EPR than to flick through the paper chart or clinic sheet. He also tells the researcher that the list of patients who are due to arrive at today's clinic are colour coded as first time or return patients making it easy to see how many first time patients are due to arrive and also to get a flavour of the number of return patients. He is familiar with a lot of the return patients and recognises most of their names.

A junior doctor enters the room carrying a patient's medical chart. She gives a short verbal summary of the patient history including the patient's name, age, and type of epilepsy and says that the patient's seizures are worsening. The consultant takes the paper chart from her and flicks through the chart to find information to verify what she is saying. Meanwhile the junior doctor states that she is not sure about the medication dosage she should change or if she should keep it unchanged. The consultant nods and then acknowledges what she is saying.

Meanwhile the junior doctor states that she is not sure about the medication dosage she should change or if she should keep it unchanged. The consultant nods acknowledging what she is saying. They leave the room and make their way to the patient. The researcher follows. The patient is unaccompanied. The consultant introduces himself to the patient and continues to read the patient's history details from the paper chart. He looks through previous discharge letters and obtains a diagnosis from one of the letter and states the diagnosis out loud. He then has the following conversation with the patient.

The consultant informs the patient that the researcher is working on a research project to capture patient information on computer and that if he needs more information about the project that the researcher will talk to him about it after the visit. He asks the patient if it is ok to record his medication information electronically on computer. The patient agrees to this.

Conversation

Ct: How are you feeling?

Pt: It feels like my brain is shaking. I am also getting headaches.

Ct: Are you aware during the episodes?

Pt: What do you mean by episodes?

Ct: Sorry I mean do you know what is happening around you when you are having a seizure?

Pt: Yes. It feels like pressure in my head.

Ct: How long does this last?

Pt: 5 to 6 hours

Ct: When did this start happening?

Pt: 3 to 4 weeks ago

Ct: How many seizures are you having every day or every week?

Pt: At least one a day, usually one a day.

Ct: When do the seizures happen? Do they happen at night, in the morning at any particular time

each day?

Pt: Usually when I am tired or if I am stressed during the day. I think they happen a lot in the morning before lunchtime.

Ct: No family history of epilepsy?

Pt: No not that I know of.

Ct: What medications are you currently on?

Patient takes the medication from his pocket and shows the doctors.

Pt: I think it's Lamictal and Epilim. I already told the nurse what I'm taking. She showed me a picture of them and I pointed them out to her.

Ct: What dosage of Lamictal are you taking?

Pt: 200mgs Lamictal daily and 800mgs of Epilim.

Ct: Any side-effects from medications?

Pt: Yes I'm sleepy and can't concentrate.

Consultant updates the EPR medication module with a side effect .

Ct: Do you work?

Pt: In a supermarket.

A nurse appears around the door and lets the consultant know she would like to talk to him when he is finished. He acknowledges her request.

Ct: Do you drive?

Pt: No.

Ct: Have you had an EEG done recently?

Pt: A good while ago.

Consultant searches through the pocket of the paper chart searching for results from previous EEGs. He is unable to locate an up-to-date result and asks the patient if he can remember the outcome (relies on patient). The patient can't remember getting the EEG done. He then accesses the EPR to obtain blood results which he successfully retrieves and spends approximately 2 minutes perusing them.

Consultant performs a neurological examination on the patient. He asks the patient to sit on the bed and pulls the curtain around the patient to uphold privacy. The examination takes approximately 3 minutes. The researcher is not privy to the examination except when the patient is asked to walk in a straight line.

Ct: That's fine, thanks you can sit back down now.

Consultant states the following information to the junior doctor -"The plan is to increase Lamictal by 25mg in the morning and at night. It is usually better to make just one change regarding a drug". He updates the EPR with the changes to the medication. Jd writes this information in the patient chart. She also gives the patient a non-AED medication for headaches. (Note – this isn't captured in the EPR, non-AEDs are not captured)

Ct: We'll see you again in about 3 months. Catherine the secretary will book you in on your way out.
Pt: thanks for your time.

Junior doctor begins to dictate the letter.

Consultant asks the researcher if the patient's information is available on the EPR. The researcher says yes as the patient's name is on the list. Consultant glances at the clinic sheet in the paper chart (the patient has previously seen the nurse and the medications on the clinic sheet have been updated by the nurse already?). He accesses the EPR, logs on using his username and password and clicks on the patient's information. He remarks that it is difficult to review the medication list as he has to scroll down to see the full list and it could be dangerous if someone cannot see the full list. He asks the researcher to help him to navigate to the appropriate medications page of the EPR and then enters the change of medication and medication side effects.

The consultant and researcher return to the consultant's room.

End of Observation

*Ct=consultant, Pt=Patient, Jd=Junior doctor, Actions are in italics

Figure 5-3: Excerpt of an observational study for a return patient with epilepsy at the Beaumont Hospital Epilepsy Clinic

Data from observational studies was examined to identify concepts to correspond to each of the three key themes human, organisational and technological based on the HOT-fit evaluation framework. The recordings of the field notes were transcribed into an MS Excel spreadsheet. The data that was recorded was read systematically and divided into meaningful segments of text. When a meaningful segment was discovered, a code based on the HOT-fit framework was assigned to a specific segment. This process of segmenting and coding data was completed for all observations recorded. The following example in Figure 5-4 is an excerpt from the field notes of the observational notes illustrated in figure 5-3 above.

Segment	Preliminary Codes	Final Theme and Codes
40 Consultant tells junior doctor -"*The plan is to increase Lamictal by 25mg in the morning and at night. It is usually better to make just one change regarding a drug*". *Consultant then updates the EPR with the changes to medication.*	*current AEDs including dosage and frequency; care plan (EIT)* *Advice (IC)* *"make just one change regarding a drug" (IV)* *Update AED module at point of care (IC)* *Human – System Use - Direct V Chauffeured Use (HOT)*	*40* Human (Behaviour) - Mode of Use

Figure 5-4 Example of a coded segment

Outcomes of the observational analysis are presented in Section 5.5 and examples from observations are outlined in section 5.6 discussion and conclusions.

5.4.2 Feedback Meetings for AED Pilot

Seven feedback group meetings to give the study participants the opportunity to openly express, discuss and record their experience with the AED module were hosted over the course of the study. A weekly meeting is routinely held by the epilepsy team and was used as a forum to gather feedback from participants and input from other members of the epilepsy team. Over the course of the 18/20 week pilot, 7 of the weekly meetings were used to discuss the AED pilot. Four of the 7 meetings were dedicated to discussing the pilot (approximately one-hour). Over the remaining 3 weekly meetings, the AED pilot was included on the agenda and approximately 10-15 minutes was awarded to the topic. On average 11 people attended each of the feedback meetings including the 4 study participants. The other attendees were members of the epilepsy programme who would become future users of the epilepsy EPR. The meetings lasted for approximately 1 hour with enthusiastic input from the user group and discussions that emerged from the BA's observations were held. They included themes around clarifying the process of AED module use at the OPD, establishing rules for retrospective data entry, EPR technical performance and graphical user interface and OPD ergonomics.

The BA recorded reflective thoughts and memos whilst recording the notes at the feedback meetings. At times, it was difficult to coordinate participant's viewpoints and perspectives as it is natural for participants who were enthusiastic about their own opinions and they were sometimes diverse. Sometimes attendees did not always find it easy to stick to the topic in hand and sometimes preferred to deviate to other topics to suit their own agenda. However, the weekly epilepsy meeting provided a good forum for participants and other group members to voice their opinions and concerns about the AED module. Given the busy nature of clinical work and the difficulty to get clinicians involved in work outside of their clinical duties, the epilepsy weekly meeting was a useful forum to gain consensus on any issues that needed to be resolved on the AED module.

The BA performed demonstrations of the AED module at the meetings to outline any updates or improvements that were made to the system. The BA also gave presentations to the group about any issues, results and recommendations from the pilot study. Minutes of the group meetings were recorded by the BA including decisions or actions agreed and sent to all members of the team for approval. Data from the feedback meetings were written up formally, collated and analysed. Key themes were drawn from the analysis and contributed

to the outcome of the AED pilot and fed back into the original requirements. Additionally the author made some memos throughout the meetings which are also included where relevant in the feedback notes but was not circulated to the group members. The outcomes are presented in section 5.5 and section 5.6.

5.4.3 Data Validation

As described in chapter 2, the paper chart is the legal and authoritative medical record at Beaumont hospital which has consequences for the introduction of an EPR. If a patient attends different services in the hospital (e.g. cardiology, endocrinology, etc.) the same paper record will be used to record the encounter. Meanwhile, the epilepsy EPR is specific to the epilepsy service. Consequently, other specialties may have no awareness of, or yet be authorised to access the epilepsy EPR. The epilepsy service is therefore obliged to ensure that information recorded electronically is available in hardcopy format in the paper chart (e.g. a printout of the most up-to-date medications) so that the other services have access to complete and up to date patient information. This led to a requirement for concurrent use of the medications module and paper chart in the epilepsy. The limitation of working with both paper and electronic systems poses significant challenges. Elicitation of clinical notes from two sources can lead to inconsistencies, missing documentation and ultimately encourage medical error.[170, 171] Hence, the transition from paper to electronic should be awarded careful consideration.

A data validation was conducted and is described below. It is important to acknowledge that the author collaborated on this work with another researcher (Patricia Breen, Researcher at Beaumont Hospital, Dublin). The author conducted 50% of the data collection, 50% of the analysis and completed the write up for this exercise. Patricia Breen conducted 50% of the data collection and 50% of the analysis.

A data validation exercise was conducted specifically for the medications module to compare the two primary sources of patient information i.e. the paper chart and the medication module of the EPR. This quantitative method was used to verify concordance in terms of accuracy (e.g. is the medication dosage strength recorded in the paper chart equal to the dosage strength recorded electronically) and completeness (was any information missing from either the paper or electronic repository) of data. This step also provided an evaluation

of the medication module printout insertion in the paper chart in fulfilling the requirement of having complete and accurate data available to all users of the paper chart.

Data validation involved cross referencing the two repositories of information e.g. the paper chart and the EPR AED module. The paper-chart contained handwritten medication data and the original medication printout (e.g. printed at time information entered). The AED module displays the medication data on the screen and stores the medication data in the database. It was necessary to firstly cross reference that the handwritten information written in the paper chart and the original medication printout was identical to the information printed in the validation medication printout (that was printed at time of data validation review). Secondly, it was necessary to cross reference the validation printout with what was stored in the EPR database. This meant what was displayed on the medication screen should be the same as the information stored in the EPR medication database. The process used to perform the cross referencing is outlined in table 5-1 below.

Table 5-2 Method to cross reference the paper chart and AED module

Task Description	Source
1. Design a spreadsheet to capture the information needed to cross check between handwritten information in the paper chart, original medication printout and validation print-out	Excel Spreadsheet
2. Obtain access from medical records department in BH to access the 49 out of the intended 70[6] paper charts for patients included in the study	Paper Chart
3. Print off patient's medication validation sheet from the EPR	EPR Screen
4. Design and request reports from IT team on medication information in the AED tables of the EPR database	EPR Database
5. Review paper charts for handwritten information in paper chart, original EPR printout and cross check them with the validation EPR printout	EPR Printouts
6. Cross reference the AED/Medication validation printout with EPR database reports	EPR Database and Printout

The information stored in the AED tables of the EPR database was queried. Detailed medication reports for the 49 patient records were generated. Information generated included the patient details, who created and modified the record, when the record was created, the list of current and prior medications and corresponding dosages that the patient

[6] At the 18 out-patient clinics there was AED module interaction for a total of 49 individual patient encounters. The remaining 21 records were either instances of pre-populated data by the epilepsy specialist nurses that was not subsequently interacted with at the OPD (n = 12), or uses of the AED module by 3 other epilepsy service doctors outside the context of this evaluation (n = 9).

was administered and the date the patient attended an OPD. The information was cross checked with the EPR validation printouts.

5.5 Conclusions of the AED Pilot Study

Overall, the participants considered the AED module to be useable and useful and of potential benefit to manage patient care. This was demonstrated through the entry of AED data for 70 patient records that were pre-populated by the epilepsy nurse specialists.

Participants interacted with 49/70 individual patient encounters over 18 out-patient clinic sessions. Two epilepsy nurse specialists pre-populated the AED module. For the purpose of this study, the nurse specialist had the responsibility of pre-populating the AED module with relevant information. Clinicians interacted with 49 of the 70 pre-populated records. The remaining 21 records were either instances of pre-populated data by the epilepsy specialist nurses that was not subsequently interacted with at the OPD (n = 12) by the clinicians, or uses of the AED module by 3 other epilepsy service doctors outside the context of this evaluation (n = 9).

Forty patients of the 49 OPD interactions that occurred were first time patients to the OPD. The two epilepsy specialist nurses pre-populated the AED module for the 9 return patients in advance of the OPD clinic. The roles of the two clinicians who participated in the study were as a senior registrar and a consultant epileptologist. In the OPD, they shared an alternating role whereby one of them was available to provide support and advice to other doctors at the OPD while the other was engaged in direct patient care. This resulted in one using the AED module of the EPR at 9 of the OPD sessions while the other used it at 12 OPD sessions. In general each of the two participating doctors used the AED module for 2 patients per clinic session.

The maximum and minimum uses recorded for a single OPD session were 4 patients and 1 patient respectively. Typically medication lists recorded in the EPR demonstrated that new patients had 2 current (range = 0–5) and 2 prior (range = 0–11) AEDs. For the return patients this was 2 current (range = 1–5) and almost 4 prior (range = 0–14) AEDs. This profile of the medication list suggests a range of complexity in the patient sample chosen by the participating clinicians for AED.

As mentioned above, on average 11 people attended each of the feedback meetings including the 4 study participants. Discussions that noted by the author included key themes such as: clarifying the process of the AED module use at the OPD, establishing rules for retrospective data entry, EPR technical performance, graphical user interface and OPD ergonomics. Each theme was categorised under the HOT-fit factors – human, organisational and technology and further defined into the HOT-fit dimensions where possible and are discussed in section 5.5.1 – 5.5.3 below.

5.5.1 Human

The human component of the sociotechnical themes that emerged from this study were categorised as (1) the participant's behaviour in relation to how the AED module was used (see 5.5.1.1) and (2) system use (see 5.5.1.2. below).

5.5.1.1 Behaviour

The BA conducted observations at the OPD and it was documented that participating doctors varied in their approach to using the AED module of the epilepsy EPR at the OPD. In general there were three modes of use employed. The first involved the participant using the EPR during the consultation with the patient, while the patient was present. The second entailed the participant using the EPR directly after the patient left the room to either add new or update that patient's AED data. In the third approach, the participant entered data into the AED module after the out-patient clinic in their own office environment by reviewing the paper chart of the patient seen at the clinic to transcribe their handwritten notes into the electronic record. This third mode was employed so as not to interrupt the participant's routine OPD work practice.

5.5.1.2 System use

For 40 (82%) of the patient encounters, the data validation exercise illustrated that the history recorded in the AED module matched that handwritten in the paper chart in terms of AED name, current/prior status and dosage details.

- In two instances, AED module indicated that a medication was discontinued as it was listed in the prior medication list, whereas the handwritten record indicated that

there was a plan to wean the patient off the particular AED which aligns with the normal standard practice of de-escalating a medication.

- On one occasion, the user selected "Nocte" from a drop-down list in the AED module when they had intended to select "Mane". To rectify this, the user wrote a correction on the AED printout without actually editing what was entered into the AED module.
- Given that the AED module was in an evaluation phase and was not fully operational, the user was able to enter a free-text numeric value into the dosage field and then select the metric unit from an adjacent drop-down field when adding or changing a medication. It was noted that it would be ideal if a drop-down list of pre-defined values for each drug was available to end-users to reduce the risk of entering an incorrect dosage and improve safety and this was noted as a future requirement. For a single AED entry to one patient's AED list the user entered the numeric value followed by µg into the free-text box while the drop-down box defaulted to mg. This resulted in two conflicting metric units in the record.
- On one occasion, the participant's intention was to change/update the medication dosage strength for one AED. However, rather than use the "Change Medication" function the "Cancel" function which deletes the AED entry was employed. This meant that the user needed to re-enter the entire AED dataset – drug name, frequency, dosage, route – when only a change to the dosage data was required.

5.5.2 Organisational

In their feedback at group meetings and in one-to-one conversations with the researcher, participants strongly agreed that the EPR had the potential to be of benefit in supporting the management of patients with epilepsy in the epilepsy clinic. However, they clearly stated that the benefits are highly dependent on the maturation of the EPR so that individual patient's records have as complete and up to date information as possible. For example, there was a strong sense that the patient's AED list, which was pre-populated by the epilepsy nurse specialist, in advance of the OPD was of great benefit. However, it was recognised that this would need additional resourcing as a highly qualified clinician would be required to retrospectively add information to the AED module and other modules of the EPR in order to maintain a high standard and quality data entry.

The organisational component of the sociotechnical themes that emerged from this study were categorised as (1) Procedures (see 5.5.2.1) was used and (2) Workflow (see 5.5.2.2. below) aligning with Yusof's et al (2008) clinical process measure (organisational).

5.5.2.1 Procedures

The researcher had informal conversations with the epilepsy specialist nurses who claimed that pre-populating a record for an individual patient was very time consuming. For example, they estimated that completing a record for a patient with a long history of epilepsy could take more than 2 hours to populate. This was because patients with a long history of epilepsy typically have a large and complex paper chart. It was difficult to locate all the relevant information on their prior AED history for one patient for one transcription to the EPR.

- In response to this, group discussions were conducted at feedback meetings to consider the question of what should be transcribed from a paper chart to the electronic AED record. For example, for a patient with a complex history, attendees at the meeting debated whether all previous data should be included or just data from a particular point in time. They also wondered how this decision should be made.
- The data validation exercise demonstrated that instead of handwriting the AED list a participant wrote "refer to EPR printout" in the paper chart for two of the patient encounters at the OPD. This was a deviation from the agreed study procedure. However, in these cases AED information recorded in the EPR matched information in letters to referring clinicians that were filed in the patient's paper chart.
- Similarly, the validation exercise found that an additional prior AED was recorded in the paper chart that did not appear in the prior AED medication list in the EPR for three of the 49 patients.

5.5.2.2 Workflow

- The study participants informed the BA at feedback meetings and with having informal conversations that introducing the new technology required a period of familiarisation which impeded on the typical rate of work.
- Participants suggested that there was a change in work practice from handwriting to using an electronic system. They noted that it was challenging and a significant change in how they worked, to move from having the freedom to record handwritten unstructured text to a more structured and rigid method of data entry (e.g. validation and alerts to enter mandatory data). According to one participant it

required "Getting used to typing rather than writing" and navigating computer screens to review information rather than "flicking" through a paper chart.

- The BA observed that participants were under strict time constraints in the busy out-patient clinic and this constraint often made it difficult to capture the entire AED history for a patient during the clinic encounter, particularly at the point of patient care. In conversations away from the clinic the participants further explained this as follows. For example, a patient who was new to the Beaumont Hospital epilepsy service, may have a long history of epilepsy and most likely would have attended other centres for management of their condition. Consequently, they may have a complex AED history. The participants found that entering this history into the AED module during the patient consultation could be unnecessarily demanding.
- For this study, participants were given the freedom to choose when to use the AED module during the out-patient clinic. They viewed their principal role at the OPD to be the provision of the clinical service rather than engagement in the study of the AED module implementation. At feedback meetings they reported that if the clinic was particularly busy or there was a backlog of patients in the waiting room, clinical demands would take precedence and the AED module was not used.
- The duplication of data into the electronic and the paper record was accepted as an absolute necessity given the stage of the EPR implementation and the need to reduce risk. However, as expected this was noted to increase workload, increase the risk of data error as transcription was conducted under the pressure of a clinic and imposed additional time pressures to an already "busy, stressful" clinic.

5.5.3 Technical

Based the feedback meetings, participants reported that they were satisfied that the design of the AED module met their original design requirements and expectations. The functionality was useful and catered for the clinical task of recording, reviewing and updating AEDs. The technical components are categorised under performance, technical concerns, ergonomics and training and the outcomes are listed below.

5.5.3.1 AED module performance

- One of the participating doctors described how the ease of access and the display of the medication information in terms of its structured text, was extremely beneficial

"in a patient whose data is already entered, the drug list is great to be able to access electronically".

- One of the doctors reported that the AED module structure prompted them to ask patients clinically relevant questions that they may not otherwise have asked and could therefore be an aid to clinical practice.
- In 2 of the 49 cases, the participant reported that a required value (folic acid) was not available from the AED drop-down list.
- Improvements to the flow of functionality of the AED module were suggested by participants. For example, one of the nurses advised that the action required to discontinue a medication and insert the reason for the discontinuation involved "too many button clicks".
- Occasionally, participants reported that the performance or the response time of the EPR was slower than expected.

5.5.3.2 Other Technical concerns

Minor technical errors or "bugs" were found in the EPR functionality. For example, the EPR is pre-set to log a user out of the EPR system if it is inactive for a set period of time to facilitate security requirements. This "time-out" was not set long enough on one occasion and the participating doctor at the OPD had to log-in repeatedly.

The graphical user interface was not optimal:
(i) Participating nurses and doctors found that the medications user interface or screen was too long and wide and required a lot of scrolling both up and down and over and back. One participant commented on the "need to squeeze all of an EPR screen on one electronic page without having to drag the mouse on the foot or side of page".
(ii) Some participants recommended that the colour scheme and labels on the AED module display be improved.

5.5.3.3 Ergonomics

The lay-out of the out-patient clinic rooms at Beaumont Hospital were not optimal for facilitating use of the EPR. For example, desks, chairs and computers were not designed or positioned to support the clinician's simultaneous use of the AED module and conversation with the patient.

5.5.3.4 EPR training

Participants were satisfied with the level of AED module training provided and the on-site support that they received throughout the study.

5.6 Discussion and Conclusions

The following discussion outlines some key points about the EPR and the role of the STS approach.

5.6.1 The epilepsy EPR is usable in practice in an epilepsy out-patient department

The EPR resulting from this STS project is acceptable to end-users, meets their requirements and is usable in practice in an epilepsy out-patient department

The most important predictors for control and remission of seizures are based on a correct diagnosis and the patient's response to the first prescribed AED. Treatment of epilepsy involves the selection of the most appropriate drug therapy.[23] The management of epilepsy using pharmacotherapy is complex. To achieve optimum management of epilepsy (e.g. seizure freedom), the clinician must choose the most appropriate AED or a combination of AEDs to suit the patient.[70] Chapter 5 outlined an evaluation study of the AED module of the epilepsy EPR in terms of its usefulness and usability having been designed using a sociotechnical approach and was evaluated from a sociotechnical perspective. Overall, the participants considered the AED module to be useable and useful and of potential benefit to manage patient care. This was demonstrated through the entry of AED data for 70 patient records that were prepopulated by epilepsy nurse specialists. At the 18 out-patient clinic sessions, participants interacted with 49/70 of the individual patient encounters i.e. of the 70 AED records that had AED information pre-populated, clinicians interacted with 49[7]. According to one of the participating doctors, it was beneficial that the medication information was structured "in a patient whose data is already entered, the drug list is great to be able to access electronically". One of the doctors reported that the AED module structure prompted them to ask patients clinically relevant questions that they may not otherwise have asked and could therefore be an aid to clinical practice because some of the structured lists acted as a "reminder" for them.

[7] See Chapter 5, section 5.5 for breakdown.

A sample of 4 participants, out of a team of 15 staff that comprise the epilepsy service, were directly involved with interacting with the AED module during the evaluation study. The BA delivered training to all staff who would become end-users of the EPR in the future following the evaluation study. Their experiences were shared over the 18 week study period at group discussions, at feedback meetings and workshops, with the wider epilepsy team (x15). All 15 potential end-users had the opportunity to comment and inform decisions which aligned with the sociotechnical Clegg's principle that design is an extended social process.

The main sociotechnical considerations that emerged from the AED pilot study and that were categorised according to Yusof's HOT-fit evaluation included changes to workflow and job roles, EPR technical issues and the ergonomics of the clinic, all of which demonstrate the use of the EPR in the epilepsy OPD from a sociotechnical perspective. The sub-findings are discussed in 5.6.1.1 to 5.6.3.5.

5.6.1.1 The deployment of an EPR in a live clinical setting results in changes to work activities

Observations at the OPD and informal conversations and feedback meetings with the participants showed that use of the epilepsy EPR in the OPD altered participants' routine workflows. It is well known that additional work effort and changes in work practices are required to accommodate the introduction of any IT system including EPRs.[102]

The BA observed that the use of the AED module in the epilepsy clinical brought about change to the usual clinic processes as there was an increase in workload. This did impact on the user's attitude towards using the EPR at the clinic as there was some resistance and lack of acceptance. This was in the context of a busy clinic where clinicians were already under time constraints and worked in a stressful clinic environment.

Clinical tasks that were considered more important than using the AED module took priority. For example, the BA witnessed that on 8 out of the 70 occasions (i.e. patient clinical encounters where data was entered for a patient and observed by the BA) the use of the EPR was abandoned if there was a backlog of patients in the waiting room. This was particularly evident if a new patient with complicated epilepsy presented with a long AED

history as it proved difficult to invest time at the OPD to record the data electronically. As stated by a senior clinician (registrar) at a feedback meeting:

> "*The pace of the overall clinic was slower I think... because using the EPR took some time to get used to in the clinic and also adding in the medications was harder to do than in training, although patient numbers may also have had an impact" (Feedback meeting ,Senior Registrar).*

A clinical nurse specialist also voiced concerns about prioritising the EPR over clinical tasks declaring that:

> *"From a nursing perspective priority will have to be given to educational needs over reviewing patients with the EPR. Multidisciplinary members are interrupting consultations with nurses to request education of their patients*" (*Informal conversation, Clinical Nurse Specialist,).*

5.6.1.2 The deployment of an EPR in a live clinical setting requires highly skilled clinical experts to pre-populate the EPR with clinical information

As mentioned above, a small sample of 4 participants, out of a team of 15 staff that comprise the epilepsy service, were directly involved with interacting with the AED module during the evaluation study. There were two participants that used the EPR in the epilepsy OPD. The other two participants were epilepsy nurse specialists with a role to pre-populate the EPR prior to its use in the epilepsy OPD. The four participants of the evaluation study, were confident that the AED module could be used in practice in the future, provided that there was good quality and pertinent clinical information pre-populated in the EPR prior to its use. Both participants agreed that the time taken to complete a full history on a patient using the AED module at the point of patient care would be a major time constraint in a busy clinic and was the biggest obstacle in introducing the AED module.

Participants considered that the EPR could only be used effectively in the clinic when the EPR was mature enough and contained good quality information. This suggests that investment in EPRs in the future must take into account the increased costs and human resources needed with deploying an EPR. This involved the task of pre-populating the AED module with detailed medication information prior to the patient's visit at the OPD which

was debated in detail at the workshops on EPR deployment. It was recognised that highly skilled clinical experts in epilepsy with a thorough understanding, appreciation and experience with epilepsy was required to populate the EPR prior to the weekly clinics. The end-users agreed that the Epilepsy Monitoring Unit (EMT) nurses would be best suited to pre-populate the EPR. Their role was to retrospectively enter data into the epilepsy EPR for patients that were due to attend the epilepsy clinic. This was outside their routine role and was based on level of goodwill from the nurse. It demonstrated the commitment from end-users to establish and maintain the epilepsy EPR. In conversations with the BA, EMT nurses noted that pre-populating a record for an individual patient was very time consuming. For a patient with a long history and consequently a large and complex paper chart, they found that more than 2 hours could be spent locating all the relevant prior AED history for transcription to the EPR.

5.6.1.3 The deployment of an EPR in a live clinical setting results in the need for a process to be established to pre-populate the patient record

Pre-populating the EPR was not as straightforward as simply entering data blindly from the paper chart to the EPR. For example, it was recognised that key information was required regarding the patient's epilepsy history in order to correlate the medications to the patient's diagnosis. This task required expert knowledge in epilepsy to ensure that the correct information was populated which was important to ensure data quality and patient safety. For example, it was essential for the clinician to be able to review the patient's epilepsy history which involved knowing the correct seizure types which had to be linked to the patient's epilepsy diagnosis which would in turn correlate to the combination of medications that were prescribed for the patients.

Group discussions were conducted at several of the feedback meetings to consider how a return patient's retrospective information should be transcribed from a paper chart to the EPR. Users debated whether all previous data should be included or should it just be data from a particular point in time. They considered how accurate the most current information in the EPR at a clinic visit was. For example, a patient could have information updated by users external to Beaumont such as their GP, or a medication change via the epilepsy telephone advice service could be made between clinic visits or dosage changes when patients are attending the hospital as in-patients. There was a possibility that a CNS could contact sources such as patients, GPs and pharmacies to capture the patient's change in

medication and pre-populate the EPR with the most up-to-date information. This is something that has been raised in the literature particularly around the evaluation of summary care records[169] where there is a risk around having no one custodian to manage the record.

> "*The benefits of the AED module will only be recognised when the system is populated with as much complete and up to date information as possible on the patient summary is the responsibility of one person*". *(Feedback Meeting, Registrar)*

5.6.1.4 The deployment of an EPR in a live clinical setting results in challenges such as the mode of use of the EPR by end-users.

Overall end-user's attitudes and behaviour towards the epilepsy EPR were positive and there was evidence that they made it an integral part of their work e.g. at their weekly meetings. However there was a shift in attitudes when end users had to use the EPR under the pressures and practicalities of a busy clinic.

There was a significant change in work practice from writing unstructured text in the paper chart to capturing medication information in a structured way (including responding to validation and alerts to mandatory data). According to one participant it required "*Getting used to typing rather than writing*" and navigating computer screens to review structured information rather than "flicking" through a paper chart.

Despite receiving training, participants deviated from the recommended mode of use (as outlined in chapter 5, which proposed that they should enter the AED medications for the patient at the point of care. The participants demonstrated three different approaches which included interacting with the AED at the point of patient care, after the patient left the consultation room (the clinician updated the AED after the patient visit and before reviewing the next patient) and after the patient-clinical encounter (e.g. when the clinician was in their own office). This deviation was most likely influenced by a fear that using the EPR would interfere with normal workflow and negatively impact on clinical productivity:[171]

> *"More time is needed to use the AED module in the clinic. The users of the EPR are not allocated additional time during scheduling to facilitate EPR update or*

familiarisation with the EPR. Priority of the EPR will not be given to updating the EPR ahead of patient needs" (Observations at epilepsy OPD, BA)

Although there was positive feedback, trust in the AED module application was not yet established given the immaturity of the system as stated by the feedback from the consultant epileptologist:

We definitely made progress on the EPR end of things as well. The more we use the better we will be able to comment on its usability and clinical applicability" (Informal conversations with BA, (Consultant comment).

It is recognised that it is challenging to encourage the use of clinical systems during patient-clinician encounters even if the clinicians regard them as important to increasing the quality of patient care.[172, 173] If clinicians use the AED module after the consultation it means that the data entry does not reflect data entry at the point of patient care and diminishes the usefulness of alerts that were designed for use of the EPR at the point of patient care.

5.6.1.5 The deployment of an EPR in a live clinical setting requires hands-on support for end-users at the initial stages of deployment

The BA provided ongoing support in the clinic and this study indicated that support must be available to end-users during the deployment phase of an EPR and that they must be aided in recognising the ultimate benefits of the additional work burden during the growth to maturity of the application. Hence hands-on support was a key role in the use of the epilepsy EPR at the initial stages of deployment. An example from observations where the BA gave hands-on support is illustrated below:

Consultant asks the researcher if the patient's information is available on the EPR. The researcher says yes as the patient's name is on the list. Consultant glances at the clinic sheet in the paper chart. He accesses the EPR, logs on using his username and password and clicks on the patient's information. He remarks that it is difficult to review the medication list as he has to scroll down to see the full list and it could be dangerous if someone cannot see the full list. He asks the researcher to help him to navigate to the appropriate medications page of the EPR and then enters the change

of medication and medication side effects (Researcher's Observations of patient-clinician interaction, BA).

This observation and request from the end-users signified two requirements in relation to further training and the need to re-examine the user interface.

5.6.1.6 The deployment of an EPR in a live clinical setting requires an appropriate environment to be set up in order to accomplish effective deployment

Beaumont Hospital out-patient clinic was designed ergonomically for a paper-based system. Arising from this study, improvement of these ergonomics, so that clinicians can seamlessly move from conversation with the patient to interaction with the AED module, was believed to be an important priority for facilitating use of the application. It was highlighted by end-users that the layout and furniture available in the out-patient clinic rooms at Beaumont Hospital were not optimal for facilitating use of the EPR as the location was not originally designed for this purpose. This issue also impedes on the clinician-patient encounter. As stated by a junior doctor at the epilepsy clinic in relation to space in the clinic:

"The issue of my room being so small is a problem when patients in wheelchairs accompanied by family are allocated as physically the space is too small and as I am very familiar with a lot of patients with disability I expect to see a lot of them in clinic" (Informal Conversations, SHO)

The issue of space in the clinic rooms were also echoed by the clinical nurse specialist:

"The end room where nurses review patients in comparison to other rooms is too small; there is no ventilation, a cupboard hanging on a wall where patients and I constantly bump into. Other MDT are floating in and out of it also (e.g.) researchers observing interactions, EPR manager, as well as relatives and external staff. I would suggest that a larger room is allocated" (Feedback Meeting, CNS)

5.6.1.7 The deployment of an EPR results in increased medical record fragmentation

During the study of the deployment of the EPR, the epilepsy service at Beaumont Hospital were the only authorised users of the AED module and other disciplines within the hospital were not authorised to use it. Also, the hospital's paper chart was (and remains) the

authoritative and legal record of patient encounters within the organisation. As a result, the deployment of the AED module resulted in an increase of medical record fragmentation. The need for other disciplines within and external to Beaumont hospital to access and use the EPR was recognised. However, in the interim, parallel use of the paper chart and the electronic record, while not ideal, was prudent. [174, 175] The accuracy (82%) of the data validation exercise conducted in this study illustrated that with some additional improvements to the process, printouts from the EPR inserted into the paper chart have the potential to replace the handwritten record.

5.6.2. Adopting an STS ethos for the design and deployment of an EPR requires ongoing engagement and commitment from end-users at all levels which is challenging in a busy clinical environment

This sociotechnical study demonstrated that end-users at all levels, including the administrator, nursing, clinicians and researchers, who worked in a fast paced, busy epilepsy clinic were fully engaged and committed to actively participating in the requirements, systems design and deployment of the epilepsy EPR. The study also suggests that employing a sociotechnical philosophy facilitated end-user's ongoing engagement and commitment.

A sociotechnical ethos to system design and deployment underpinned the development of the epilepsy EPR and became embedded into the requirements and system design processes. From the outset of the study, the development of the epilepsy EPR was the responsibility of the end-users and they actively participated in all phases. Clinical buy-in was demonstrated by the end-users' commitment to design, test and use the medication module in the live clinic and their willingness to contribute suggestions and improvements to the EPR.

The BA's role was to enable the end-users to own the epilepsy EPR development by encouraging and supporting them to continuously engage in the analysis and requirements and system design process. The latter involved the formation of data requirements and prototyping in order to assist the end-user to design the EPR so it could fit effectively with how they conduct their work at the epilepsy clinic. The BA achieved this by organising and hosting three initial kick off meetings (x1 hr) over a period of one month, with both end-users and the software development team to enhance a feeling of a "shared project".[14, 102]

It was emphasised that all opinions would be listened to and equally considered in relation to the EPR design based on the ST principle of *"fostering a democracy"* [126] regardless of seniority within the organisation. At the initial kick off meetings, the BA conducted educational sessions about sociotechnical philosophy and eHealth and presented project plans and requirements engineering processes to educate the end-users about the study [176]. The attendance rate was high at the initial meetings with representation from senior clinicians at each meeting which demonstrated senior management support for the study. Fundamental sociotechnical principles were presented by the BA and there was a consensus by end-users to trial them and they were used effectively throughout the study. They included the following sociotechnical concepts:

- End-users were considered the experts in their field and they acknowledged that they needed technology such as an EPR to support them in their work (*Clegg, principle 2 values and mindsets*)
- End-users were fully responsible for making decisions about the EPR design and deployment in order to reflect how the EPR could best fit with their work (*Clegg, principle 12 Problems should be controlled at source*)
- A multidisciplinary approach to design is more likely to foster creative and innovative solutions [127]. For example, the IT and the multidisciplinary clinical team were included in design and deployment as much as possible. The design effort was enhanced by combining the different roles and background and different skillsets (this includes the developers) in order to share different experiences, expertise and viewpoints and this presented an opportunity to educate each other (*Clegg Principle 17 Design involves multidisciplinary education.* The BA, end-users and developers also designed initial data requirements, prototyping which was a joint, iterative process.

5.6.2.1 The engagement of non-permanent medical staff that rotate frequently between different clinical domains is particularly challenging when employing an STS philosophy

It was essential to gain access to the most knowledgeable clinical and administrative end-users to elicit the clinical requirements. The BA found this was difficult at times as the end-users worked in a clinical environment that meant clinicians and all auxiliary staff were extremely restricted with their time. They often worked in a healthcare service that was

under-resourced and they followed a busy schedule. It was of benefit to have a BA embedded in the team who was familiar with the research and could access the end-users to obtain their requirements, demonstrate prototypes and decision making.

The BA observed that end-users were fully committed to their role of patient care in the clinic, that they were aware of each other's tasks and that each individual had a clear understanding of their own role and responsibilities and the expectations of them to perform the work at the clinic. Importantly there was a collaborative team effort and clear communication between end-users when reviewing a patient. For example, it was observed that patients had interaction with multiple healthcare professionals including a CNS, epilepsy pregnancy nurse, community nurse, SHO and consultants (although all patient info is validated by the clinician) and sometimes other healthcare professionals external to the epilepsy service such as pharmacists, dieticians and neuropsychologists at each visit and there was collaboration between them all.(2) This was conducive to designing and deploying the EPR in the clinic as there was a sense of teamwork and collaboration already among end-users. However, one of the challenges identified by the BA was in relation to junior doctors who rotated in the clinic every three to six months. As they were not a permanent member of the team it was understandable that they were not as engaged in the EPR research. However, they did contribute and engage to a certain extent as there was strong clinical leadership and senior clinicians and the consultant were clear that it was an important part of their rotation to engage in the EPR research.

5.6.3 The business analyst plays an important role when designing and deploying an EPR based on STS thinking

The author played the role of a BA, as described in chapter 1 and chapter 4, performing a liaison role between the multidisciplinary clinical and administrative end-users and the software developers. The BA worked on the design and deployment stages of the EPR. The BA played a key role in order to deliver the EPR in a live clinical environment alongside other key factors such as strong project management, clinical leadership and user ownership. The BA co-designed the EPR with the end-users with some influence from the technical team.

5.6.3.1 The business analyst ensures the end-users are the owners of the EPR and are at the centre of the requirements, design and deployment processes.

The management of user requirements and user expectations was a significant part of the BA's role and was challenging given the complexity of introducing an EPR into a healthcare environment which is information intensive and involves complex business processes. The BA was the liaison and communicator between the end-users and technical team. This primarily involved fully engaging with end-users about their requirements and putting the end-users at the centre of the requirements, design and deployment processes. This was facilitated by gaining a thorough understanding of the user's environment.

5.6.3.2 The elicitation of requirements is a significant part of a BA's role and managing end-user's different viewpoints is challenging

The elicitation and gaining agreement of requirements was a significant part of the BA's role. One of the most challenging aspects was managing end-user's different viewpoints on requirements particularly when one user could be overpowering with their opinion or agenda. A good level of trust was formed between the BA and the end-users and as a result it was possible to champion the EPR and elicit information from the end-users as they were more comfortable with the role of the BA. It took time to build this relationship with the end-users particularly because they were unfamiliar with BA's observational role and because observing work patterns can be threatening to some individuals. The BA was visibly present at weekly clinics and that gave a certain level of assurance to the end-users that this research was important and it provided some level of assurance to the end-users that there was a role dedicated to the EPR.

5.6.3.3 The BA's role is the liaison between the end-users and technical IT team and plays a key role in enhancing effective communication between them

The BA was instrumental in promoting awareness and progress of the EPR among the end-users and technical team and was able to deal with issues as they arose. For example, the BA found that what could be considered a "small" issue or non-important issue for a technical person such as a change to a value on a value list was particularly important to an end-user and caused frustration if it was not updated and needed to be flagged as a priority. As mentioned in chapter 1, the role of the BA and the fact that the EPR was a bespoke build with a dedicated in-house development team meant that the BA could manage change requests which were prioritised and therefore dealt with a quick turnaround time. Importantly, the BA was able to access the end-user team when key decisions needed to be

made about design and deployment and also relay to the development team the most pertinent user requirements.

5.6.3.4 The BA role is a key role in understanding the organisation of staff and workflow which is important for the design and deployment of an EPR using a sociotechnical approach

The BA's role was important in observing the end-user's environment and establishing how the EPR could fit together with the social and organisational aspects of their work and its environment. As outlined by Berg et al. (1998) "medical work is a social process, and the medical record is interwoven within this work in complex ways".[14] An example is illustrated below (in relation to chart allocation) and demonstrates how the end-users changed their work pattern based on analysis that the BA carried out prior to the introduction of the EPR. This change in workflow was important for the deployment of the EPR as it would have been difficult to deploy the EPR in an environment that carried out its business in an ad hoc way. It also helped to engage the end-users in the research.

In the case of the epilepsy EPR, the BA conducted observational studies at the epilepsy clinic over 10 consecutive weeks. The BA observed the process of how clinicians were allocated to patients. The normal process was for senior medics to review first time patients, for junior medics to review well-controlled return patients and the consultant played a "floating" role between all staff in the clinic to provide decision making and verification of drug-treatment, plans etc. when required.

The BA presented key themes from the observation notes to the end-users at a weekly meeting and suggested that there should be preparation of charts prior to the clinic i.e. that patient charts should be allocated to the clinical roles. This involved the consultant neurologist allocating the different patient types to the different clinician role the day before the epilepsy OPD took place. The changes also impacted on the secretary who had to ensure that the charts were available on the day before the clinic. The outcome from the trial was documented by the BA at a weekly meeting and the consultant reported that it took one hour prior to the clinic to organise and allocate patient charts to clinic staff. The patient types were allocated to the following clinical roles:

1. First time patients and patient's with learning disabilities allocated to registrars on alternate weeks
2. Return patients who are a mix of patients with refractory epilepsy and well controlled epilepsy awarded to senior house officers
3. Follow-up post-surgical patients allocated to the clinical nurse specialists

Overall the end-users continued to use the new system (or way of working) and some concerns were raised. Feedback and comments were recorded by the BA which were conflicting as one CNS stated that:

> *"The amount of patient charts allocated was too many in order to meet the patients' needs aswell as the educational needs of other patients attending other multidisciplinary teams" (Feedback meeting, CNS).*

compared to another CNS who was happy for the opportunity and did not feel overwhelmed by the number of charts that were allocated and did not feel it was interfering with the typical practice of advising patients:

> *"Very happy with the clinic allowing the nurse specialists to review and partake in clinical decisions in caring for patients with epilepsy alongside consultants" (Feedback meeting, CNS).*

The BA followed up with both CNSs through informal conversations and one of the CNS was still frustrated with the chart allocation:

> *"Charts allocated to nurses are left outside a room that is 20 feet away, unsure what the rationale is for this, while charts for doctors seeing patients on back corridor are left outside nurses room, where they get mixed up with educational material" (Informal conversation, CNS).*

Other comments from registrars that were very positive included how they would welcome being about to review the same patient at each return visit in order to enhance their learning about epilepsy:

"You get to follow up on the patients you have seen previously and that in itself is good for learning" (Feedback meeting notes, Registrar 1) and

"*It would be ideal if a NCHD could follow a patient at each clinic visit, or perhaps if the patient was admitted as an in-patient through their hospital visit. This would mean the NCHD could get to know the patient's history and follow the patient journey from admission through to discharge e.g. know the patient from a previous consultation" (Feedback meeting notes, Registrar).*

This scenario aligns with the sociotechnical principle of "evolving and sustaining new ways of working" that exploit the technological potential effectively and safely. This example demonstrated how the organisation of staff and workflow was important in order for the EPR to be designed and deployed. By improving workflow and identifying gaps in work processes it helped with the design through engagement with users and with deployment as it was a more organised way of working and it meant that when prepopulating the EPR with first time patients the BA knew that a senior clinician would be using the EPR.

Achieving an optimum EPR solution for end-users at the epilepsy OPD requires viewing the social and technical dimensions of the organisation, in this case the epilepsy OPD, as a network. Embedding the sociotechnical ethos should start as early as possible in the development lifecycle and all dimensions should receive adequate attention so there is human and organisational readiness for the technology.

Part II

The Clinical Document Architecture

Chapter 6 HL7 Clinical Document Architecture (CDA)

6.1 Introduction

Part two of this research focuses on the importance of interoperability standards, in particular, the HL7 CDA, to support the integration of eHealth systems. The purpose of the HL7 CDA is to provide structure and semantics to clinical documents in order to facilitate the electronic exchange of clinical information between eHealth systems in a meaningful way.

This chapter reviews the literature on interoperability standards in healthcare, principally the HL7 CDA standard, and the literature around mapping from existing relational databases to the HL7 CDA document standard. Section 6.2 gives an overview of healthcare interoperability and the various types of interoperability standards that have been developed by international Standards Development Organisations (SDOs) to support communication between eHealth systems. Section 6.3 gives an overview of the HL7 suite of standards with a comprehensive description of the HL7 CDA described in section 6.4. Section 6.5 provides literature on mapping data from an existing relational database to the HL7 CDA standard.

6.2 Healthcare Interoperability

Healthcare is a highly information-intensive business, with large volumes of data generated at various clinical environments (primary, community, secondary and tertiary care), at different locations (community settings, outpatients, theatre, wards) and by a variety of users (GPs, community care nurses, hospital doctors, administrators etc.). Healthcare professionals rely on information from multiple sources to make decisions regarding a patient's care and require access to clinical systems that are often disparate legacy systems operating in parallel.[177] This type of model hinders the sharing and integration of health information and consequently increases the duplication of information resulting in redundant data.[178] It is still commonplace in hospitals and healthcare organisations to discover that "…seamless electronic communication between systems and between health professionals is not the rule but rather the exception"[178, 179] highlighting the need to support interoperability between systems in order to facilitate data sharing.

It is important that healthcare interoperability should not be viewed as simply the physical connectivity and integration between eHealth systems. Various organisations and individuals

have attempted to identify and define the different types of interoperability in the healthcare domain. The HIMSS Dictionary of Healthcare Information Technology Terms, Acronyms and Organisations[180] identifies 17 different definitions of interoperability ranging from technical, organisational, functional, political, legal and social interoperability.

Interoperability has been researched extensively by one of the main international Standards Development Organsiations (SDO) in healthcare, the Health Level Seven (HL7) EHR interoperability group, who determined three major types of interoperability[181] namely technical, semantic and process interoperability:

- "Technical interoperability is the exchange of data between computer system A and computer system B. Systems do not know about the meaning of what is exchanged
- Semantic interoperability guarantees that system A and system B understand the meaning of the data in the same way[182]. It is the ability of systems to use and interpret the data that is exchanged in a meaningful way.
- Process interoperability incorporates business processes. It is important that business process also interoperate and the people involved in supporting systems share a common understanding to enable system A and B to work together".[183]

6.2.1 Importance of eHealth Interoperability Standards

The benefits of joined up healthcare, to provide the right information to the right person at the right time and place, is based on using appropriate standards. The International Standards Organisation (ISO) define a standard as "a document, established by consensus and approved by a recognised body, which provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context".[184] One of the fundamental enablers of eHealth is healthcare interoperability standards whose purpose is described as "the ability of different information technology systems and software applications to communicate, to exchange data accurately, effectively, and consistently, and to use the information that has been exchanged".[185] Interoperability standards can be implemented within or across different geographical healthcare boundaries. For example, interoperability can exist within a single healthcare provider from one department to another or between ancillary systems like Laboratory Information Systems (LIS) or Radiology Information Systems (RIS) to an EHR system to ultimately sharing information externally between health care institutions.[181]

It is recognised that adopting and adapting recognised international interoperability standards is fundamental in supporting efficient and cost-effective information exchange.[186] In Ireland, the national eHealth strategy was published in 2013[12]and recognised the importance of standards to enable eHealth initiatives. The number of healthcare ICT standards available is summarised in a report prepared by Empirica GmbH on behalf of the European Commission who identified 22 different ICT standards in healthcare.[179]

As outlined by Empirica, the major SDOs that play a leading role in EHR standards development include:

- ISO: the International Organisation for Standardisation - the largest developer of world-wide standards.
- CEN: the European Committee for Standardisation, the principal SDO in Europe.
- IHTSDO: the International Health Terminology SDO, the developer of the SNOMED-CT terminology standard.
- HL7: Health Level 7, the developer of the most widely used standards for electronic messages and documents in healthcare.
- OpenEHR: an open source community for electronic health records.
- IHE: Integrating the Healthcare Enterprise as a major e-health systems interoperability initiative.[179]

6.2.2 Clinical Coding of health information

Many systems can achieve technical interoperability but the real challenge is when different EHR systems attempt to share clinically meaningful information.[187] Semantic interoperability can only be achieved when a reference model, data structures and terminologies or clinical classifications work together harmoniously and not as separate entities. The CDA standard dictates that the document content is human readable by supporting narrative information but also providing structure to support clinical coding to facilitate semantic interoperability. [188, 189]The CDA identifies a framework for specifying the full semantics of clinical documents by enabling the use of codes from a variety of healthcare terminological systems such as the International Classification of Diseases (ICD), clinical terminological systems such as the Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT) and the Logical Observation Identifiers Names and Codes (LOINC).[190]

The degree to which coding is applied to a document is important as the more investment is made in coding information, the better the reusability of the data. At the semantic level, the interoperability problem remains very difficult, as medical information in itself is complex regardless of providing support for clinical coding.[191] For example, when clinical information is exchanged, much of the clinical meaning is derived from how the information is organised and grouped; clinical meaning is not derived from the individual data values. Clinicians tend to interpret clinical statements based on how they are hierarchically nested within a record. Information may be grouped under headings or clinical problem lists such as epilepsy, or linked to a preceding healthcare event such as a previous description of patient's seizure. Information about certainty, severity and negation or absence of findings must be represented unambiguously. Currently, in Ireland, there are recommendations for implementers to use SNOMED CT as the clinical terminology to code information at the point of patient care.[192] SNOMED CT has many benefits such as its granularity, its comprehensiveness in terms of coverage, claiming to provide a code for nearly all clinical concepts. The difficulty with developing SNOMED CT subsets of information, such as an epilepsy medication subset, is that they are time consuming to develop and would require a considerable amount of expertise, from both a SNOMED Clinical Terms clinical terminologist and a subject matter expert in epilepsy.

6.2.3 EHR Architecture

The purpose of EHR architecture, from a technical viewpoint is to ensure interoperability, modularity, migration, stability, management, maintenance and cost-effectiveness. The main SDOs in healthcare do not agree on an exact definition of a healthcare record architecture (EHR architecture) but there is consensus that exchanging messages between various systems is not a viable long-term solution to achieve a shareable record and a common architecture is necessary.[193] Therefore an architecture based on a reference information model is more suitable. A reference model is an important artefact in computer design, informing software and database design and is necessary for standards development as it acts as a starting point for developers formally documenting what has been agreed in a standard.[194]

One of the main global candidate standards for EHR reference models is the HL7 Reference Information Model (RIM). The other main contender for EHR interoperability standards is the ISO/EN 13606 Part 1 openEHR Reference Model based on the openEHR two-level model

approach. Other eHealth interoperability standards that exist for the representation and communication of clinical information include clinical data structure definitions e.g. openEHR archetypes, ISO/EN 13606 Part 2, HL7 CDA templates and clinical terminology systems including LOINC and SNOMED CT.

6.3 Health Level Seven (HL7) Standards

HL7, the organisation, was founded in 1987 and is a U.S. based non-profit ANSI accredited SDO. HL7 develops standards to support the exchange, management and integration of healthcare information.[189] HL7 provide a suite of interoperability standards including hl7 v2.x, v3 and the CDA.

The most common HL7 standards available are the HL7 v2.x suite of standards the HL7 v3 and the HL7 CDA. HL7v3 arose out of concerns about the lack of "coherence, cohesion, and consistency" in the v2 standard. HL7 v3 provides a level of semantic interoperability that is not matched in other HL7 versions and in other standards. It has been the standard of choice for countries with national implementations in the UK (the English NHS), the Netherlands, Canada, Mexico, Germany and Croatia. The HL7 v3 was designed to support large-scale health information exchange. Within the US, jurisdictional agencies have adopted HL7 v3 to support large scale integration (e.g. CDC, FDA).[195]

HL7v3 is a standard and is divided into domains such as pharmacy, medication, orders, observations etc. to describe its functional content. The main goal of HL7v3 is to establish semantic interoperability across a variety of domains (e.g., laboratory, clinical health record data, public health, research, etc.[196] The v3 greatly reduces ambiguity in the specification because it uses a formal object oriented (OO) design methodology to increase the "detail, clarity, precision and granularity" of message specification. In summary, the v3 standard is based on a formal OO design methodology, with strong emphasis on using vocabularies such as SNOMED CT which addresses vocabulary much more precisely than v2.x.[183] This is because v3 can "bind" a vocabulary to a data field.[197, 198]

6.3.1 Reference Information Model (RIM)

The RIM is the source from which other HL7v3 information models is derived and get their information-related content and meaning. Given that the RIM is a shared information model and the root for data content for all messages (and documents), it means that data can be

represented in a consistent way and reused across multiple information artefacts e.g. messages, documents, templates.[199] This is intended to provide a framework that supports database and schema design by creating a single environment for messaging which can be shared by all healthcare institutions.[200]

The RIM defines six foundation classes (See figure 6-1) of the health domain as well as the associations between those classes and their specialisations are summarised by Blobel and Oemig (2009)[197] as follows:

- 'Act: 'A record of something that is being done, has been done, can be done, or is intended or requested to be done' such as an observation, procedure, supply, medication
- Participation: The context for an act in terms of who performed it, for whom it was done, where it was done, etc
- Entity: A Representation of the physical things and beings that are of interest to, and take part in health care. entities, e.g. organization, living subject, materials, location)
- Role: The role that each entity plays in its participation e.g. patient,provider, employee, specimen, practitioner);
- ActRelationship: This class represents a relationship or link between acts
- RoleLink: A connection between two roles expressing dependence between them'

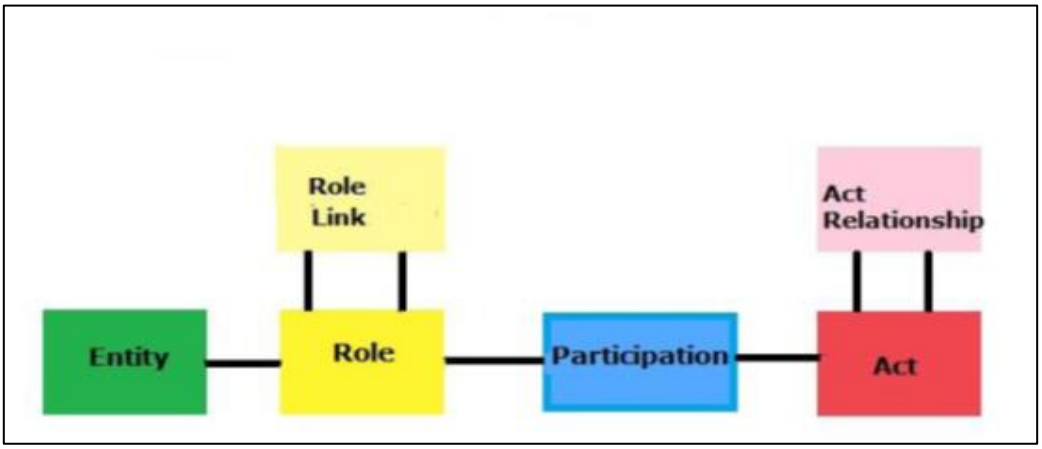

Figure 6-1 Diagrammatic representation of the associations between RIM classes

(Taken directly from Hinchley A., 2007)[201] Figure 6-1 illustrates that Entities such as people, places and things (i.e. nouns) are related to other Entities through roles, and through their Participations (verbs). The Participation, ActRelationship and Rolelink classes represent a different kind of relationships between acts. The ActRelationship represents a relationship between two Acts through ActRelationships.[196]

The HL7 CDA model called the CDA RMIM is a constraint on the RIM and is defined in detail in section 6.4 below.

6.4 HL7 Clinical Document Architecture (CDA)

In addition to creating health care messaging standards, HL7 also develops standards for the representation of clinical documents. The most recent version is the CDA release two (CDA R2) normative edition published in 2005. CDA is considered the success story of the HL7 standards and is successfully adopted worldwide by organisations and industry as a standard to underpin clinical information exchange.[202] It is noteworthy that industry has embraced the CDA standard most likely due to it being easier to implement than the HL7v3 Standard.[203] This is partly because unlike the HLv3 standard, CDA does not use the entire RIM to derive its content and information-meaning for document development. Instead, the CDA is based on a refined subset of the RIM and is called the refined RIM or R-MIM. To implement the CDA, it is necessary to gain a good understanding of the RIM given that the CDA RMIM (CDA object model) is a constraint on the generic RIM model.

CDA implementation guides(IGs) describe the use of the standard for a specific document type in a specific context or scenario and can be defined at regional or local level. CDA IG's have been developed in Germany, Japan, France, Italy, United States and Britain and large scale CDA projects have been implemented in Greece, England, Canada, Denmark, New Zealand and Finland.[190]

6.4.1 Clinical Documents

Clinical documents have unique characteristics that distinguish them from other forms of information (e.g. messages, records, extracts). Typically there are two ways to document clinical information. In the paper world, information is recorded as "free or narrative text" usually in the form of documents, reports, and forms, supporting human readability of information, but limiting reusability of information. This is in contrast to structured data, for example fields in a database[204], where information can be stored and managed efficiently, and which facilitates content driven analysis and reporting, making reusability of information more attainable. A paper published by Feng et al. (2011)[205] explored the issue of extracting data records from unstructured text and concluded that the lack of structure made it very difficult to derive meaning from artefacts and values without using language analysis techniques.

It is estimated that approximately 70% of all medical data is available in free text format and is not structured. However, electronic documents can be easily developed to include a blend of free text (narrative speech) and structured data making it more compatible with existing paper documentation.[190] Documents can provide a "snapshot" in time of the most pertinent clinical and administrative data of a patient.[181]

Different information exchange scenarios may be best supported by messages or documents. Messages allow the transmission of events as they occur (transaction based activity) and may not require human interaction. Therefore the HL7 v2 messaging standard is more suited for exchanging laboratory ordering and results.[206] Documents are a more suitable method to convey health information given that healthcare practitioners are trained in the creation and use of documents. For example, clinicians routinely exchange referrals and discharge summaries, albeit usually on paper and not in a standardised, structured or electronic format.[190, 195]

The need for a clinical document standard, such as the HL7 CDA, results from the broad variability in clinical notes in terms of their goal, structure, content and presentation. HL7 defines clinical documents as historical, human readable healthcare records that "mix discrete data and free-flowing narrative and are always (at least theoretically) attested".[207] The characteristics of a CDA clinical document are outlined below (based on HL7 V3 primer)[208]

- Persistent - A clinical document continues to exist in an unaltered state, for a period defined by local and regulatory requirements.
- Stewardship - A clinical document is maintained by an organisation entrusted with its care.
- Potential for Authentication - A clinical document is an assemblage of information that is intended to be legally authenticated.
- Context - A clinical document establishes the default context for its content
- Wholeness - Authentication of a clinical document applies to the whole and does not apply to portions of the document without the full context of the document.
- Human readability - Clinical document is human readable.

6.4.2 Goal of the CDA Standard

The HL7 CDA is a standard that structures material within clinical documents using a mark-up language and provides semantics of a clinical document for the purpose of exchange.[207] It is a defined and complete object information model that can include text, images, sounds and other multimedia content and can exist independently or be transmitted as part of the payload of a message such as the HL7 v2.x (or the v3 message that HL7 recommend for transporting CDA).[188] CDA documents can be used to render different types of clinical document including: referrals, discharge summaries, consultation notes, laboratory and pathology reports and ultimately any attested document that contains clinical information about a patient.[190]

CDA is a standard that is marked up using XML, enabling the CDA documents to be processed for human readability whilst also enabling computer processing. The human readable portion can be verified by the appropriate authorised clinician and rendered in a browser using a stylesheet. The latter is achieved by the CDA deriving its semantic content from the RIM (using RIM data types), coupled with clinical terminologies.[209]

CDA specifies a format whereby an electronic document contains a number of sections, which in turn may contain a number of computable "entries". Each entry adheres to the HL7 RIM clinical statement pattern such as observations, medications, adverse events documented in clinical reports. By further encoding clinical statements, it becomes possible to compare the contents of documents created on disparate information systems with very different characteristics.[188] Coded entries are core to achieving semantic interoperability amongst systems that need to share CDA documents.[210]

6.4.3 Incremental Semantic Interoperability

One of the reasons why the CDA standard has been successfully adopted internationally is because of the different ways it can be implemented, defining documents that are simple to those that are more complex. The CDA defines a layered architecture with three hierarchical levels - level one, two and three enabling developers to evolve documents from very simple documents to more complex documents.[207] The levels provide a "migration route" or pathway for adding more specificity to the markup of a document.[211] Importantly, the different levels will not alter the clinical content, just the degree to which clinical content can

be constrained and processed. The purpose of the different hierarchical levels is to support incremental semantic interoperability. The three levels of document definition are outlined in detail below:

- CDA Level one – this is the most generic architecture (e.g. the most unconstrained) and is the root of the hierarchy. Level one has a header and a body. The body is human readable and can be an unstructured blob with perhaps some simple formatting markup. Although the most general of the three levels, it is possible to distinguish between different types of documents such as referrals and consultation notes, as there are different type code values in the header of the document instance.

- CDA Level two – the body can be an unstructured blob facilitating compatibility with level one or it can contain one or more sections. Level two allows for further constraints on a document by creating templates at the section level for each of the document types e.g. an Epilepsy Discharge Summary or a Diagnostic Imaging Report. Each section is associated with a code that defines its purpose and a corresponding templateID, a globally unique reference (can be an OID) which further details what the contents of the sections are.

- CDA Level Three – is the most constrained and provides additional constraints at the 'Entry' level, and optionally at the 'Section' level.[181, 207]

6.4.4 CDA Structure

Every CDA document consists of one header and one body part (see figure 6-2 below). The primary purpose of the header is to provide contextual information or metadata (expressed in a v3 structure) about the document itself i.e. on the identification of the patient, identification of the encounter, identification of the providers, authentication information, etc.[188, 190, 191] The CDA metadata enables the classification of clinical documents making retrieval from registries and databases possible.[181] The header is specified in the CDA Header model and has a minimum number of required fields. Some examples of where the metadata in the CDA header has been selected to support different exchange architectures include; the centralised model of the National Health Service (NHS) in England, the

distributed model of the record locator service established in Finland since 2001 and the IHE Cross-Enterprise Document Sharing project.

The body has a generic structure that can be used to represent the structure of any document type and was designed to express any clinical content, demonstrating its flexibility. Essentially, the body of a CDA document contains the clinical report organised by sections that can be nested within each other and may contain a single "narrative block" (sections) allowing any number of CDA entries (and external references). Entries can be encoded using controlled vocabularies.[191]

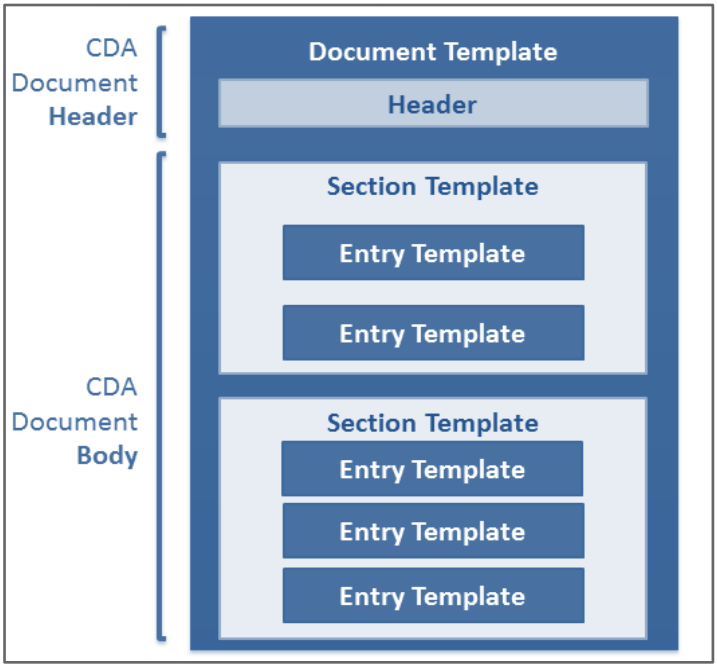

Figure 6-2 Structure of a CDA Document

(Taken directly from companion guide to consolidated CDA for meaningful use 2)[212]

The body can be structured or unstructured. It can either be an unstructured blob or can be comprised of structured markup (using XML as defined by the CDA specification). HL7 advocate the use of the XML standard to encode documents. If a document conforms to an unstructured body, it may contain any human readable data such as plain text or other formats such as rtf, html or pdf or an image (gif, jpeg, png, tiff or g3fax).[208] It is

represented using a <nonXMLbody> element. A structured body is used for XML encoded data and is the root node for one or more sections.[181]

6.4.4.1 CDA Document Section Level

A CDA document is a means of organising information and it is possible to assemble the information in a variety of ways. Sections are a key component of CDA and consist of a title, text elements (parts that have to be presented as narrative text so they can be rendered human readable) and an optional code (to classify its content).[190] The narrative block called Section.text contains the human-readable content of the section. It was originally intended (in CDA R1) for each section to encompass an entire document or large parts of a document, as is the case for a composition or section in EN13606. However, some implementations such as the NHS care record service chose to implement sections as "fine grained sections", whereby each section would correspond to only a single line or entry. The advantages of implementing sections with such granularity are to facilitate more flexible ways to sort and report information.[181]

6.5 CDA Templates

CDA templates are data structures that are used to express a further set of constraints on the CDA RMIM (e.g. the object model/ generic CDA specification). They specify how CDA can be used for particular purposes and specific use cases. Templates allow the definition of partial, reusable structures or allow document validation.[190] For example, CDA templates can be included in implementation guides and in schematrons[8] that provide validation rules to verify conformance to the constraints on the CDA RMIM.[213] Template definitions can be generated at the document-level, section-level and entry-level (NHS), such as patient identification, provider organisation or observation entry respectively. HL7 templates are expected to have a templateID (usually defined by an OID) indicating that an instance of the CDA schema (e.g. XML document), conforms to both the HL7 CDA standard (generic model) and the constraints specified in an implementation guide.[181] The templateID, which could be an OID or locally defined, is used to indicate which template is being used.

[8] schematrons (a rule-based validation language for making assertions about the presence or absence of patterns in XML trees)

6.6 Mapping from existing relational models to Object Oriented (OO) Models

The purpose of the HL7 CDA standard is to facilitate the exchange of clinical documents between healthcare systems. In many healthcare organisations, clinical information is usually stored in local, often disparate relational databases that contain historical information and have applications that interface with these databases to manipulate the data. In order to achieve semantic interoperability between existing eHealth systems, it is important that all systems conform to a standard. The ideal situation is that all eHealth systems adhere to national or regional CDA implementation guides. For example, if a national CDA implementation guide for a patient summary has been developed, that implementation guide should be used for electronically exchanging patient summary documents. Given that relational databases (such as Oracle, IBM DB2 and MS SQLServer 2000) are still widely used as the back-end databases in most healthcare organisations, it is important to address how to map from the existing database to the standard for exchange purposes.

The HL7 CDA standard is well documented in the literature particularly around the creation, implementation and storage of CDA clinical documents but there is little published research of mapping from relational databases to the CDA standard. The author completed a thorough review of academic literature, using the exact terms "mapping from relational databases to the HL7 CDA RMIM standard" which did not return an exact match. A broader search was conducted on mapping from relational databases to the HL7 CDA standard and two key results were returned (Umer et al., 2012)[214] and Gul et al.,(2010)[215] although the direction of the mapping was the opposite to what the author required. The author also searched for synonyms and related terms given the lack of literature on the exact terms. They included topics such as: mapping techniques, mapping to and from relational databases to the CDA standard and more generally mapping from relational databases to OO schemas, CDA implementation guides and CDA templates. The sources of information searched included journals, primary data, conference proceedings, books and dissertations.

The provision of this mapping is important in order to be able to preserve the investment in existing (relational) systems as opposed to a "rip and replace" policy if an organisation wants to implement standards.

Chapter 7 of this research outlines a methodology to map an extract from a pre-existing relational EPR (in this case the medication module of the epilepsy EPR) to make it conform to a corresponding medications template defined according to the Hl7 CDA standard. This involved mapping from a source relational database extract to a destination CDA implementation guide (IG) based on a CDA RMIM. The HL7 RIM is a common data model for healthcare and the CDA RMIM is a subset of the RIM. This research is concerned with mapping at the schema level and not with instance data. It involves mapping extracts or subsets of a database and not the complete database schema.

The literature on mapping from relational models to object oriented models is discussed in this section in order to inform the development of the mapping methodology in chapter 7. Some literature does exist that discusses mapping from the HL7 RIM model to relational databases (e.g. using the entire RIM information model and v3 standards as opposed to the CDA RMIM). However, this thesis is concerned with mapping from an existing relational EPR to the HL7 CDA RMIM. Given that the CDA RMIM is a subset or is a constraint on the RIM, the mapping literature about the RIM can be applied. Two key issues emerge in the literature mainly the complexity of the RMIM and the importance of investing work effort to understand and interpret the RMIM model accurately; and secondly that mapping between a complex model such as the RMIM and a relational database requires both domain and technical expertise.[214]

6.6.1 Data Modelling

It is commonplace across different healthcare providers and within healthcare organisations for heterogeneous EHRs/ EPRs to co-exist in terms of using different platforms, data models and semantics (clinical terminologies).[216] The task of mapping between different healthcare systems is therefore complicated given the heterogeneity of the different types of data models (relational, object-oriented) that can be supported.[214] Fahrner and Vossen (1995)[217] describe a data model as "a logical organisation of real world objects (entities), constraints on them, and the relationships among objects". Some of the most common methodologies for modelling data include hierarchical models, network models, relational models, Entity Relationship models, Entity-Attribute-Value models, and object-oriented (OO) models.[218] This research is concerned with relational and OO models.

6.6.2 Data Models and Concepts

Data modelling defines the real-world artefacts that need to be represented in a database. Navathe (1992)[219] describes a data model as a "set of concepts that can be used to describe the structure of and operations on a database". EHRs/EPRs can use different data model types and the types of data model that describe different levels of abstraction are conceptual, logical and physical models. Conceptual modelling is the first level of abstraction and represents real world problems. Following from this a logical model is created and includes associated textual descriptions and is described in business language that should be easily understood and verified by business users and domain experts. Use the logical data model as the basis of the physical data model. The third level of abstraction is the physical data model which represents the data, tables, fields, data types and relationships. The physical data model can be understood by both engineers and possibly domain experts who have expertise in physical data modelling.

6.6.3 Physical Data Model Concepts

Physical data modelling involves the conversion of the logical or business model into a relational database model. This thesis focuses on the physical relational model which is derived from a pre-existing relational database. The relational model consists of tables which are structured with attributes (fields) and tuples (rows). The fields of a table identify the attributes such as firstname or last name. The rows contain data for an instance of the table such as the person's full name. In the relational model, every row must have a unique key which identifies each row in a table. A primary key in one table can exist in another table which allows a join between the two tables. This concept is also known as a foreign key.

6.6.4 OO Data Model Concepts

An OO data model contains a collection of objects or classes, class relations, attributes, methods and inheritance. Relationships represent logical links between two or more classes. There are several types of relationships between classes that are represented in an object model. The types of relationships include association, generalisation specialisation and aggregation and are described below:

- **Association** describes the relationship between classes. It describes how the instances (objects) of one class have a relationship with instances (objects) of another class. The relationship is structural and has a defined meaning.[220]
- **Generalisation** is the process of extracting common characteristics (attributes and behaviour) from two or more similar types of classes and combining them in a generalised superclass.[221]
- **Specialisation** involves creating some new classes which are created from an existing superclass to do a particular type of job.[221]
- **Aggregation** is a special form of association. New functionality is created by taking other classes and composing them in a new class.[222]

The most common language used for OO modelling is the Object Management Group's Unified Modelling Language (UML). The RMIM is an object model presented using notation similar to the UML.[214] The RMIM model represents concepts in the healthcare domain using classes that contain attributes connected with associations. Classes are represented as rectangles, and associations between classes denoted by arrows (see figure 6.1). Both classes and associations have attributes which conform to specified HL7 datatypes. Data types can be either simple or compound. A simple HL7 defined data type corresponds to a single field or element, such as a string or a numerical value. A compound HL7 defined data type has two or more attributes, which may themselves be simple or compound. Most of the HL7 data types are more complex as there are multiple parts to a complex data type that need to be modelled differently.[223]

6.6.5 Mapping from Physical Data Model

The objective is to identify mappings from a physical data model which is derived from an existing database to a CDA RMIM object orientated model. For this study, a mapping is defined as a relationship between table fields of one relational database table and one or more class attributes of the RMIM model. Different matching techniques are used to identify mapping equivalents and mapping inconsistencies between:

- Relational database tables and CDA RMIM classes (entity, role, participant and acts)
- Relational database table fields CDA RMIM class attributes
- Relational database data types and HL7 v3 data types

6.6.6 Matching Techniques

Multiple matching techniques can be used to achieve a single mapping. Matching techniques were used in the mapping methodology described in chapter 7 and include exact, pattern, structure based, synonym and variation matching. Each technique is described below in relation to a relational database and the CDA RMIM:

- **Exact matching** – this technique is based on matching database (tables, table fields) to RMIM classes (names, attributes).[214]

- **Pattern matching** – this technique is based on matching name patterns. For example, a pattern could be matched between the relational database (tables, table fields) and the RMIM classes (names, attributes). A pattern match may contain the same pattern and some other characters.[214]

- **Structure based matching** - this technique is used where tables and table fields are in similarly structured groups, have similar relationships or paths to RMIM classes and attributes.[224]

- **Synonym matching** - this technique use a synonym match between the database (tables, table fields) and RMIM classes (names, attributes) where both matching items correspond to the same thing.[214]

- **Variation matching** - this technique is applicable to person names as person naming conventions vary in different parts of the world. Once the table field person name format is identified each name part can be mapped to the associated HL7 standard name parts (Family, Given Name, Prefix).[214]

- **Constraint matching** - this technique is applicable to data types, uniqueness and nulls.[224]

6.6.7 Taxonomy of Matches

Rahm and Bernstein (2000)[224] present a taxonomy that covers individual and composite matching approaches at different levels which include schema level, element level and structural level. In addition each level may apply different matching approaches such as linguistic and constrained based. This thesis is concerned with schema information and not instance data and also draws on the element, structure, language, constraint matching using the matching techniques outlined in section 6.6.6. The classification of matching approaches is outlined in the taxonomy table 6-1 below.

Table 6-1 approaches to automatic schema matching
(Taken Directly from Rahm and Bernstein)[224]

Classification	Description
Instance vs Schema	Matching approaches can consider instance data (i.e., data contents) or only schema-level information.
Element vs structure matching	Match can be performed for individual schema elements, such as attributes, or for combinations of elements, such as complex schema structures.
Language vs constraint	Matcher can use a linguistic based approach (e.g., based on names and textual descriptions of schema elements) or a constraint-based approach (e.g., based on keys and relationships).
Matching cardinality	The overall match result may relate one or more elements of one schema to one or more elements of the other, yielding four cases: 1:1, 1:n, n:1, n:m.In addition, each mapping element may interrelate one or more elements of the two schemas. Furthermore, there may be different match cardinalities at the instance level.
Auxiliary information	Most matchers rely not only on the input schemas S1 and S2 but also on auxiliary information, such as dictionaries, global schemas, previous matching decisions, and user input.

6.6.8 Mapping methodologies for relational EPR to HL7

A summary of mapping methodologies is described throughout this section**.** Pecoraro et al., (2011)[218] proposed a technique to create a logical data model that closely matches the HL7 RIM model in order to map between HL7 messages and a relational database. Similar approaches are proposed in the literature. Eggebraaten (2009)[223] uses two models, firstly the entity-relationship (ER) and secondly the entity-attribute-value (EAV) model to map the RIM classes into tables of the physical data model. Their proposed methodology, the EAV

model is applied in particular to RIM Observation class to capture different data types of the attribute *value,* while ER model is used to map the other RIM classes. Based on Eggebraaten approach, Yang et al., (2009) mapped the RMIM and CMET classes (which are based on the HL7 v3 messaging) into a physical database. Umer et al (2012)[214] developed an 'Automation Tool for HL7 RIM-to-Relational Database Mapping". The methodology followed was to analyse various clinical databases and then identify the matching fields in corresponding HL7 V3 messages using the laboratory domain model. A repository was established containing the matching fields between the relational database tables and the HL7 RIM classes and is known as the knowledge base. Using this knowledge base, mappings were performed and once analysis was performed, mapped is then completed automatically. Gul et al.,(2010)[215] developed an "interactive mapping tool for HL7 RIM-to-Relational database using knowledge game" which is a question and answer game whereby the fields from a database are mapped to the HL7 RIM. A case study was used based on the RMIM for the laboratory domain. The approach depends on a repository of questions covering different aspects of R-MIM that the end-user is asked and based on the answer mapping is performed. The author has specified that this research did not focus on the integration of EPRs but specifically on mapping.

6.7 Conclusion

This chapter presented a review of the HL7 CDA standard which is the most appropriate standard to use for the representation and exchange of clinical documents. A key point from this review is that semantic interoperability, enabled by interoperability standards like the CDA, is fundamental to support efficient, safe and meaningful information exchange. HL7 CDA has emerged as a popular standard because implementation of CDA documents can be achieved incrementally. Implementers have the option to develop and exchange simple documents at CDA level one initially and build on them to develop more complex documents up to CDA level three. Complex documents are both structured and coded so semantic interoperability is possible.

It is not uncommon for hospital systems to use relational databases for storage of structured data. Often clinical data is held on disparate (relational) databases which have different underlying data models and which do not conform to any or the same standard. In order to exchange standardised clinical information existing databases need to be mapped to a standard (as opposed to rip and replace) in order to make them standards compliant.

Matching techniques were identified from the literature to inform the mapping methodology described in chapter 7 and include exact, pattern, structure based, synonym and variation matching.

Chapter 7 of this research will describe a methodology for mapping from an existing relational database to the HL7 CDA standard. The methodology is illustrated by a case study. The case study involves mapping the demographics and medication section of an epilepsy discharge summary document to a HL7 CDA standard.

Chapter 7 Mapping from an existing relational EPR database to the HL7 CDA Standard

7.1 Introduction

Semantic interoperability facilitates the communication of health information between healthcare providers that is meaningful to both computers and clinicians allowing them to share and reuse information effectively. A detailed literature review on healthcare interoperability standards was provided in chapter 6, highlighting the importance and benefits of employing standards to facilitate semantic interoperability in EPRs. It also provided a comprehensive overview of the HL7 CDA standard. This standard enables the safe exchange of meaningful and unambiguous clinical documents between providers, when used in combination with a clinical terminology such as SNOMED CT. Chapter 6 also presented an overview of the literature on mapping from existing relational databases to the CDA standard.

This chapter presents a methodology, which has been validated, to enable the mapping from relational EPR databases to the CDA standard. As a reminder to the reader, background information and definitions that are important to understand the mapping methodology are outlined in section 7.2. The methodology, described in section 7.3, was designed based on a relational EPR database (the epilepsy EPR database as described in part one of this thesis), an internationally recognised CDA implementation guide and literature on mapping alongside the author's work experience with healthcare communication standards. Section 7.4 illustrates a case study to demonstrate the validity of the methodology. The case study involved mapping an extract (the medications section of the discharge summary) of the existing epilepsy EPR relational database to the CDA implementation guide (at entry level). The remainder of this chapter concentrates on the findings in section 7.5 followed by a discussion and conclusions in Section 7.6.

7.2 CDA Implementation Guides and Rules for CDA Templates

Chapter 6 provided literature on the CDA standard including CDA templates and implementation guides. It is important to summarise and further explain some key advantages of using implementation guides and CDA templates. An implementation guide is a specification that describes how the CDA standard should be implemented in a specific

business environment to meet local requirements such as national patient summaries. In order to use the CDA RMIM model for a specific use case (such as exchanging a medication section of a discharge summary document), it is necessary to constrain the CDA RMIM model, i.e. to apply more rules around optionality, data types etc., which is done using HL7 templates. CDA templates are documented in a CDA implementation guide (IG). A CDA document must conform to the HL7 CDA R2 Standard which is generic and therefore constraints , as described above, are needed and are defined in a CDA IG e.g. the CDA RMIM model and templates.

There are valid reasons why it is useful to employ an existing internationally recognised CDA IG as opposed to developing a new one. HL7 recommends that developers reuse work that is already published, tried and tested and is publically available. Significant work effort has already been invested in developing, governing and piloting a CDA IG. Employing a CDA IG guide can simplify the mapping process for the following reasons:

- Significant domain expertise has already been invested into developing the CDA IG.
- CDA IGs usually inherit templates from other IGs including the constraints from that template, therefore reusing work that has been tried and tested.
- CDA templates have a corresponding OID that has been registered (usually by a national healthcare agency) and recognised by HL7 which can be adopted.
- CDA IG has validated document instances against the HL7 CDA schemas and devised their own schematrons[9].
- Pilot projects have been used to demonstrate how functional the IG is in practice.
- IGs include models and also XPath expressions which can aid considerably with understanding and interpreting the CDA RMIM.

In order to map from an existing relational EPR database to a CDA IG, rules around CDA templates need to be understood. Examples of the rules that need to be adhered to in order for an existing system to conform to the CDA IG templates include:

- CDA standard supports the implementation of local requirements by allowing additional XML elements and attributes to be included in implementation guides. These local extensions should only be included when there is no corresponding

[9] Schematrons - The Schematron schema language is a rule-based language that uses path expressions instead of grammars. This means that instead of creating a grammar for an XML document, a Schematron schema makes assertions applied to a specific context within the document

representation in the CDA standard. The extensions to the IG can then be fed back to HL7 Structured Document Working Group where a decision can be made whether or not to add the changes into subsequent versions of the CDA standard.

- A specialisation e.g. a new data element that may need to be added to a CDA template is possible if the CDA data element is constrained from an optional element to a required element.
- If the optionality of a data element is required in a CDA IG, it cannot be loosened to optional.
- An element that is optional in the IG can be omitted to meet local requirements but it has to be declared as an adaptation of the CDA template (given that the template is open and allows for this).

Section 7.3 below outlines the methodology for mapping from a relational EPR physical data model to an OO model (using the CDA RMIM and CDA IG) and Section 7.3 illustrates the case study used to validate the mapping methodology.

7.3 Methodology for mapping

There are 4 main steps involved in the mapping methodology which is outlined below.

Methodology for mapping a relational EPR physical data model to the CDA Standard

Step 1 **Define Requirements and Use Cases for semantic interoperability**

Step 1.1 Establish a stakeholder group to include clinical, domain experts and technical personnel.

Step 1.2 Define business requirements or examine existing business requirements regarding interoperability.

Step 1.3 Refine the business requirements to include business rules where required.

Step 1.4 Develop user requirements from the business requirements.

Step 1.5 Define use cases and scenarios based on the user requirements. Based on the use case defined, a corresponding CDA document is identified e.g. a CDA Referral, Discharge Summary document.

Step 2 Identify appropriate CDA Implementation Guide (IG)

Step 2.1 Analyse CDA implementation guides in order to select the most suitable one to use. A CDA implementation guide needs to satisfy the use case and align with the business and user requirements that were identified in Step 1. This step involves input from the stakeholder group including domain and technical experts.

Step 2.2 Examine the CDA implementation guide to assess the alignment with overall requirements. This involves the stakeholder group deciding on what is in scope or out of scope. The type of decisions that need to be made are outlined in the following sub-steps:

Step 2.2.1 Decide on IDs - this involves identifying the OIDS required to identify clinical documents

Step 2.2.2 Decide on CDA Levels: CDA can be defined with three different levels (1 to 3) and the richness of the data increases, starting with lowest level 1 to highest 3.

Step 2.2.3 Decide on the terminology or classification systems and code sets that best suit the use case.

Step 2.2.4 Identify each mandatory element of the CDA header. Decide on CDA optional header elements – optional elements are not required but it is best practise to use these elements if a suitable mapping candidate is identified at the mapping stage in step 4 below.

Step 2.2.5 Review the mandatory sections and decide on the optional sections of the CDA body. This includes the required section level templates and the optional entry level templates.

Step 2.2.6 Examine the CDA RMIM model concepts including classes, class attributes and associations.

Step 3 Identify existing Relational EPR Database Extract

Step 3.1 Select the appropriate existing relational EPR database (extracts which match the CDA IG requirements and scope decided upon in Step 2.2 (such as demographics and medication tables)

Step 3.2 Derive a logical data model and physical data model from the selected database. The scope of each data model is driven by the scope of the CDA IG identified in step 3.

Step 3.3 Derive a data dictionary from the selected database model which provides a comprehensive record of all fields in the database. The data dictionary should contain the field name, field size, data type, data format, description and example for every field which in each table defined in the physical data model.

Step 4 Perform mapping from a relational EPR physical data model to a CDA IG schema

Step 4.1 Map using a table-by-table approach from tables in the relational EPR database to the RMIM class attributes.[225]

Step 4.2 Establish mappings using the matching techniques outline in section 6.6:

Step 4.2.1 Perform Exact matching-For example, if the table field patient name is defined as name and if a class attribute patient name found is name then this will be the an exact match .[214]

Step 4.2.2 Perform Pattern matching-For example the pattern match "gender" is used to match PATIENT_DEMOGRAPHIC table field "gender" to the CDA PATIENTROLE class attribute "administativeGenderCode".

Step 4.2.3 Perform Structure-based matching-For example the PATIENT_DEMOGRAPHIC table has a field called "dateOfBirth" and the CDA PATIENT class has an attribute called "birthtime". The structure similarities of the database field "dateOfBirth" (Patient demographic table) and the CDA class field "birthtime" (patient/birthtime) indicate the same thing which is a patient's date of birth.

Step 4.2.4 Perform Synonym matching-For example the PATIENT_DEMOGRAPHIC table field "title" can be matched to the PATIENT class attribute "prefix" because both are synonymous.

Step 4.2.5 Perform Variation matching – this technique is applicable to person name as person naming conventions vary in different parts of the world. Once the table PATIENT_DEMOGRPAHIC person name fields are identified each name field can be mapped to the associated HL7 standard person name parts (e.g. "family name", "given name", "prefix").

Step 4.2.6 Perform Constraint matching – this technique is applicable to complex data types like demographic address data type (AD) which contain multiple address part components such as "streetAddressLine", "city" and "country". These address parts can be mapped from the database address data

type (VARCHAR). In addition this technique can also apply the HL7 nullFlavor value set for matches which may contain nulls.

Step 4.3 Map codes from clinical classifications or terminology systems in the source system to the clinical classifications or terminology systems

Step 4.4 Represent mappings from steps 4.1 to 4.3 in a mapping table and use the headings and rows as illustrated in table 7-1 below.

Table 7-1 Example of the Mapping Table and Headings

Source Database Headings			Destination CDA IG (RMIM) Headings				Matching Outcome	
Database Field	**DB Data Type**	**Database Table**	**IG Schema XPath (example epSOS IG)**	**CDA RMIM Class**	**Optionality /Cardinality**	**Data Type**	**Matched**	**Inconsistency**
LastName	varchar	Patient_ Demographic	recordTarget/patientRole/patient/name/family	Patient	R/[1..*]	PN	TRUE	FALSE
Title	varchar	Patient_ Demographic	recordTarget/patientRole/patient/name/prefix/	Patient	O/[0..*]	PN	TRUE	FALSE
FirstName	varchar	Patient_ Demographic	recordTarget/patientRole/patient/name/given	Patient	R/[1..*]	PN	TRUE	FALSE
Gender	varchar	Patient_ Demographic	recordTarget/patientRole/patient/administrativeGenderCode	Patient	R, use nullFlavour/ [1..1]	CE	TRUE	FALSE

The headings in the mapping table have three sections:

- **Source Database Heading**: The headings describe the matching criteria of the mapping source which is the physical database model. The headings are database table, field and data type.

- **Destination RMIM Heading:** The headings describe the mapping criteria of the destination including the RMIM element path (using an example from the epSOS IG XPATH), RMIM class, Optionality of each element, Cardinality of each element and Data Type.

- **Mapping Outcome Heading:** The mapping outcome is either TRUE (represents a match) or FALSE (highlighting an inconsistency). The 'Matched' heading indicates if a match between the source and destination criteria was successful. The 'Inconsistency' heading indicates if the destination RMIM class attributes have a mapping inconsistency.

7.4 Case Study: Mapping from an existing relational epilepsy database to the HL7 CDA Standard

The mapping methodology in section 7.3 above was validated using a case study. The case study involved exporting a medication section of an epilepsy discharge summary document from secondary to primary care. The CDA IG that was used in this case study was a European cross border CDA IG called epSOS[226] that is recognised internationally and is described in detail in step 2 below. The epSOS IG specifies patient summaries for level three CDA documents (alongside ePrescribing and eDispensing).

More specifically, this case study involved mapping from the demographics and medication tables of the epilepsy relational database to the epSOS CDA IG header and medication summary template. Mapping from the demographics to the CDA header is applicable to all document types. The medication section of the discharge summary was chosen for this case study because the medication section is a mandatory section and is required to ensure compliance with the epSOS IG.

Each step of the methodology, from 1 to 4, is outlined in the case study below.

Step 1 Define Requirements and Use Case for semantic interoperability

The author held discussions with the epilepsy EPR technical team lead about the business and user requirements for interoperability for the epilepsy EPR. Relevant documentation was discussed regarding the requirements for the epilepsy discharge summary and clinical scenarios and use cases were defined. The author played the role of BA in part 1 of the thesis and therefore gained insights into the business and technical domain that someone coming new to the mapping exercise would not have had.

The use case defined was to provide a "*summary of an epilepsy patient's pertinent information for the continuation of care following a discharge".* Therefore, a CDA discharge document was identified as an appropriate document to use. To clarify the use case, the author documented the following real life scenario. It illustrates the current situation (As is - unstructured epilepsy discharge summary) and the goal of the scenario (To be) which was to exchange a CDA epilepsy discharge summary document from a secondary to primary care setting.

- **As is Scenario**

Discharge summaries are transmitted from the epilepsy OPD to general practice via a healthcare messaging broker called Healthlink. Healthlink use the messaging standard HL7v2.4. It transforms messages and sends the conformant HL7v2.4 messages to GP practice management systems (GPMS). The epilepsy discharge summaries are exchanged in an unstructured HL7 v2.4 message. The clinical information within the epilepsy discharge summary is sent from the epilepsy OPD to Healthlink in the form of a Character Large OBject (CLOB) making semantic interoperability impossible as it is in an unstructured format. The issue with transmitting and mapping a CLOB of data is that it cannot be mapped to a single CDA element as it is too large. Furthermore, it is not good practice to store important information in a CLOB as it cannot be queried easily. In this instance, the primary recipient of the electronic discharge summary is the healthcare provider who was providing the patient care prior to the admission to hospital OPD and who is the patient's usual GP (or primary health service). The GP is able to view the information as it can be displayed by a web browser but it does not facilitate the GP to import the structured information into their local GPMS.

- **To be Scenario**

The "To be" scenario highlights the enhancements that could be made to the "As is" scenario in order to work towards a more semantically interoperable solution. This involves the introduction of a CDA level 3 compliant document that facilitates structure and coding of the information. The scope of the "To be" scenario is to extend the existing EPR web application to provide a web service approach which includes a HL7 CDA XML interface to

allow third party client applications (e.g. Healthlink broker) to request and retrieve EPR clinical content in the form of HL7 CDA XML structured messages.

Step 2 Identify appropriate CDA implementation guide (IG)

The CDA normative specification and the CDA RMIM were researched, analysed and interpreted. Several CDA implementation guides including European and International implementations were assessed to select the most appropriate specification that would best suit the epilepsy discharge summary scenario. These included the HL7 Implementation Guide, HL7 CDA R2 Continuity of Care Document (CCD), the epSOS Semantic Implementation Guidelines, Integrating the Healthcare Enterprise, Patient Care Coordination Technical Framework (IHE PCC) and the Australian specification on the e-Prescription CDA Implementation Guide Version 2.1

The epSOS implementation guide was chosen as the most appropriate IG to use. The epSOS project was an eHealth interoperability project funded by the European Commission (EC) and member countries. The goal of this project was to develop a service infrastructure that enables the exchange of patient data across EU borders. The epSoS project defined a patient summary (PS) document to enable the exchange of clinical information which was derived from the HL7 CDA R2.0 standard and is documented in the epSoS IG v1.4. This version of the epSOS was used as the basis for the mapping in this research. The epSOS project ended as of June 30th, 2014 but several EU countries have committed to continue the services beyond the project duration. The epSOS patient summary IG was chosen for this research for the following reasons:

- It has widespread support and was selected by a consortium of 45 healthcare organisations (ministries of health, national/regional centres and industry participants) in 25 European countries as a base standard for cross-border exchange of EHRs in Europe.

- It reused work (templates) from the HL7 CDA Standard, the HL7 clinical care document (CCD) specification and the IHE PCC (e.g. it reuses some of the IHE PCC templates).

- The epSOS project had close collaboration with other Standards Development Organisations (SDOs) including ISO, WHO, CEN, ETSI, HL7, IHTSDO.

- It covers the EU jurisdiction whereas the IG's such as the HL7 Clinical Care Document are US-based and are based on different requirements.

- On analysing various IGs, the epSOS IG was found to be the closest match in terms of the templates that were defined for a medication summary. The author examined the CDA RMIM and interpreted the model including the classes, attributes, data types, and relationships. The CDA templates from the epSOS IG for the document header and medication templates were also examined. This included parameters for each CDA template required in the epSOS CDA specification include the name of the data element, the description, data type, xpath expression, the cardinality and the associated vocabulary.

- The epSOS IG uses various vocabularies and their value sets include the ICD classification system, the WHO ATC and the SNOMED CT.

Step 3 Identify existing Relational EPR Database Extract

The existing relational EPR database extracts that matched the epsSOS IG were identified. These included the demographics and medication tables. The author obtained the logical and physical data models from the IT technical team lead (See Appendix B and C). In the absence of a data dictionary, the author analysed epilepsy documentation including the medication information model, and the user and data requirements for both demographics and medications. The demographics and medication database schemas were analysed and discussed with the IT technical team lead regarding its structure (number of tables, data items), metadata, data types, and content (format of the content e.g. structured (lists,) v unstructured data (free text data) and how it is used by the end-user in order to ensure the schemas were correctly interpreted.

Step 4 Perform mapping from a relational EPR to a CDA Schema IG

Based on the knowledge that was gathered and investigations that were conducted in steps 1 to 4, mapping was performed between the source (relational epilepsy EPR database

schema) and target (epSOS IG schema). The demographics and medications database schemas from step 4 were analysed and the data fields and their parameters were listed.

The mandatory elements of the epSOS templates for the header (represents the metadata and context of the document) were examined alongside the medications summary template. The fields of the relational database model were then examined in order to find a corresponding match.

The following sections will outline the outcome from the mapping from the demographics and the medications schemas to the epSOS IG schema templates that are derived from the CDA RMIM (and represented in XML at implementation stage).

- **Demographics and CDA header Mapping**

The epilepsy EPR demographic schema contains 15 tables to facilitate patient demographics and is illustrated in Appendix B. The table fields required in the demographics tables of the epilepsy EPR were identified based on what is required in the CDA Header.

The purpose of the CDA header is to provide the metadata for the document, to identify and classify the document and provide information on the authentication, the encounter, the patient, and the involved providers. At a high level, the header components, participants and relationships need to comply with the CDA standard. The epSOS IG also requires legal authenticator and use the participant element for Patient Contact Information. The header participants required for this exercise include the legal Authenticator, Author, Custodian and recordTarget. The CDA Header element recordTarget represents the person whose chart the document belongs to, typically this is the patient who is also the subject of the report.[227] The recordTarget includes REQUIRED components such as patient contact (which can accommodate the Next of Kin) and the patient's preferred health care provider. It also specifies the healthcare professional and the healthcare facility they belong to.

An example of the mapping from the epilepsy demographics relational schema to the CDA IG is the PATIENT_DEMOGRAPHIC, ADDRESSDETAILSD and ADDRESSTYPE tables which exist in the relational database model and corresponds to the RMIM classes PATIENT (Entity) and PATIENTROLE (Role). The XPath in the epSOS IG outlines the path for this interpretation of the CDA RMIM.

The mapping from the epilepsy demographics database model to the epSOS CDA header is outlined in Appendix D. The following components were included in the epSOS CDA header: Author, Custodian, recordTarget, Patient Contact, HCP and Healthcare facility. There were a total of 80 data elements identified in the epSOS CDA header (See table 7-2 for breakdown). 52.5% of the elements were optional and 47.5% were mandatory. Out of the mandatory elements 57.9% were matched and 42.1% were not matched from the relational database (see figure 7-3 for matching results). The main reason why 47.5% of the required elements were not matched was because the required document details (id, title, code, creation date, last updated and confidentiality code), Patient Guardian contact details (phone, email) and all Patient Contact Person details were absent from the database. 12 elements that are required for the CDA Author and Custodian components are matched by the healthcare professional and provider tables in the demographics schema. Two of the 3 elements that are required for the epSOS IG healthcare facility were matched in the demographics schema. The inconsistencies that were found are shown in Table 7-3.The matching inconsistencies identified were:

- An inconsistency was identified in relation to matching from ADRESSDETAILS database table field "email" to epSOS IG Patient element "telecom" (recordTarget/patientRole/telecom). The epSOS IG specification for telecom fields requires the use of a nullFlavor attribute with the value 'NI' to highlight when there is no information present e.g. some patients may not have an email address.

- An inconsistency was identified in relation to matching from PATIENT_DEMOGRAPHIC database table field "nextOfKinTelephone" to epSOS IG Patient Guardian element "telecom" (patientRole/patient/guardian/telecom). The epSOS IG specification for telecom fields requires the use of a nullFlavor attribute with the value 'NI' to highlight that no information is present e.g. patient may not have the patient guardian (NOK) telephone number.

Table 7-2 Total epSOS IG Header elements

ESPOS Header	Elements	Percentage
Total Elements	80	
Total Optional Elements	42	52.5%
Total Required Elements	38	47.5%

Table 7-3 Matching results of required elements

Required Elements		
Matched	22	57.9%
Not Matched	16	42.1%
Matched with Inconsistency	4	10.5%

- **Medications Mapping**

The epilepsy EPR medication physical database model contains 24 tables to facilitate the administration of a list or summary of medications (See Appendix C for physical database model). The reason there are a large number of tables in the medication physical database model is because it is designed to capture more than a medication summary. It is more complex because the epilepsy end-users require the option of administering a dosage calendar for the administration of medications. This allows the end user to escalate or deescalate a medication. For example, there could be a plan to start a patient on a medication at a certain dosage and then increase the medication over a number of weeks or there could be a plan to wean the patient off a medication over a certain amount of time.

- **Mapping from the medication tables to the CDA Body: CDA epSOS Medication dataset and template**

The following 7 data elements constitute the dataset for the epSOS requirements for a medication summary list

- Start and Stop Date
- Frequency
- Route of administration
- Dose
- Product (Name)
- Strength
- Ingredient Code
- *Instructions (Optional)*
- *Indication (Optional)*

There are 7 elements that are mandatory to fulfil a CDA epSOS medication template for a medication summary and include:

- Medication Summary Active ingredient description (display name)
- Medication Summary Active ingredient code
- Medication Summary Strength
- Medication Summary Number of units per intake
- Medication Summary Frequency of intake
- Medication Summary Duration of treatment
- Medication Summary Date of onset of treatment

Mapping from the medication table of the epilepsy EPR (source) to the epSOS IG medication template was performed (See table 7-4). Data elements and their associated parameters (e.g. optionality, data types etc) were listed for both source and target and a comparison was carried out and inconsistencies were investigated. The findings found that the fields in the medication table matched the epSOS CDA medication summary template. However, in order to conform to the epSOS CDA medication summary template, the epilepsy relational database would need to include the active ingredient code required for the data element Medication Summary Active ingredient code(entry/substanceAdministration[templateId/[@root='']/consumable/manufacturedProduct/manufacturedMaterial/ingredient/[@classCode='ACTI']/ingredient/code@code).

Table 7-4 schema matching from medication table (source) to the CDA IG schema (Target)

Database Field	Database Data Type	Database Table	epSOS IG Schema xPath	RMIM Class	Optionality/ Cardinality	Data Type	Matched	Inconsistency
Medication Summary Active Ingredient Description								
Description	Varchar	TradeDrug	entry/substanceAdministration/consumable/manufacturedProduct/manufacturedMaterial/ingredient/[@classCode='ACTI']/ingredient/code@displayName	substanceAdministration	RNFA/ [1..1]	ST	TRUE	FALSE
Description	Varchar	GenericDrug	entry/substanceAdministration/consumable/manufacturedProduct/manufacturedMaterial/ingredient/[@classCode='ACTI']/ingredient/code@displayName	substanceAdministration	RNFA / [1..1]	ST	TRUE	FALSE
Medication Summary Active Ingredient Code								
N/A	N/A	N/A	entry/substanceAdministration[templateId/[@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.4']/consumable/manufacturedProduct/manufacturedMaterial/ingredient/[@classCode='ACTI']/ingredient/code@code	substanceAdministration	RFNA/ [1..1]	CD	FALSE	FALSE
Medication Summary Strength								

Quantity	Varchar	Administration	entry/substanceAdministration[templateId/[@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.4']/consumable/manufacturedProduct/manufacturedMaterial/ingredient/[@classCode='ACTI']/quantity	substanceAdministration	RFNA/ [1..1]	PQ PQ	TRUE	FALSE
Medication Summary Number of units per intake								
Quanity	Varchar	Administration	entry/substanceAdministration[templateId/[@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.4']/doseQuantity/low@value	substanceAdministration	R/[1..*]	INT	TRUE	FALSE
TargetDosage	Varchar	Administration	entry/substanceAdministration[templateId/[@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.4']/doseQuantity/high@value	substanceAdministration	R/[1..*]	INT	TRUE	FALSE
Medication Frequency of intake								
DailyFrequencyID	Number	DosageCalendarEntry	entry/substanceAdministration[templateId/[@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.4']/effectiveTime[2]	substanceAdministration	R/[1..*]	TS IVL_TS PIVL_TS EIVL_TS SXPR_TS	TRUE	FALSE
Medication Summary Duration of treatment								

ActivatedDate	TimeStamp	Duration	entry/substanceAdministration[templateId/@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.4']/effectiveTime[1][@xsi:type='IVL_TS']/low/@value	substanceAdministration	RNFA	IVL_TS	TRUE	FALSE
DeactivedDate	TimeStamp	Duration	entry/substanceAdministration[templateId/@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.4']/effectiveTime[1][@xsi:type='IVL_TS']/high/@value	substanceAdministration	RNFA	IVL_TS	TRUE	FALSE
Medication Summary Date of onset of treatment								
MedicationStartDate	Date	DosageCalendarEntry	entry/substanceAdministration[templateId/[@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.4']/effectiveTime[1][@ xsi:type='IVL_TS']/low	substanceAdministration	RNFA	TS	TRUE	FALSE
Medication Summary Pharmaceutical Dose Form								
N/A	N/A	N/A	entry/substanceAdministration[templateId/[@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.4']/consumable/manufacturedProduct/manufacturedMaterial/formCode	substanceAdministration	O/[0..1]	CD	FALSE	FALSE

7.5 Discussion

Part 2 of this research focused on the importance of interoperability standards, specifically the HL7 CDA, to enable semantic interoperability of eHealth systems. The purpose of the HL7 CDA is to provide structure and semantics to clinical documents in order to facilitate the safe electronic exchange of clinical information between eHealth systems in a meaningful way. Chapter 7 of this thesis outlined the development of a methodology for mapping from an existing relational EPR database to the HL7 CDA document standard that was validated using the epilepsy discharge summary use case. The main constraints that were identified from the mapping methodology included issues regarding data types, relationships and clinical coding.

7.5.1 Data Types

As outlined in chapter 6 of this research, CDA uses HL7 v3 data types, which are complex and are made up of composite classes of standard data types such as their CD data type (Concept descriptor codes) and instance identifiers (II) that specify identity.

- **Complex HL7 data types -** It is well documented that there is an issue with the complexity of the CDA data types. The majority of HL7 datatypes are more complex than relational EPR database types. HL7 CDA use the HL7 v3 data types. There are many different complex HL7 data types which include data types which have multiple components such as Address (AD) and data types which are collections of elements such as Set and Bag. The majority of the HL7 v3 data types are complex but some are simple data types. The simple data types can be mapped directly from relational database types, such as the string (ST) data type which can then be mapped directly to a variable length character (VARCHAR) database column. TIMESTAMP and DATE (TS) is a valid data type in the CDA standard. For example, numerical datatypes in a relational database such as INTEGER can be mapped to the HL7 CDA *NM* (NUMERIC). The NUMBER (numeric data type) in the epilepsy RDBS is used for all IDs. NUMBER is more difficult to map as it can be construed as an INT, PQ, II or as a frequency data type (TS, IVL_TS, PIVL_TS, EIVL_TS, SXPR_TS which represent intervals of time) in the CDA standard depending on the context. Complex HL7 datatype mapping can be problematic and does require manual intervention to realise appropriate mappings. For example when mapping to a complex data type

Address (AD) the best approach is to 1) Identify the components of the data type and 2) Identify what relational database datatypes can be mapped to the components. The relational database Address fields datatype (VARCHAR) can be mapped to the HL7 AD components such as streetAddressLine (ST), city (ST), country (ST). Also for example, a patientID in the epilepsy RDBS has a NUMBER data type whereas the patientID in the CDA epSOS specification has a more complex data. The epilepsy relational database supports a single null value when a value is left unpopulated whereas each HL7 v3 data type contains a nullFlavor property, which supports up to 11 ways to indicate why a value is empty.[225]

- **Clinical Coding**

The AED module of the epilepsy EPR allows the user to manage a patient's epilepsy medication information in a local setting i.e. the epilepsy OPD. At the time of this study, the user could select non-coded (e.g. non-standardised) medication provided structured data and fulfil the user requirements for managing patients locally i.e. in the Beaumont hospital epilepsy OPD, it does not facilitate sharing information at a national level or between epilepsy services at different sites or between secondary and primary care. The main disadvantage of managing information in isolation is that all knowledge is locked into local systems. It becomes difficult, if not impossible, to share information electronically between departments or with external organisations, to develop decision support systems or to develop alerts for drug interactions. To achieve semantic interoperability, the epilepsy EPR requires standards such as CDA and SNOMED CT working in combination. Clinical coding is important in order to enable true semantic interoperability. In order to facilitate this, clinical codes need to be linked to the CDA templates at the entry level. Coding clinical information is crucial to producing good quality patient information that clinicians can share between each other ensuring clinical meaning is retained. Literature on coding clinical information is described in chapter 6, section 6.2.2 of this research. In order to achieve true semantic interoperability a CDA level three document encoded with SNOMED CT is a powerful combination for delivering a well-structured and meaningful clinical document that can be exchanged among multiple healthcare providers (e.g. it specifies the highest level of machine processable documents alongside providing clinical meaning). A CDA document facilitates the coding of clinical information for exchange providing

slots for codes from terminology and classification systems and clinical terminologies such as SNOMED CT.

At the time of this study, the epilepsy relational EPR did not link to any internationally recognised clinical terminology system. The CDA epSOS IG specifies a wide variety of internationally recognised value sets which are comprehensive and it also specifies its own epSOS defined value sets. Some of the value sets available in epSOS include the: Anatomical Therapeutic Chemical (ATC) value set used as a mandatory code for the Active Ingredient of medications in the medications summary, LOINC to define which category the document belongs to, the EDQM Value Set is used to encode the (optional) "Route of Administration" for a given medication in the medication summary. SNOMED CT and the UCUM (Unified Code for Units of Measure) value sets are used as clinical vocabularies that are recommended for use in the CDA epSOS IG. Also, currently in Ireland, there are no OIDs to identify HL7 clinical documents and they would have to be issued from a standards setting organsiation such as the National Standards Authority in Ireland. However, an OID from an existing implementation guide can be reused which would be the case for this research.

- **Relationships** – The HL7 RMIM models clinical information through classes and related attributes which are connected with associations. Both the epilepsy EPR physical data model and HL7 RMIM support relationship types one-to-many and one-to-one therefore these relation types can exist between the EPR physical data model (tables and fields) and the RMIM model (classes and attributes) .The majority of mappings between the EPR physical data model e.g. tables and fields and the CDA RMIM model i.e. classes and attributes are one to many. Confusion arises when, for example, there is an id in the patient table field on the database side which maps to a person_id rather than the patient_id. This suggests the need for both clinical and technical expertise. A technical expert who understands the language in the implementation guide including the CDA RMIM and the XPATH and the clinician or domain expert who can translate the business need.

7.5.2 Challenges involved with mapping

This thesis would recommend, as outlined in the mapping methodology, that subject matter experts are involved in the mapping process given that there are challenges around interpreting the CDA RMIM. For example, a domain expert in pharmacy or a clinician should be involved to interpret the CDA epSOS IG particularly for medications as the language can be quite intricate. Significant time needs to be invested to understand the CDA RMIM which can initially be complex to interpret given that the model is made up of complicated business process. For example, different "acts" such as the act of administering a medication can be associated with different participants who can take on various roles to carry out that act. The mapping process is robust when these prerequisites are met.

The CDA RMIM is broad and the CDA standard is very generic. A specification like the epSOS IG has already constrained the model for a use case like a medication summary which is beneficial in terms of the level of detail that exists to specify the medications. Additionally, HL7 would recommend that templates from internationally recognised CDA specifications are reused. However, conforming to the same specification summary may be difficult to achieve across multiple sites. The "reusable" templates may be incompatible with clinical content across different disciplines and can break the templates causing problems for schema validation. To ensure that semantic interoperability happens on a national scale between multiple sites, a standard is needed between all sites involved and agreement on the same coding systems which would require significant effort.

7.5.2.1 The mapping from a relational EPR to the HL7 CDA standard requires input from both clinical and technical expertise so the process cannot be fully automated.

It is acknowledged that the manual process of identifying relational EPR schema and RMIM mappings (which the CDA RMIM is a subset of) is time-consuming, tedious and error prone and requires "manual intervention and low level decision making"[214] The CDA RMIM is broad and generic and interpreting relevant classes and attributes requires considerable effort to understand RMIM concepts. For example, different "acts" such as the act of administering a medication can be associated with different participants that can take on various roles to carry out that act. The task of mapping requires both clinical and technical expertise to interpret the CDA RMIM and associated CDA implementation guides (contains CDA RMIM models and XPATH expressions for specific CDA templates). For example, a

domain expert in pharmacy or a clinician must be involved to interpret the epSOS IG particularly for medications as the language can be quite intricate. Significant time needs to be invested to understand the CDA RMIM which can initially be complex to interpret given that the model is made up of complicated business processes.

Chapter 8 Discussion and Conclusions

8.1 Overview

This final chapter of the thesis reviews the key aspects of this study. Section 8.2 revisits the research questions and objectives. Section 8.3 highlights the main findings and discusses some of the key issues derived from the findings and presents conclusions. Section 8.4 considers how the findings could be generalisable to other areas. The limitations of the study are outlined in section 8.5 and suggestions for future research are discussed. The contributions that were achieved from the study are outlined in 8.6 and finally the final conclusion is presented in 8.7.

8.1.1 Context

This thesis concentrated on how a sociotechnical approach to EPR requirements, design and deployment can be used to meet clinical requirements. It used a case study of the epilepsy EPR, designed and deployed in a live clinical setting at one of the main Dublin teaching hospitals. At the time of this research, the epilepsy service conducted clinical care and research providing services that included: an epilepsy out-patient department (OPD), a nurse specialist telephone advice service, the epilepsy pregnancy register, community services, and a long term monitoring unit. This work was conducted through a multidisciplinary team of 15 staff comprising administrative, clinical, researchers and healthcare professionals. The epilepsy EPR was based on bespoke software and did not conform to any international eHealth standards. This thesis also investigated the feasibility of how EPRs can safely share and communicate health information using healthcare interoperability standards.

8.2 Research Questions, Objectives and Thesis Structure Revisited

There were two separate but closely related areas that were investigated in this research. As stated in chapter one, the research questions are separated into part one and two as follows:

- Part one: How can a sociotechnical approach be used to ensure that the design and deployment of an EPR meets clinical requirements?

- Part Two: What methodology is required to map an extract (in this case a discharge summary) from a pre-existing relational EPR (in this case epilepsy) to make it conform to a corresponding template (for a discharge summary) defined according to the Health Level Seven Clinical Document Architecture (CDA)

In order to address the research questions, a number of research objectives were derived. Part one is covered by objectives A-D and part two is addressed by objectives E-F.

A. Research relevant academic and grey literature concerned with the condition of epilepsy and STS philosophy in requirements engineering, system design and deployment
B. Examine the practicalities of how to design and deploy an epilepsy EPR using an STS perspective in a real world clinical environment
C. Identify the sociotechnical clinical requirements needed to satisfy the design and deployment of the epilepsy EPR
D. Evaluate the use and usability of the EPR using the anti-epileptic drug (AED) module, a complex and core component of the EPR, as an exemplar
E. Research relevant academic and grey literature concerned with eHealth standards, specifically the HL7 CDA standard and literature on mapping from relational data models to object oriented models.
F. Develop and validate a process for mapping an existing relational EPR extract to the HL7 CDA standard based on an internationally recognised CDA implementation guide and literature on mapping data models for interoperability.

Part 1 of this study used a qualitative case study approach in order to address the research questions and objectives. It drew on a broad range of literature and data collection comprised of interviews, participant observation studies and document analysis. Part 2 of this study also used a case study approach to validate a mapping methodology. This thesis consists of eight chapters, as summarised in Table 8-1 below.

Table 8-1 Summary of the Thesis Structure

Title	Overview of Chapters
Chapter 1 Introduction	Chapter 1 provided an introduction to the study and indicated the research questions, objectives and the scope. A brief overview of the research findings and contributions were also given.
Chapter 2 The role of the EPR in the management of epilepsy	Chapter 2 described the literature on the role of the EPR to facilitate the management of chronic disease such as epilepsy. There is evidence to suggest that EPRs can facilitate and enhance the management of chronic diseases such as diabetes or epilepsy. This chapter described the organisation and operation of a clinical out-patient department (case study) which provides context for the study.
Chapter 3 Sociotechnical Requirements engineering in Healthcare	Given the multiple strands of the literature which had to be drawn on for this research, the literature review in Chapter 3 was wide-ranging. Chapter 3 covers literature on requirements engineering, sociotechnical systems (STS) theory and design methods. It also reviewed the field of ethnography, a qualitative research method that is strongly aligned with sociotechnical thinking. The literature suggested that STS principles and design and ethnographic techniques are well suited to system design in healthcare.
Chapter 4 Designing an epilepsy EPR using a sociotechnical perspective	Chapter 4 gives a detailed account of the sociotechnical principles that were used to guide the EPR design. It also outlined the data collection methods used including observational studies of the clinic environment and people who worked there and interviews with end-users. The data collected provided rich descriptions to help design the EPR. This chapter concluded with a description of the Anti-Epileptic Drug (AED) module.
Chapter 5 **Evaluation of the epilepsy EPR deployment**	Chapter 5 examined the use and usability of the AED module of the epilepsy EPR deployed in a *live* epilepsy clinic and categorises the key findings under sociotechnical components: human, organisational and technology. The findings suggested that end-users were able to use the EPR in a clinical environment and that it met their clinical requirements.
Chapter 6 **HL7 Clinical Document Architecture(CDA)**	The second part of this research was concerned with mapping extracts from an existing relational EPR database to an international eHealth interoperability standard called HL7 CDA. This concept is an important step towards facilitating interoperability from relational non-standards compliant EPRs to a standards based EPR in order to share patient information. Chapter 6 emphasised the importance of interoperability to achieve safe electronic communication between eHealth systems such as EPRs alongside a comprehensive overview of health information standards and mapping from relational to OO models.

Chapter 7 **Mapping from an existing relational EPR database to the HL7 CDA Standard**	Chapter 7 described a methodology that was developed and validated for mapping an existing epilepsy relational database with the CDA document standard based on an internationally recognised CDA implementation guide and literature around mapping.
Chapter 8 **Discussion and Conclusions**	The final chapter highlighted the key aspects of the thesis and re-examined the research questions and objectives. The main findings were identified, discussed and conclusions were presented. Areas where the findings were generalisable were outlined alongside the limitations of the thesis and suggestions for future research. Chapter 8 also identified the contributions of this thesis and presented final conclusions.

8.3 Key Findings, Discussion and Conclusions

The key findings are presented below and the remainder of section 8.3 describes each finding including examples from the study. This research has identified five key findings which are discussed in detail throughout this chapter.

1. The EPR resulting from this STS project is acceptable to end-users, meets their requirements and is usable in practice in a busy epilepsy out-patient department.
2. Adopting an STS ethos for the design and deployment of an EPR requires ongoing engagement and commitment from end-users at all levels which is challenging in a busy clinical environment.
3. The business analyst plays a central role when designing and deploying an EPR based on STS thinking in a clinical setting.
4. It is possible to map an extract from an existing relational EPR to the HL7 CDA standard to enable interoperability subject to certain constraints such as mapping datatypes, relationships and clinical coding.
5. The mapping from a relational EPR database to the HL7 CDA standard requires input from both clinical and technical expertise so the mapping cannot be fully automated.

8.3.1 Discussion

The following discussion outlines detail on some of the key findings and contributions from the thesis and includes reflections on the following: literature around the sociotechnical approach and the methods used specifically ethnography, how the business analyst acts as a mediator between the end-users and the IT development team, the usefulness of the HOT-fit framework for evaluating EPR systems, including the challenges of operationalising it and considerations around the mapping methodology from relational models to the HL7.

8.3.1.1 Sociotechnical approach to system development in healthcare

A finding from this thesis was that the 'EPR resulting from this STS project is acceptable to end-users, meets their requirements and is usable in practice in a busy epilepsy out-patient department' and the thesis 'demonstrates that the design and deployment of an EPR using an STS perspective in a real world clinical environment resulted in a workable and usable system'. This is convincingly shown in chapter 4 and chapter 5 of this thesis and aligns with existing literature that was outlined in chapter 3. In particular, the finding and contribution mentioned above aligns with existing literature that discusses how to integrate a sociotechnical approach into practice. This draws on the work of Baxter and Somerville(2011)[84] who outline that introducing STS into practice is challenging because aligning STS with existing software engineering system methodologies is cumbersome particularly in relation to changing processes and in persuading developers of its benefit. Some efforts have been made in health informatics to drive the STS agenda into practice. Whetton and Georgiou (2010)[111] propose that 'academics and professionals need to engage in a critical dialogue to identify, discuss, and question different perspectives and understandings' of STS in healthcare in order to fully exploit its potential. Li's (2010)[109] publication outlines a model to help link theory and practice of STS in health informatics.

The literature around sociotechnical systems in healthcare were well reviewed throughout this thesis and it was clear from the literature that the success of EPR adoption is improved by using a sociotechnical approach. This thesis highlighted that the introduction of an EPR within a hospital resulted in altered clinical roles and work processes (patterns, behaviours and routines).[115, 116] To help to accommodate this change, an EPR should be viewed as an active component of the clinical environment that should seamlessly integrate with clinical

staff work processes and behaviours and any organisational considerations that need to be adhered to. An EPR should not be viewed in isolation in its intended clinical environment.[228, 229] The human, organisational and technological elements of an EPR project should be viewed and managed as a network rather than separate entities.[102] Any new change that impacts a business such as the introduction of an EPR will affect all three components of a STS.[228] This thesis revealed that active user engagement in the requirements and design phases of system development, although necessary and important, is not sufficient to ensure smooth adoption. An *in vivo* socio-technical study revealed that a mix of human, organisational and technical issues which are often inter-related need to be managed alongside the deployment of the system.

8.3.1.2 Assessment of how using the ethnographic methods contributed to the socio-technical approach

In this research, sociotechnical is defined as dynamic networks of people and technologies that have three interrelated components: human, organisational and technology. A contribution that emerged from this thesis is that it 'presents rich descriptions on how to design and deploy an EPR using an STS perspective and ethnography'. This is particularly evident in chapter four and five of this thesis which gives detailed examples of how ethnography provided descriptions that helped to clarify requirements and design of the EPR.

In order to design and deploy an EPR using a sociotechnical approach it was necessary to employ a methodology that could enable this. Ethnography is a qualitative methodology that is aligned with the sociotechnical philosophy. The literature provides evidence that using an STS philosophy combined with traditional RE and ethnography for EPR design and deployment is highly valuable and suitable in a healthcare environment. Employing a sociotechnical approach involves capturing rich content and descriptions about the end-user's expectations, needs and work environment. Often there is a need to employ alternative methods that go beyond the traditional data collection methods of questionnaires and surveys. Because ethnography is a qualitative research method, it is an effective means to understand the nuances and intricacies of a complex healthcare organisation and to gain an understanding of the how end-users work and how an EPR could integrate with their work.[134]

Ethnographic analysis is a method that allows designers to examine and understand individuals in their own work environment which is a non-trivial exercise. The author used ethnography, through observational studies, to elicit requirements in the requirements elicitation phase of the design of the epilepsy EPR (see chapter 4). Both the social characteristics of current work practice and the technical features of the system should be considered when performing requirements gathering and analysis.

Observational studies are a valuable technique for gaining an understanding of clinical need and to analyse how healthcare workers communicate among themselves.[142, 169]

Observational studies were also used at the evaluation stage of this study to understand how the EPR was being used, how useful the EPR system design was in the epilepsy service (see chapter 5). The findings from the observations were fed back into the requirements.

Merriam (1988)[144] suggests structuring observations using criteria such as the participants, the setting that the observations take place in, activities and interactions, frequency, duration and non-verbal interactions. Ethnography allows the researcher to understand how clinicians and other healthcare staff behave by observing how they practice their work. Importantly, the researcher can view the participants' beliefs and practices as they occur and in the context in which they occur.[134, 145] It gives the ethnographer a nuanced and intricate understanding of the cultural context and the relationships between people.[137] This helps to generate a thick or rich description of the people and their environments.[146] The benefits of generating rich descriptions is that it allows the researcher to interpret description by looking for repeatable thoughts and behaviours with various participants and in different situations.[151] However, field notes of observations or recordings should not simply provide a description of the event or scene but need to include a specific context. The success of an ethnographic study and how recordings are interpreted are dependent on the researcher's skills and ability to be objective, their interpersonal skills and prior professional and academic (theoretical) experience influencing how rich descriptions are gathered and interpreted.[152, 153] It is important to describe the observation by recording the most relevant and noteworthy detail that is meaningful rather than recording data in isolation[147]as is the "Taylorist" research approach.[148] To mitigate this risk, the author conducted observational studies using field notes and recorded conversations between clinicians and patients and among clinicians themselves. The context of where the

conversations happened were noted by the author alongside any actions that the author considered important such as a new task carried out by the clinician or change in work practice which contributed to the implementation of the sociotechnical approach.

Chapter three of this thesis outlined limitations in relation to the ethnographic methodology including difficulty gaining access to the research field, establishing relationships with the participants so the observer remains non-bias and avoiding the possibility of becoming so immersed in the culture known as "going native" whereby the observer can loose sight of the research focus.[157] A possible risk is the Hawthorne effect where the participant may change their behavior or be more motivated to please the observer as they are conscious of being under scrutiny (i.e. the demand effect).[156]

This thesis aligned with the literature regarding the importance of eliciting requirements and considering design from a sociotechnical perspective using ethnography as one of the main sociotechnical design approaches. For example, the ability to provide rich descriptions sometimes resulted in a complete change to an original requirement. The author who played the role of business analyst had a responsibility to elicit and clarify requirements by examining and gaining a thorough understanding of the end-user's environment, how end-users carried out their work activities and tasks, in order to approach the design and deployment of the EPR from a sociotechnical perspective. It was apparent that end-users were not always clear about what they wanted and would often have "fuzzy" goals and requirements. Observations of end-users in their own environment helped to clarify requirements. For example, at a requirements engineering meeting, a requirement emerged that the end-user should be able to 'change an AED' which included the ability to change an AED name, dosage, metric unit and frequency. This requirement appears straightforward and completely necessary. However, through observations at the clinic and through analysing existing documentation, the BA observed how a patient was given a "dosage" sheet to instruct them how to take a 'new medication'. The process of administering a new medication consists of the clinicians escalating a new drug over a period of time until the patient reaches the recommended "target dosage". Similarly to wean a patient off a medication, an instruction sheet or "dosage calendar" was used to taper dosages. The original requirement did not take into account this fundamental practice of escalating and de-escalating medication and it was through observing the clinicians work practice that an updated requirement emerged. An interim workaround was developed and a protocol on how to change a current dose to a new dose was defined. This involved how the end-user

had to input the new dose in the "Target" field which displayed the current dosage and the planned new dose. This demonstrated the complexity that was involved in implementing one component of AED medication management and that it was necessary to involve users and gain an understanding of how they worked with the EPR in practice before it became clear that the requirement needed to change.

Although there are no prescribed rules or guidance to practice ethnography, the author attempted to mitigate some of these risks by being reflexive[10]. The researcher also aimed to provide an unbiased interpretation of what a participant was saying or doing and documented evidence in order to justify any interpretation made.(150) The author's field notes were not simply a description of the event or scene but also included a specific context. The author also developed a skill to be objective when interpreting field notes of observations and compared the findings with other observations recorded from different clinicians in order to establish patterns, compared against interviews and participant feedback sessions in order to triangulate results. The author also believes that by conducting observational studies over time enhanced the author's interpersonal skills and prior professional and academic (theoretical) experience influenced the observational studies. It is the author's opinion that it would be difficult if not impossible to conduct a sociotechnical implementation without using ethnography as it is important to capture the interactions that exist in a clinical environment.

8.3.1.3 Business analyst acts as a mediator between the end-users and the IT development team.

The author played the role of a BA, as described in chapter 1 and chapter 4, performing a liaison role between the multidisciplinary clinical and administrative end-users and the software developers. The BA worked on the design and deployment stages of the EPR. The BA played a key role in order to deliver the EPR in a live clinical environment alongside other key factors such as strong project management, clinical leadership and user ownership. The BA co-designed the EPR with the end-users with some influence from the technical team.

[10] Reflexivity is described as the "sensitivity to the ways the researcher and the research process have shaped the collection of data, including the role of prior assumptions and experience".143.
Mays N, Pope C. Qualitative research: observation methods in health care settings. BMJ. (1995);311(182–4.).

The key methods that the author employed to enable success in the role of the BA are summarised in this section. The management of user requirements and user expectations was a significant part of the BA's role and was challenging given the complexity of introducing an EPR into a healthcare environment which is information intensive and involves complex business processes. The author ensured that the end-users were aware that they were the owners of the EPR and emphasised to the end-users that the EPR was clinician led and not an IT initiative. This meant that the end-user were the centre of the requirements, design and deployment processes. The liaison role between the end-users and IT primarily involved fully engaging with end-users about their requirements throughout all stages of the software development lifecycle and communicating this information to the IT team. This involved ongoing meetings at different levels including weekly meetings, requirements workshops and joint meetings between the end-users and the IT team. The outcome of all meetings was documented and all requirements were recorded and managed. Establishing clear communication was the key to this process. The BA was visibly present at weekly clinics which gave a certain level of assurance to the end-users that this research was important and it provided some level of assurance to the end-users that there was a role dedicated to the EPR. The BA was instrumental in promoting awareness and progress of the EPR among the end-users and technical team and was able to deal with issues as they arose.

In order to fulfil the ambition of using a sociotechnical ethos throughout the EPR design and deployment, the BA observed how end-users carried out their work activities and tasks in order to clarify requirements. This involved establishing a relationship with end-users that ensured a level of trust between the two parties so that it was comfortable for the end-user to have an observer present. This relationship evolved over time.

8.3.1.4 The usefulness of the HOT-fit framework for evaluating EPR systems, including the challenges of operationalising it.

The HOT-fit framework was used in this thesis to evaluate the deployment of the AED module and was discussed in chapter 3 and chapter 5. The HOT-fit, designed by Yusof et al. (2006)[125], is a framework that evaluates how three factors, 'Human, Organizational and Technology' interrelate when implementing health information technology such as an EPR. There are eight dimensions in total and each dimension is associated with a number of evaluation measures. The measures of interest in the evaluation study for this thesis

included user's perception of usefulness and ease of use of the AED module, observations of the impact of the technology on work processes in the epilepsy OPD and accuracy of use of the AED module use. Emerging issues from the study were grouped into three key themes based on sociotechnical components human, organisational and technological based on the HOT-fit framework.

The HOT-fit framework, which aligns with the STS components of human, organisation and technology was chosen as the basis for this evaluation study for a variety of reasons namely that the authors had conducted critical appraisal of other HIS evaluation frameworks and they analysed other models on information system evaluation in order to inform the HOT-fit. The HOT-fit evaluation framework was built on two different models, the first called the Information Success Model developed by DeLone and McLean (2003)[129] and an IT Organization Fit Model (Scott Morton, 1991). The author chose the HOT-fit framework because it is well-validated by other studies and combined a comprehensive scope, with regard to the different components and it covered a wide range of dimensions.
Since its introduction in 2006, some studies have empirically tested and validated relationships within the model. This included the case study on a fundus imaging system used in a primary care organisation in the UK and they found that 'comprehensive, specific evaluation factors, dimensions and measures in the new framework (HOT-fit) are applicable in HIS evaluation' and more recently the HOT-fit was used to evaluate the EMR system in a hospital in Indonesia.

As outlined, the HOT-fit framework provides comprehensive criteria to evaluate EPRs including the three factors that are associated with multiple dimensions and in turn multiple factors. Although it appears to be a reasonably straightforward model to it, operationalizing the model into a research design, in this case involving observational studies, data validation and user feedback sessions required identifying the relevant variables to be evaluated within each dimension. Furthermore the dimensions must be translated into concepts relevant and meaningful to the epilepsy staff. As such, the model provided a framework within which more specific details must be developed, in order to make the model functional within the health care domain.

The author found that identifying measures required some effort. In particular, the author discovered that there was overlap with the measures of one dimension with another which initially caused some confusion. For example, the measure 'usefulness' exists under two

dimensions (1) the dimension technology (system quality) has a dimension (usefulness of system features) and (2) the dimension Human (user satisfaction) has a dimension (perceived usefulness) . Although it is clear they are used for different contexts, it is necessary to become familiar with the framework given the number of measures. While the HOT-fit framework is valuable for its comprehensiveness and relative simplicity, its usefulness in the area of health could be improved, if the measures could be made more specifically relevant to the domain, and standard definitions around the measures could be developed.

8.3.1.5 Reflections on mapping from relational database to the HL7 standard

The following section discusses the two key findings in relation to mapping. Firstly, it outlines how it is 'possible to map an extract from an existing relational EPR to the HL7 CDA standard to enable interoperability subject to certain constraints such as mapping datatypes, relationships and clinical coding' and secondly how 'the mapping from a relational EPR database to the HL7 CDA standard requires input from both clinical and technical expertise so the mapping cannot be fully automated'. In order for existing eHealth systems to integrate and comply with the CDA standard, there is a need for mapping between the CDA classes and the tables of the database schema. This can be a difficult task due to the heterogeneity of data models and schema structures they support. The CDA model may or may not align well with the way information is structured in an organisation's clinical database which results in the need for mapping.[(230)] It was important to investigate mapping as the provision of mapping is important in order to be able to preserve the investment in existing (relational) systems as opposed to a "rip and replace" policy if an organisation wants to implement standards. The mapping process can be more manageable by using a CDA implementation guide which will have defined the model in xpath expressions according to the use case and document type. The author identified that it was possible to map an extract from an existing relational EPR to a HL7 CDA Standard, by adhering to the mapping methodology that was developed in chapter 7 and was validated using the epilepsy discharge summary document. This thesis confirmed that it is feasible to map an extract from an existing relational EPR to the HL7 CDA standard to enable interoperability subject to certain constraints such as mapping datatypes, relationships and clinical coding. This finding is aligned to existing literature as outlined in section 6.6.8 of this thesis on 'mapping methodologies for relational EPR to HL7' and section 7.5 which gave a comprehensive review on the constraints on mapping.

- **Mapping requires input from both clinical and technical expertise**

Umer et al., (2012)[214] have worked on developing an automation tool for HL7 RIM-to-Relational database mapping. The basic methodology used was to analyse various clinical databases and then identify the matching fields that correspond to the HL7 v3 laboratory domain. From this study the authors learned that it is necessary to perform mapping manually prior to automation given the complexity of the HL7 RIM. Gul et al (2010)[231] also conform to this theory and acknowledge that automatic tools that map HL7 still require human intervention as well as a deep knowledge of both HL7 and the domain of application.[231] A leading expert in the CDA, Boone has described experiences with mapping CDA into existing database structures and discusses the need for 'human intervention when mapping because of the complexity of the RIM'. Boone cites that it has not been possible 'except for the simplest of things, to go from exchange format to useful database structures or object models, without significant human intervention. The introduction of the smallest bit of recursion, or data type dependency leads to the need for manual guidance. Umer et al (2012)[214] also recognise the need to provide the end user with guidance for mapping as it is highly possible that an incorrect field could be mapped because the context is not known and mapping 'requires a deep understanding of each and every concept of HL7 RIM, which is a highly cumbersome phenomenon'.

The automation of mapping may be required and more appropriate if mapping across several relational databases to the RIM model. The scope of this research was not to investigate automation of the mapping process and concentrated on manual mapping which is appropriate as the case study focussed on mapping an extract of data from a single database, the epilepsy EPR to the medication template of the CDA RMIM model.

It is acknowledged that the manual process of identifying relational EPR schema and RIM mappings (which the CDA RMIM is a subset of) is time-consuming, tedious and error prone and requires "manual intervention and low level decision making".[214] This case study supports this as the case study had a narrow scope it still required substantial work to map.

8.4 Generalisability

The findings from part one of this study reinforce the importance of sociotechnical approaches to the development of eHealth projects such as EPRs. It has been argued that many eHealth projects fail because they are too techno-centric and there is not enough attention given to the social and organisational aspects of system design. This study takes a step towards understanding how the sociotechnical approach can be used to design and deploy an EPR, as detailed in chapters 4 and 5. The author recognises that this study was conducted within controlled boundaries that may limit the generalisability of this research. For example, the scope of part I of this research was: (1) limited to the design and deployment stages of an EPR (as opposed to the complete development lifecycle of an EHR which would involve a larger scale development and evaluation (2) specific to the disease of epilepsy (3) confined to a single case study setting of an epilepsy out-patient department of a single hospital with a small sample of participants (the epilepsy service with a team of 15).

However, there are valuable lessons learned from this sociotechnical study that could potentially influence the design and deployment of other EHR/EPR projects. This study can be proposed as a practical contribution as it may be of significant importance and relevance to those who wish to develop EPRs, particularly in the context of chronic disease.

Importantly, the partial generalisability of the approach taken in this research has already been demonstrated as the epilepsy EPR has been implemented in other epilepsy centres nationally. Importantly, the epilepsy EPR has become a "lighthouse" project for other EPRs as part of the national eHealth Ireland (2016) programme and also as part of the HSE ICT initiatives. The author would advocate, based on the findings of this research, and the available literature, that the use of a sociotechnical approach would benefit the introduction of such a project at a national level. However, the author acknowledges that there are differences. For example, given that the HSE ICT need to implement national systems, the HSE ICT are concerned with developing large scale EHR implementations and would need to take a top-down approach to design and deployment of a national EHR, as is the case with most other countries. This approach differs from the bottom-up approach that was used in the development of the epilepsy EPR. The identification of the clinical requirements for the epilepsy EPR which is in routine clinical use in an epilepsy OPD could be potentially generalisable to other chronic diseases. For example, in relation to the data structures around medications e.g. that a medication has a frequency, dosage etc.

There were some contributing factors that underpinned why it was possible to use a sociotechnical approach and that may not be practical in other settings. For example, this study presented a unique opportunity to undertake the design and deployment of the EPR that was underpinned by sociotechnical principles including:

- This study was part of a wider research programme which provided significant financial backing alongside strong institutional, senior managerial and clinical support from the outset.
- The influence that senior clinicians had in the study was significant. There was excellent clinical and managerial leadership with this study and a committed clinical team.
- The epilepsy EPR was a bespoke design and development and this presented a real opportunity for the end-users to own the EPR by providing input and decision making at critical points in the design and deployment processes and provide evaluation on it.
- A dedicated business analyst and in house IT team that were allocated solely to this research project.

As an in-house development, there was flexibility to change functionality when required without sizeable financial cost. The author would argue that it is because of the ability to make these changes and continuous iterative trial and error of prototypes and changes/additions to requirements that a workable and usable solution was designed that met the end-users requirements. Mumford (2006) note that most systems that employ sociotechnical systems design were based on systems that were designed in-house. The epilepsy EPR was not introduced in a "big bang" approach but rather it was delivered in stages.

The literature highlighted that there are significant challenges in transposing a sociotechnical design approach into real practice. There is little evidence of good working examples to demonstrate that an STS approach has succeeded in making the "transition from the research laboratory to widespread commercial usage"[232] because sociotechnical systems design is theory based (based on principles) without any concrete methodologies. This thesis demonstrated that the STS ethos was used in the design and deployment of the epilepsy EPR that is used in practice.

8.4.1 Generalisability of mapping

The main finding from part II of this study outlined that it is possible to map an extract from an existing relational EPR to the HL7 CDA standard to enable interoperability subject to certain constraints. As mentioned above, the provision of mapping is important in order to preserve the investment in existing (relational) systems as opposed to a "rip and replace" policy if an organisation wants to implement standards. The mapping methodology that was designed by the author, can inform existing relational EPRs to interoperate with the CDA standard. But as stated above, the mapping process cannot be fully automated given constraints that exist and it cannot be a completely automated process as it requires manual intervention from both clinical and technical expertise.

8.5 Limitations and Suggestions

Despite the important findings that emerged in this research, the author identified a number of limitations, in particular, relating to the research being based on a single case study i.e. the epilepsy clinic, data collection, research methodology employed and the evaluation study outlined in chapter 5.

The study was based on a single case study and the author observed and evaluated only one service within the epilepsy programme, the epilepsy clinic. The findings would surely be different if the study had taken place at an epilepsy service in a different hospital, or if the study was based on a different chronic disease. The author recognises that the sociotechnical requirements, system design and deployment issues would differ from those that emerged in this case study. Further studies comparing a different type of setting, end-users and chronic disease could provide valuable insights. As elucidated in the generalisability discussion, it would be useful to examine how some of the findings identified in part one could be applied to an off-the shelf EPR product which can be customised which is a much more likely scenario than an in-house solution.

Data collection for the research question part one, sociotechnical design and deployment of the epilepsy EPR, was gathered through feedback meetings, workshops, semi-structured interviews, informal conversations, and participant observation. The author validated interviews and observations that were captured in very busy interview and fieldwork settings through follow-up meetings and informal conversations. In hindsight, it might have been

advisable to record the interviews (but in terms of observations this could have complicated the issue of obtaining consent with patients). Although the methods listed above are based on one case study, the author drew on established literature to confirm findings.

The data collection period was relatively short in the clinics. For example, for the evaluation study fieldwork was carried out over 4 hours attending the clinic over 18 weeks with approximately half an hour spent per patient. However the author had spent considerable time carrying out preliminary research in the form of an MSc in this area (see chapter 4). Ideally, the researcher would have liked to return to the case study setting to validate the findings of future enhancements to the EPR.

As highlighted in chapter 1, 2 and 3, healthcare systems and eHealth systems such as EPRs are highly complex and it was not possible to address all aspects of the field of health information that relates to EPRs using a single case study. For example, the author could not cover all issues relating to EPRs and Health Information standards that are needed to successfully deploy EPRs including, for example, Individual Health Identifier's (particularly relevant in the Irish context), and information governance, etc. In addition, due to the limited scope of a PhD study, the author could only briefly discuss several topics that influence interoperability standards. It was not possible although interesting, to cover in detail essential topics that are required to enable semantic interoperability such as clinical coding.

8.5.1 Limitations of the evaluation study (chapter 5)

There are a number of limitations associated with the evaluation study as outlined in chapter 5. There was a small sample of participants (2 doctors and 2 nurses) for the deployment study and it cannot be claimed that this sample is representative of a larger population.

There was bias in the study as convenience sampling was used. Participants were able to select the patient encounters during which they would use the AED module. This was because organisational practice caused some difficulty in recruiting subjects e.g. first time patients. A patient must have a diagnosis of epilepsy to qualify for entry to the epilepsy EPR. Not all first time patients were considered eligible for the study as they may not have had a formal diagnosis of epilepsy at their first visit or were considered "query" epilepsy following consultation. Hence, patient inclusion was finalised on the day of clinic.

It is also recognised that entering medication data which is highly structured and can be facilitated by modestly sized drop-down lists is less of a challenge than, for example, entering clinical symptoms or a detailed epilepsy history.

Before the AED module was deployed in this study, UAT was conducted and end-users tested the AED module with test data based on clinical scenarios and they verified that the application worked as intended. This approach was conducive to the concept that requirements are clarified using working prototypes in clinical routine practice[233] and conforms to the concept of "in-use design".[234] Nevertheless, it is recognised that a formal usability laboratory could have added benefit.

Given the sociotechnical nature of the design and deployment of the AED module of the epilepsy EPR, it should be noted that the participants in this study were also the domain experts who participated in the design phase of the epilepsy EPR which presents another source of bias. This meant that participants were already enthusiastic and engaged end-users by the time they were involved in the deployment stage which may not be representative of future users. However, as it was a small team that delivered the epilepsy service, it was not feasible to separate a subset of clinicians to inform the design from those who would use the *live* system.

Results of our assessment of the EPR deployment were categorised into three themes, namely – human, organisational and technological. However, the boundaries of these themes were sometimes blurred so that a result could equally be classified under human behaviour or organisation workflow.

8.5.2 Limitations of mapping

The HL7 CDA standard is well documented in the literature particularly around the creation, implementation and storage of CDA clinical documents but there are few (if any) published research of mapping from existing relational databases to the HL7 CDA RMIM or HL7 CDA implementation guides. However, the author did draw on literature that was available in relation to the HL7 RIM and mapping as there were some aspects that could overlap. For example, the HL7 CDA model is a subset of the HL7 CDA RIM and the literature around schema matching in the context of HL7 RIM to relational database was useful although the

direction of mapping was different. For example, Umer et al. (2010) have contributed to the area of mapping and have proposed the development of an automation tool for HL7 RIM-to-Relational database mapping and also recognise that it is also necessary to perform mapping manually given the intricate nature of the HL7 RIM.

Two key issues emerged from the literature regarding the RMIM, mainly the complexity of the RMIM model which required investing significant work effort to understand and interpret the RMIM model accurately; and secondly that mapping between a complex model such as the RMIM and a relational database requires both technical and clinical domain expertise.

This case study involved exporting an epilepsy discharge summary document from secondary to primary care. However, the author acknowledges that it would have been useful to use a second document such as a referral document to further validate the mapping methodology. It is possible that the medications section of the discharge summary made certain things easier or totally avoided some issues that a different choice might have encountered.

Other limitations included the fact that the mapping was performed manually although the author would argue that this was suitable given that the mapping was based on one use case and mapping was not conducted across multiple databases. However, it must be recognised that manually mapping is time consuming and can be error-prone. Another barrier to conducting the mapping was that the lack of a data dictionary for the epilepsy data requirements which meant that more discussions had to be held with end-users in order to confirm data definitions.

8.6 Contributions

This research has made a theoretical contribution to health informatics research.
It also has relevance to practice. Specifically, the study improved understanding in the following areas:

1. Demonstrates that the design and deployment of an EPR using an STS perspective in a real world clinical environment resulted in a workable and usable system.

2. Presents rich descriptions on how to design and deploy an EPR using an STS perspective and ethnography.

3. Provides a methodology which was validated on the same case study (a medication section of discharge summary) for mapping from a relational EPR database model to the HL7 CDA RMIM.

4. Identifies that the mapping from a relational data model to the HL7 CDA object oriented model requires input from both clinical and technical expertise.

8.7 Conclusions and Final Thoughts

The findings from part 1 of this study reinforce the importance of a sociotechnical approach to the development of eHealth projects such as EPRs. It has been argued that many eHealth projects fail because they are too technology focused and there is not enough attention given to the social and organisational aspects of system design. This study takes a step towards understanding how the sociotechnical approach can be used to design and deploy an EPR to meet clinical requirements. It used a case study of the epilepsy EPR, designed and deployed in a live clinical setting at one of the main Dublin teaching hospitals. A sociotechnical evaluation study on the use of the epilepsy EPR was also conducted.

This study has concluded that the STS approach offers significant benefits principally that the end-users were viewed as the owners of the epilepsy EPR throughout the epilepsy EPR development lifecycle. The end-users remained engaged and committed to the epilepsy EPR design and deployment and the epilepsy EPR is currently being used in clinical practice at Beaumont hospital, alongside being rolled out for use at a national level. However, the author recognises that it may be difficult to realise a sociotechnical approach to EPR development given that this study had some important underlying factors that contributed to the possibility of employing sociotechnical approach. They included excellent clinical and senior managerial leadership and support, a committed clinical team who worked collaboratively together and were committed to engaging in research alongside their clinical role, significant financial backing alongside strong institutional, senior managerial and clinical support from the outset. Additionally, the epilepsy EPR was a bespoke, in house development and this presented a real opportunity for the end-users to own the EPR by providing input and decision making at critical points in the design and deployment

processes and provide evaluation on it. Also, there was a dedicated business analyst and in-house software development team that were allocated solely to this research project.

This thesis also investigated the feasibility of how EPRs can safely share and communicate health information using healthcare interoperability standards. The epilepsy EPR was based on bespoke software and did not conform to any international eHealth standards. This study demonstrated that it is possible to preserve investment in existing legacy (relational) EPR systems while at the same time allowing then to share data with other systems through the use of international interoperability standards.

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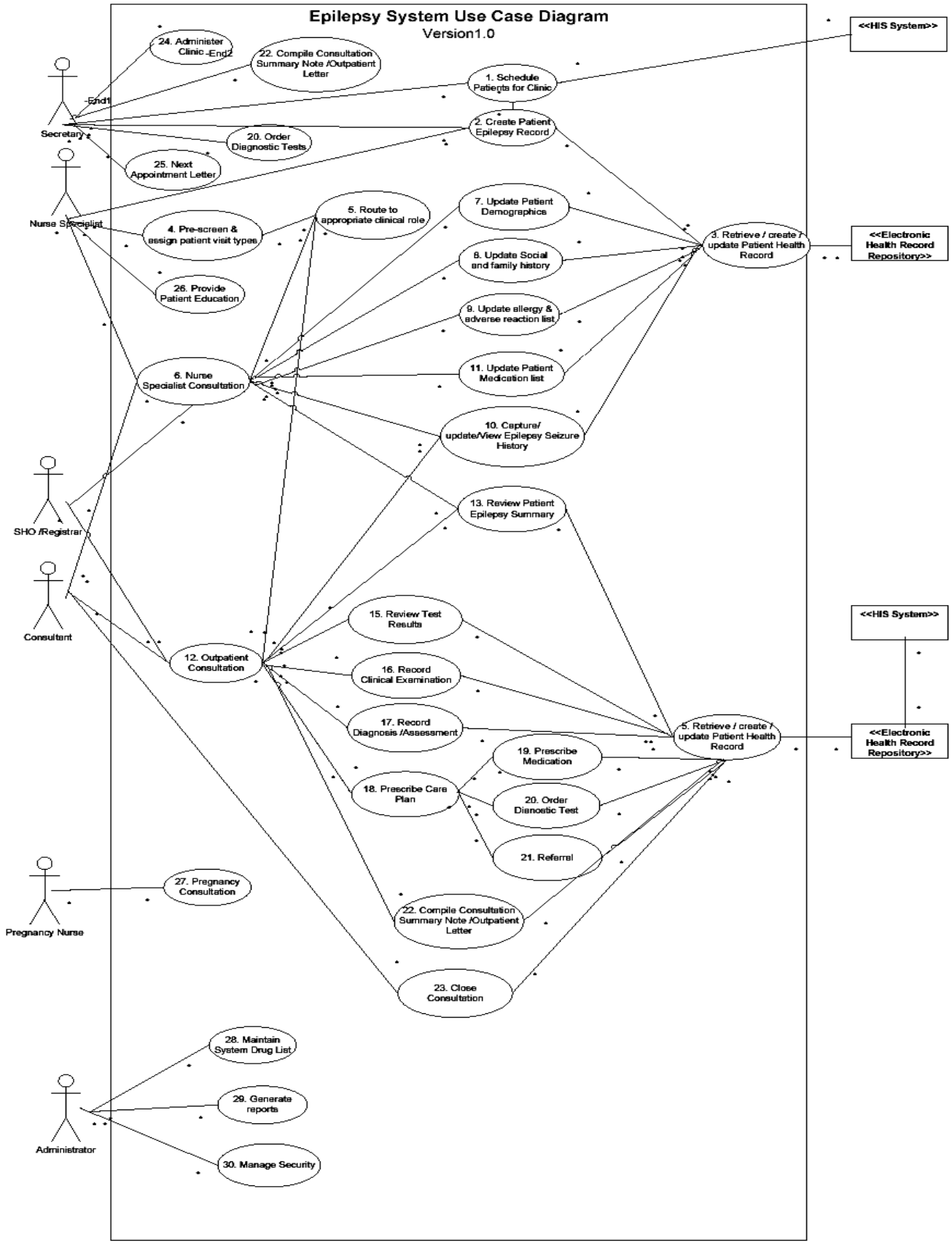
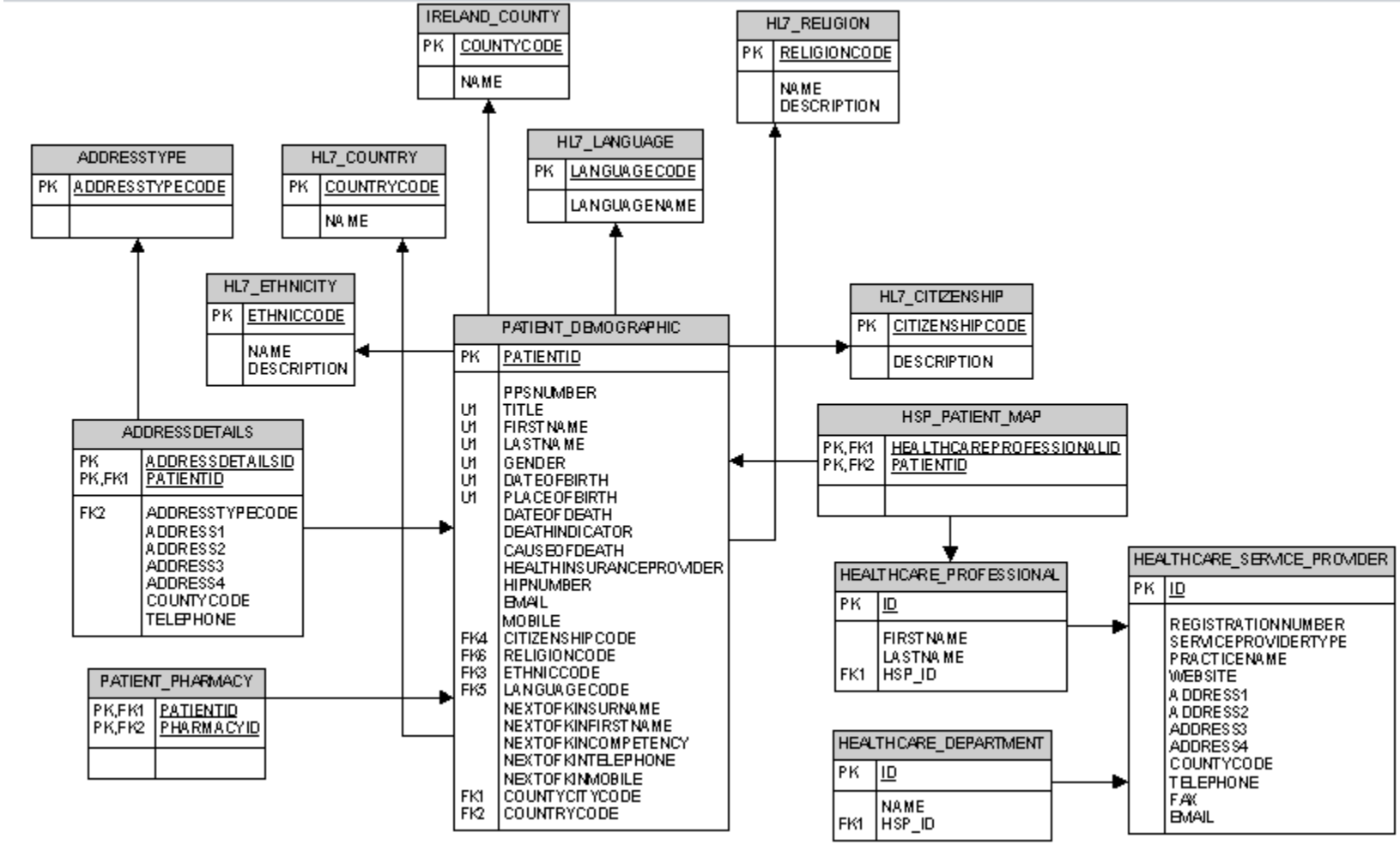
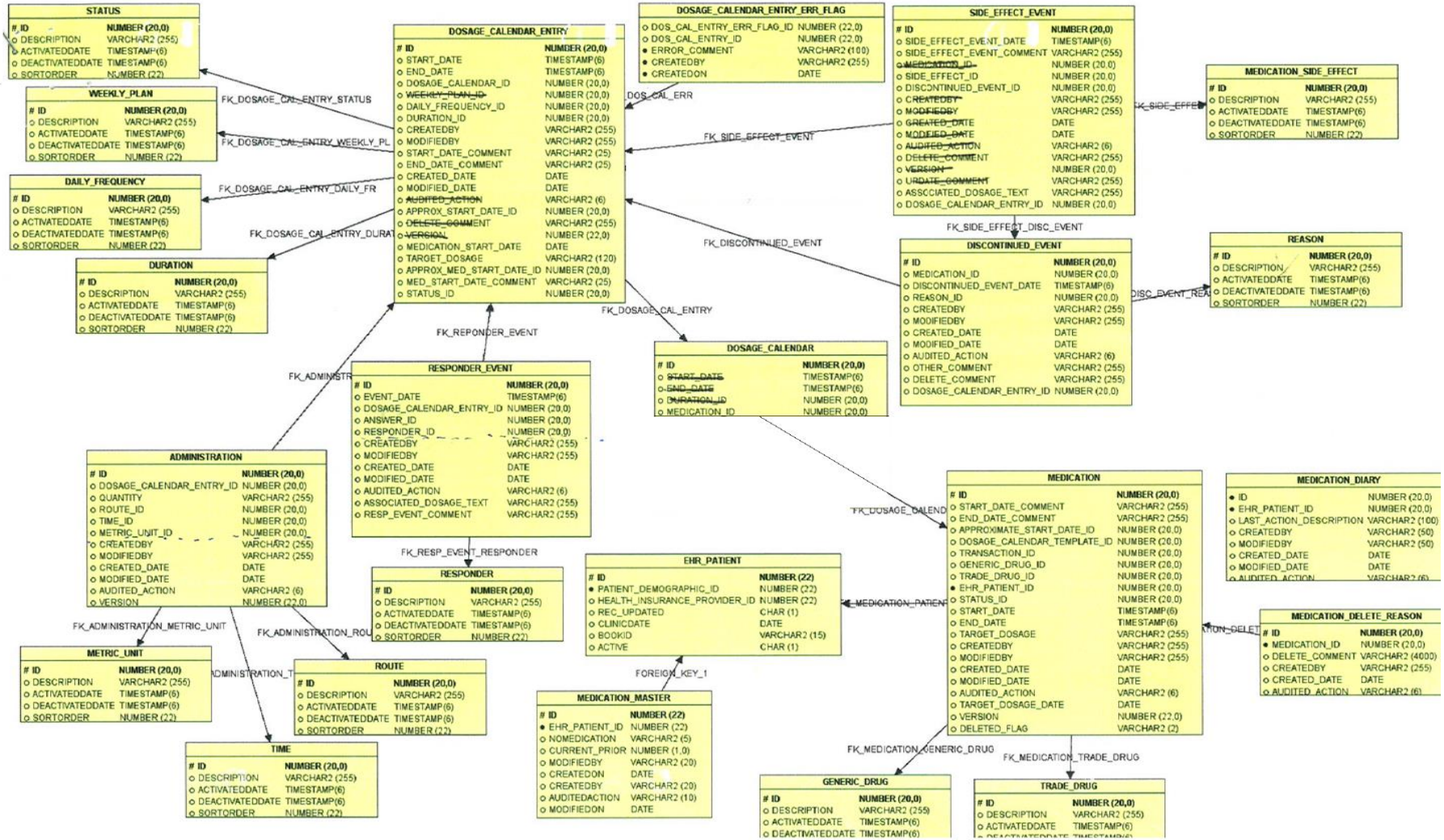
Appendix A Use Case Diagram for the epilepsy EPR



Appendix B Epilepsy EPR Demographics Physical Data Model



Appendix C Epilepsy EPR Medications Physical Data Model



Appendix D Mapping Table for Demographics and Medications

DB Field	DB Data Type	DB Table	Epsos IG Schema xPath	RMIM Class	Optionality / Cardinality	Data Type	Matched	Inconsistency
PatientRole								
PPS	Varchar	Patient_Demographic	recordTarget/patientRole/id	PatientRole	R/[1..1]	II	TRUE	FALSE
N/A	N/A	N/A	recordTarget/patientRole/id	PatientRole	O/[0..*]	II	FALSE	FALSE
Patient (PatientRole/Patient)								
LastName	Varchar	Patient_Demographic	recordTarget/patientRole/patient/name/family	Patient	R/[1..*]	PN	TRUE	FALSE
Title	Varchar	Patient_Demographic	recordTarget/patientRole/patient/name/prefix/	Patient	O/[0..*]	PN	TRUE	FALSE
FirstName	Varchar	Patient_Demographic	recordTarget/patientRole/patient/name/given	Patient	R/[1..*]	PN	TRUE	FALSE
Gender	Varchar	Patient_Demographic	recordTarget/patientRole/patient/administrativeGenderCode	Patient	R, use nullFlavour / [1..1]	CE	TRUE	FALSE
DateOfBirth	DateTime	Patient_Demographic	recordTarget/patientRole/patient/birthtime	Patient	R/[1..1]	TS	TRUE	FALSE
Patient Address (PatientRole/Addr)								
Address1	Varchar	AddressDetails	recordTarget/patientRole/addr/streetAddressLine	PatientRole	O/[0..*]	AD	TRUE	FALSE
Address2	Varchar	AddressDetails	recordTarget/patientRole/addr/streetAddressLine	PatientRole	O/[0..*]	AD	TRUE	FALSE
Address3	Varchar	AddressDetails	recordTarget/patientRole/addr/streetAddressLine	PatientRole	O/[0..*]	AD	TRUE	FALSE

Address4	Varchar	AddressDetails	recordTarget/patientRole/addr/streetAddressLine	PatientRole	O/[0..*]	AD	TRUE	FALSE
CountyCityCode	Varchar	Patient_Demographic	recordTarget/patientRole/addr/city	PatientRole	O/[0..*]	AD	TRUE	FALSE
N/A	N/A	N/A	recordTarget/patientRole/addr/postalCode	PatientRole	O/[0..*]	AD	FALSE	FALSE
CountryCode	Varchar	Patient_Demographic	recordTarget/patientRole/addr/country	PatientRole	O/[0..*]	AD	TRUE	FALSE
Patient Telephone & Email (PatientRole/telecom)								
Mobile	Varchar	Patient_Demographic	recordTarget/patientRole/telecom/@value	PatientRole	R, use nullFlavor/ [1..*]	TEL	TRUE	FALSE
Mobile	Varchar	Patient_Demographic	recordTarget/patientRole/telecom/@use	PatientRole	R, use nullFlavor/ [1..*]	TEL	TRUE	FALSE
Email	Varchar	Patient_Demographic	recordTarget/patientRole/telecom/@value	PatientRole	R, use nullFlavor/ [1..*]	TEL	TRUE	TRUE
Email	Varchar	Patient_Demographic	recordTarget/patientRole/telecom/@use	PatientRole	R, use nullFlavor/ [1..*]	TEL	TRUE	TRUE
Patient Language (PatientRole/Patient/languageCommunication)								
LanguageCode	Varchar	Patient_Demographic	patientRole/patient/languageCommunication/languageCode	Patient	O	CS	TRUE	FALSE
Patient Guardian (PatientRole/Patient/Guardian)								
NextOfKinSurname	Varchar	Patient_Demographic	patientRole/patient/guardian/guardianPerson/name/family	Guardian	R, use nullFlavor/ [1..*]	PN	TRUE	FALSE

NextOfKinFirstName	Varchar	Patient_Demographic	patientRole/patient/guardian/guardianPerson/name/given	Guardian	R, use nullFlavor/ [1..*]	PN	TRUE	FALSE
Patient Guardian Address (PatientRole/Patient/Guardian/addr)								
N/A	N/A	N/A	patientRole/patient/guardian/addr/streetAddressLine	Guardian	O/[0..*]	AD	FALSE	FALSE
N/A	N/A	N/A	patientRole/patient/guardian/addr/streetAddressLine	Guardian	O/[0..*]	AD	FALSE	FALSE
N/A	N/A	N/A	patientRole/patient/guardian/addr/city	Guardian	O/[0..*]	AD	FALSE	FALSE
N/A	N/A	N/A	patientRole/patient/guardian/addr/postalCode	Guardian	O/[0..*]	AD	FALSE	FALSE
N/A	N/A	N/A	patientRole/patient/guardian/addr/state	Guardian	O/[0..*]	AD	FALSE	FALSE
N/A	N/A	N/A	patientRole/patient/guardian/addr/country	Guardian	O/[0..*]	AD	FALSE	FALSE
Patient Guardian Email & Telephone (PatientRole/Patient/Guardian/Telecom)								
NextOfKinTelephone	Varchar	Patient_Demographic	patientRole/patient/guardian/telecom/@value	Guardian	R, use nullFlavor/ [1..*]	TEL	TRUE	TRUE
NextOfKinTelephone	Varchar	Patient_Demographic	patientRole/patient/guardian/telecom/@use	Guardian	R, use nullFlavor/ [1..*]	TEL	TRUE	TRUE
N/A	N/A	N/A	patientRole/patient/guardian/telecom/@value	Guardian	R, use nullFlavor/ [1..*]	TEL	FALSE	FALSE
N/A	N/A	N/A	patientRole/patient/guardian/telecom/@use	Guardian	R, use nullFlavor/ [1..*]	TEL	FALSE	FALSE

Patient Contact Person (participant/associatedEntity/associatedPerson)								
N/A	N/A	N/A	participant/associatedEntity/associatedPerson/name/family	AssociatedEntity	R, use nullFlavor/ [1..*]	PN	FALSE	FALSE
N/A	N/A	N/A	participant/associatedEntity/associatedPerson/name/given	AssociatedEntity	R, use nullFlavor/ [1..*]	PN	FALSE	FALSE
Patient Contact Address (participant/associatedEntity/addr)								
N/A	N/A	N/A	participant/associatedEntity/addr/street/streetAddressLine	AssociatedEntity	O/[0..*]	AD	FALSE	FALSE
N/A	N/A	N/A	participant/associatedEntity/addr/street/streetAddressLine	AssociatedEntity	O/[0..*]	AD	FALSE	FALSE
N/A	N/A	N/A	participant/associatedEntity/addr/city	AssociatedEntity	O/[0..*]	AD	FALSE	FALSE
N/A	N/A	N/A	participant/associatedEntity/addr/postalCode	AssociatedEntity	O/[0..*]	AD	FALSE	FALSE
N/A	N/A	N/A	participant/associatedEntity/addr/state	AssociatedEntity	O/[0..*]	AD	FALSE	FALSE
N/A	N/A	N/A	participant/associatedEntity/addr/country	AssociatedEntity	O/[0..*]	AD	FALSE	FALSE
Patient Contact Email & Telephone (participant/associatedEntity/telecom)								
N/A	N/A	N/A	participant/associatedEntity/telecom/@value	AssociatedEntity	R, use nullFlavor/ [1..*]	TEL	FALSE	FALSE
N/A	N/A	N/A	participant/associatedEntity/telecom/@use	AssociatedEntity	R, use nullFlavor/ [1..*]	TEL	FALSE	FALSE

N/A	N/A	N/A	participant/associatedEntity/telecom/@value	AssociatedEntity	R, use nullFlavor/[1..*]	TEL	FALSE	FALSE
N/A	N/A	N/A	participant/associatedEntity/telecom/@use	AssociatedEntity	R, use nullFlavor/[1..*]	TEL	FALSE	FALSE
Health Care Provider Name (participant/associatedEntity/associatedPerson/name)								
PracticeName	Varchar	HealthCareServiceProvider	participant/associatedEntity/associatedPerson/name	AssociatedEntity	R, use nullFlavor/[1..1]	ON/PN	TRUE	FALSE
LastName	Varchar	HealthcareProfessional	participant/associatedEntity/associatedPerson/name/family	AssociatedEntity	R, use nullFlavor/[1..1]	PN	TRUE	FALSE
FirstName	Varchar	HealthcareProfessional	participant/associatedEntity/associatedPerson/name/given	AssociatedEntity	R, use nullFlavor/[1..1]	PN	TRUE	FALSE
Health Care Provider Address (participant/associatedEntity/addr)								
Address 1	Varchar	HealthCareServiceProvider	participant/associatedEntity/addr/streetAddressLine	AssociatedEntity	O/[0..*]	AD	TRUE	FALSE
Address 2	Varchar	HealthCareServiceProvider	participant/associatedEntity/addr/streetAddressLine	AssociatedEntity	O/[0..*]	AD	TRUE	FALSE
Address 3	Varchar	HealthCareServiceProvider	participant/associatedEntity/addr/streetAddressLine	AssociatedEntity	O/[0..*]	AD	TRUE	FALSE
Address 4	Varchar	HealthCareServiceProvider	participant/associatedEntity/addr/streetAddressLine	AssociatedEntity	O/[0..*]	AD	TRUE	FALSE
County code	Varchar	HealthCareServiceProvider	participant/associatedEntity/addr/city	AssociatedEntity	O/[0..*]	AD	FALSE	FALSE
N/A	N/A	N/A	participant/associatedEntity/addr/postalCode	AssociatedEntity	O/[0..*]	AD	FALSE	FALSE

N/A	N/A	N/A	participant/associatedEntity/addr/state	AssociatedEntity	O/[0..*]	AD	FALSE	FALSE
N/A	N/A	N/A	participant/associatedEntity/addr/country	AssociatedEntity	O/[0..*]	AD	FALSE	FALSE
Health Care Provider Telephone & Email (participant/associatedEntity/telecom)								
Telephone	Varchar	HealthCareServiceProvider	participant/associatedEntity/telecom/@value	AssociatedEntity	R, use nullFlavor/ [1..*]	TEL	TRUE	FALSE
Telephone	Varchar	HealthCareServiceProvider	participant/associatedEntity/telecom/@use	AssociatedEntity	R, use nullFlavor/ [1..*]	TEL	TRUE	FALSE
Email	Varchar	HealthCareServiceProvider	participant/associatedEntity/telecom/@value	AssociatedEntity	R, use nullFlavor/ [1..*]	TEL	TRUE	FALSE
Email	Varchar	HealthCareServiceProvider	participant/associatedEntity/telecom/@use	AssociatedEntity	R, use nullFlavor/ [1..*]	TEL	TRUE	FALSE
Health Care Facility (ClinicalDocument/author/assignedAuthor/representedOrganization)								
PracticeName	Varchar	HealthCareServiceProvider	/ClinicalDocument/author/assignedAuthor/representedOrganization/name	Assigned Author	R, null flavor/ [1..1]	ON	TRUE	FALSE
ID	Number	HealthcareProfessional	ClinicalDocument/author/assignedAuthor/representedOrganization/id O	Assigned Author	R null flavor/ [1..1]	II	TRUE	FALSE
Health Care Facility Address (ClinicalDocument/author/assignedAuthor/representedOrganization/addr)								
Address 1	Varchar	HealthCareServiceProvider	ClinicalDocument/author/assignedAuthor/representedOrganization/addr/streetAddressLine	Assigned Author	O/[1..1]	AD	TRUE	FALSE

Address 2	Varchar	HealthCareServiceProvider	ClinicalDocument/author/assignedAuthor/representedOrganization/addr/streetAddressLine	Assigned Author	O/[1..1]	AD	TRUE	FALSE
Address 3	Varchar	HealthCareServiceProvider	ClinicalDocument/author/assignedAuthor/representedOrganization/addr/streetAddressLine	Assigned Author	O/[1..1]	AD	TRUE	FALSE
Address 4	Varchar	HealthCareServiceProvider	ClinicalDocument/author/assignedAuthor/representedOrganization/addr/streetAddressLine	Assigned Author	O/[1..1]	AD	TRUE	FALSE
County	Varchar	HealthCareServiceProvider	/ClinicalDocument/author/assignedAuthor/representedOrganization/addr/city	Assigned Author	O/[1..1]	AD	TRUE	FALSE
N/A	N/A	N/A	/ClinicalDocument/author/assignedAuthor/representedOrganization/addr/state	Assigned Author	O/[1..1]	AD	FALSE	FALSE
N/A	N/A	N/A	ClinicalDocument/author/assignedAuthor/representedOrganization/addr/postalCode	Assigned Author	O/[0..*]	AD	FALSE	FALSE
N/A	N/A	N/A	/ClinicalDocument/author/assignedAuthor/representedOrganization/addr/country	Assigned Author	R/[1..1]	AD	FALSE	FALSE
Health Care Facility Email & Phone (ClinicalDocument/author/assignedAuthor/representedOrganization/telecom)								
Telephone	Varchar	HealthCareServiceProvider	/ClinicalDocument/author/assignedAuthor/representedOrganization/telecom/@value	Assigned Author	O/[0..*]	TEL	TRUE	FALSE

Telephone	Varchar	HealthCareServiceProvider	/ClinicalDocument/author/assignedAuthor/representedOrganization/telecom/@use	AssignedAuthor	O/[0..*]	TEL	TRUE	FALSE
Email	Varchar	HealthCareServiceProvider	/ClinicalDocument/author/assignedAuthor/representedOrganization/telecom/@value	AssignedAuthor	O/[0..*]	TEL	TRUE	FALSE
Email	Varchar	HealthCareServiceProvider	/ClinicalDocument/author/assignedAuthor/representedOrganization/telecom/@use	AssignedAuthor	O/[0..*]	TEL	TRUE	FALSE
Clinical Document - Date of Creation, Date of last update, Document ID, Document Code, Document Title, Confidentiality Code, Language code								
N/A	N/A	N/A	/ClinicalDocument/effectiveTime	ClinicalDocument	R/[1..1]	TS	FALSE	FALSE
N/A	N/A	N/A	/ClinicalDocument/effectiveTime/high	ClinicalDocument	R/[1..1]	TS	FALSE	FALSE
N/A	N/A	N/A	/ClinicalDocument/id	ClinicalDocument	R/[1..1]	II	FALSE	FALSE
N/A	N/A	N/A	/ClinicalDocument/code	ClinicalDocument	R/[1..1]	CE	FALSE	FALSE
N/A	N/A	N/A	/ClinicalDocument/title	ClinicalDocument	R/[1..1]	ST	FALSE	FALSE
N/A	N/A	N/A	/ClinicalDocument/confidentialityCode/@code	ClinicalDocument	R, use nullFlavor/[1..1]	CE	FALSE	FALSE
N/A	N/A	N/A	/ClinicalDocument/languageCode	ClinicalDocument	R/[1..1]	CS	FALSE	FALSE
Legal Authenticator								
N/A	N/A	N/A	/ClinicalDocument/legalAuthenticator/assignedEntity/representedOrganization	ClinicalDocument	R, use nullFlavor/[1..1]	CE	FALSE	FALSE