

The Obstacles and Enablers to implementing a Patient Held Prescribing Record in Ireland

Paul Fahey

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Declaration

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

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Abstract

The need for high quality patient information at each point of care has been widely recognised as one of the most critical factors in the provision of safe and effective healthcare. However, in Ireland, significant gaps exist in health information in the patient's journey through the healthcare system which can cause delays and less optimal care. One of the critical information gaps is a lack of information on patients' current medication and allergies.

Some countries have introduced Personal Health Records to try and bridge this information gap, where the patient has control of who will have access to their information. The main objective of this dissertation is to investigate the possibility of introducing a similar Personal Health Record in Ireland that would carry information on a patient's current medication and allergies.

The importance of Personal Health Records was investigated and the role they have come to play in empowering patients to take control of their health information and how this can be used to optimise patient care through the increased availability of information at point of care. A review of current literature provided an outline of the obstacles and enablers to the introduction of such a record. Case studies into similar records in France, Scotland and the Netherlands were then undertaken to ascertain what lessons might be learned for an Irish context.

It was concluded that for a Personal Health Record to be introduced in Ireland, unique individual health identifiers and health information and interoperability standards will be required. An independent "trust centre" that would act as a national data controller for the Personal Health Record should be established incorporating a robust patient consent model with strict governance provisions to ensure continued patient confidence should be implemented. The scope and purpose of the record would need to be clearly defined and the best outcomes can be achieved where there is significant stakeholder engagement and consultation from an early stage. A benefits measurement strategy would need to be in place from the outset that would allow for measurement of financial and non-financial benefits of the project.

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Abbreviations

AAP- American Academy of Pediatrics

A & E- Accident & Emergency Department

AFSSAPS- Agence Française de Sécurité Sanitaire des Produits de Santé, the French medicines and medical devices regulatory agency

AMIA- American Medical Informatics Association

ASIP- Agence des Systèmes d'Information Partagé de Santé, the French Government agency responsible for eHealth and the national EHR programme

ASP- Active Server Pages

ASTM- American Society for Testing and Materials

BSN- Unique Patient Identifier in the Netherlands

CIBG- Central Information Point for Healthcare Professionals (Netherlands)

CCR- Continuity of Care Record (ASTM standard)

CDA- Clinical Document Architecture

CIP- Drug dictionary in France

DOHC- Department of Health and Children (Ireland)

DP- Dossier Pharmaceutique (France)

ECS- Emergency Care Summary (Scotland)

EHR- Electronic Healthcare Record

EHR IMPACT- series of ten evaluation studies commissioned by the EU Commission Directorate General for Information Society and Media on good practice in interoperable electronic healthcare record systems and ePrescribing systems in Europe

EMD- Electronic Medication Record in the Netherlands

EPD- National Electronic Healthcare Record in the Netherlands

ePHR- Electronic Personal Health Record

EU- European Union

GP- General Practitioner

HAS- Haute Autorité de Santé, the French National Health Service

HIMSS- Health Information and Management Systems Society

HIQA- Health Information Quality Authority

HIT- Health Information Technology

HL7- Health Level Seven International

HSE- Health Service Executive (Ireland)

ICD- International Classification of Diseases

ICEHR- Integrated Care Electronic Healthcare Record

ICT- Information and Communication Technology

IHE- Integrating the Health Enterprise

IHTSDO- International Health Terminology Standards Development Organisation

IMIA- International Medical Informatics Association

ISO- International Organisation for Standardisation

IT- Information Technology

KIS- Key Information Summary (Scotland)

KNMP- Pharmacy representative body in the Netherlands

LOINC®- Logical Observation Identifiers Names and Codes

LSP- National Switch Point (Netherlands)

NEHTA- National E-Health Transition Authority (Australia)

NHS- National Health Service

NPFIT- National Programme for IT (United Kingdom)

OECD- Organisation for Economic Co-operation and Development

Nictiz- National IT Institute for Healthcare (Netherlands)

ONP- Ordre National des Pharmaciens (French pharmacy regulatory body)

OOH- Out of Hours services

OTC- Over the counter medicines (not requiring a prescription)

OZIS- Open Zorg Informatie Systeem (translated to English is the Open Care Information System)

PCEHR- Personally Controlled Electronic Health Record (Australia)

PCRS- Primary Care Reimbursement Service (Ireland)

PHR- Personal Health Record

PKI- Public Key Infrastructure

SCR- Summary Care Record

UZI- Unique healthcare professional identifier in the Netherlands

UZOVI- Unique insurer provider identifier in the Netherlands

WDH- Electronic General Practitioner Record in the Netherlands

1 Chapter One: Background

1.1 Introduction

The past two decades in Ireland have seen significant advances in medical treatments which have resulted in the use of more complex medicines including novel compounds and biotech medicines and also a marked increase in general prescribing levels. The increase in prescribing levels can also be attributed to the ageing of the population and increased life expectancy. Statistics have shown that average life expectancy at birth in 1991 to be over 72 years of age and this had increased to almost 80 years of age in 2009 (Department of Health and Children 2009). Data from the Primary Care Reimbursement Service in relation to the Medical Card Scheme shows that the average numbers of items per prescription form for 1999 was 2.25 and in 2009 the equivalent number was 3.11. Similarly in 1999 the total number of items dispensed to medical card patients was 21,679,000 while in 2009 this figure had risen to 50,722,000 (HSE Primary Primary Care Reimbursement Service 2009). These figures are indicative of increased prescribing both in relation to the number of medicines being prescribed for each patient and also to an increase in the number of patients being prescribed medication. These increased prescribing levels and the use of more complex medicines may lead to increased risk to patients where there is misprescribing, misuse/abuse of medicines and omission of medication. Furthermore, there has been a marked increase in hospital activity in the last decade with a 50.1% increase in the number of hospital discharges increasing from 847,530 in 2001 to 1,440,497 in 2010 (Department of Health and Children 2010).

In Ireland, patients' health information is often fragmented and inaccessible at time of need and is currently held on many disparate paper based and electronic patient record systems (Health Information Quality Authority 2011a). There is currently no central repository for holding information for patients on their health status that could be accessed by patients themselves or by clinicians seeking to provide healthcare. Information is often held on standalone electronic patient records (EPRs) (where such exist) in the local GP practices, local pharmacy, and hospital outpatient clinic or in-house hospital EPR systems. Therefore, in situations where patients are moving through the health system, their information does not move with them resulting in information gaps which can result in delayed treatment where healthcare professionals may be seeking access to information that is required for clinical decisions on treatment choice.

1.2 Current situation in Ireland

This information gap is particularly relevant where patients are transiting between Primary and Secondary Care and also where outpatient care is being provided in the hospital setting. An example of this is where patients are receiving chemotherapy in hospital on an out-patient basis; as the patient will have had the medicine administered in the hospital setting no prescription will have been notified to the community pharmacy. In such cases, the pharmacy will not have knowledge of the chemotherapy medication and may unwittingly dispense prescribed medicine to the patient that may interact with the chemotherapy medication. Similarly, where patients present to Accident and Emergency Units or Out of Hours GP services, healthcare professionals may not have information on the patient's current illness and treatment. In these instances, patients may not have or are unable to provide the information to the healthcare professional. In 2011 the Health Information Quality Authority (HIQA), while acknowledging that despite good examples of use of Information and Communication Technology (ICT) in healthcare, the current infrastructure in Ireland is fragmented causing information gaps which often results in patients being asked to provide the same information on many occasions (Health Information Quality Authority 2011b). These information gaps may cause delays in treatment or in worse case scenarios, inappropriate treatment. Much research has been done on patient safety during transition in patient care from the secondary to the primary care setting and vice versa. Research in Ireland (Grimes, Delaney, Duggan, Kelly, et al. 2008) suggests that 65.5% of patients at discharge had discrepancies in their medication of which 20.9% was drug omission.

Research in the USA (Cornish et al. 2005) revealed that 53.6% of patients after admission had a discrepancy in their medication; drug omissions were reported in 46% of cases where there was a discrepancy. In a review of progress of and future trends for electronic patient records, it was concluded that paper discharge documents from hospitals can often be incomplete or not arrive on time to the patient's GP for maintaining continuity of care for the patient (Knaup, Bott, Kohl, Lovis, et al. 2007). Research in Queensland, Australia (Forsythe, MacDonald & Wilhelm 2011) compared two hospitals of similar size and clinical speciality; one used paper records and the other electronic records and discharge summaries. Results from the study indicated that in the case of the paper based hospital, only 39% of GP's received completed paper summaries compared with 82% of GP's from the electronic based hospital. Satisfaction of GP's with the paper summaries was rated at 7% compared with 93% satisfaction with the electronic summaries. It was also shown that 75% of electronic summaries were sent by the "electronic" hospital to GP's within 48 hours. In Austria research has concluded that information exchanged between healthcare professionals using paper

documents is prone to error, often of poor quality and too slow to arrive thus causing interruptions in continuity of patient care (Schabetsberger et al. 2006).

The Commission on Patient Safety and Quality Assurance in 2009 recommended that medicines reconciliation should be carried out when patients are moving from one care setting to another. In its report, it defined medication reconciliation as *“the process of obtaining a complete and accurate list of each patient's current medications from all available sources at all points of contact and verifying and reconciling medications to reduce medication errors”* (Madden Commission 2008). If this information moved with the patient the medication reconciliation process would be more easily achieved.

The use of a Personal Health Record (PHR) that would include an up to date profile of the patient's medication may be an important step in filling this information gap and optimising patient care. Such a record could be a Patient Held Prescribing Record (PHPR) which would be accessible by health professionals providing care to the patient with the patient's consent. The introduction of a Patient Held Prescribing Record in Ireland may also have the potential to be the first step in sharing of patient information across and within the primary and secondary care domains.

In this dissertation the current State of the Art in relation to Personal Health Records within the context of a Patient Held Prescribing Record will be explored. Case studies from countries where Personal Health Records have or are currently being implemented will also be conducted. Based on the State of the Art and the research conducted, I will examine the current state of play in Ireland and attempt to answer the following research question;

“What are the Obstacles and Enablers to implementing a Patient Held Prescribing Record in Ireland?”

1.3 Overview of Dissertation

Chapter Two of this dissertation will explore the current State of the Art in relation to definitions of Personal Health Records and their potential role in optimising patient care and improving patient safety. The current trends into what information should be held on a record similar to a Patient Held Prescribing Record is examined and the external environment that is required to support the introduction of Personal Health Records in Ireland is also explored within the context of international examples of existing Personal Health Records whose main function is to carry medication information.

Chapter Three provides an outline of the research methodology used to answer the research question and the limitations of the methodology adopted.

In Chapter Four is a detailed description of the research conducted and consists of an in depth study of the implementation and roll out of the Dossier Pharmaceutique in France and the Emergency Care Summary in Scotland. An analysis of the proposed Electronic Medication Record (EMD) in the Netherlands is also undertaken. Data Protection issues that may arise in relation to the introduction of a Patient Held Prescribing Record in Ireland are also explored.

Chapter Five provides an outline of how the data collected in Chapter Four was analysed and how common themes across the various cases studies were identified. An analysis of the data is presented to identify the obstacles and enablers that exist within the Irish context that relate to the introduction of a Patient Held Prescribing Record.

Finally Chapter Six which is the conclusion summarises the research and the subsequent findings. The potential limitations of the findings are discussed and suggestions are proposed for possible future research in this area.

2 Chapter Two: Literature Review

2.1 Introduction

As stated in Section 1.3, this chapter will explore the current State of the Art in relation to Personal Health Records. As this dissertation is principally an examination of Personal Health Records within the context of a Patient Held Prescribing Record, I have confined the research to the current State of the Art to Personal Health Records whose main function is to carry medication information.

Section 2.2 describes the search strategy used to identify potential data sources for the examination of the State of the Art.

Section 2.3 explores the various definitions of Personal Health Records and the need for the purpose and scope of a Patient Held Prescribing Record to be clearly defined in the first instance.

Section 2.4.1 explores the need for Personal Health Records and how they have come to be recognised as an important tool in bridging information gaps that can occur during the patient's journey through the healthcare system and improve patient safety. Section 2.4.2 outlines the role that Personal Health Records have in empowering patients to take control of their healthcare and facilitating patients to be placed at the centre of healthcare delivery as opposed to the more traditional organisation centred approach that has existed in many healthcare delivery systems.

Section 2.5 examines which information should be held in a Patient Held Prescribing Record and how the dataset included will largely depend on the purpose and scope of the record.

Section 2.6 examines international evidence in relation to factors that enable or impede the implementation of Personal Health Records. Among the factors discussed are unique health identifiers for individuals, healthcare professionals and organisations; health information and interoperability standards, benefits realisation and the challenges that exist in measuring the impact of eHealth programmes; stakeholder engagement prior to, during and after the implementation of Personal Health Records and finally governance and administrative arrangements required to support eHealth programmes.

Section 2.7 summarises the main findings from the examination of the State of the Art.

2.2 Search Strategy

The strategy used to identify literature of relevance to the subject being studied consisted of development of search terms that would yield the most relevant results. The following search terms were used in the initial searches; “personal health record(s)”, “electronic prescription record”, “personal medication record”, “electronic medication record”, “personal prescription record”, “medication discrepancy”, “medication discrepancies”, “patient care summary”, “patient care summaries”, “summary care record(s)”. The resulting material was then filtered using sub search terms such as “patient safety”, “patient empowerment” and “data set”. This allowed the literature sources to be narrowed down to sources that were deemed of relevance within the context of a personal health record that contained medication information. As it was previously known to the author that the European Commission’s Electronic Healthcare Record Impact programme (EHR IMPACT) had commissioned several reports on progress on the implementation of eHealth in Europe, these documents were also sourced. Literature sources were also identified from national reports published by the Department of Health and Children, the Health Service Executive and the Health Information Quality Authority.

2.3 Definitions of Personal Health Records

A Personal Health Record (PHR) in its simplest form can be a paper record generated by the individual, an online record created using proprietary software such as Microsoft Vault, or using the bespoke software of an individual’s healthcare provider such as a Government insurance fund, public or commercial healthcare provider such as a health insurer (Tang, Ash, Bates, Overhage, et al. 2006).

Attempts at defining Personal Health Records are numerous and vary in emphases. For instance the Finnish Government as part of its concept and roadmap for electronic healthcare services has defined personal health records based on the Markle Foundation’s Working Group on Policies for Electronic Information Sharing between Doctors and Patients Report published in 2004. It defines a personal health record as *“An internet-based set of tools that allow people to access and coordinate their lifelong health information and make appropriate parts of it available to those who need it.”* (Markle Foundation 2004). The Finnish Government further defines the Personal Health Record as being *“..... owned and controlled by the citizen and patient while an Electronic Health Record is owned by the professional healthcare service provider. An Electronic Health Record is a legal document and there are strict rules for how information is created, edited or deleted. A Personal Health Record is not a legal document. A Personal Health Record supports patient-directed healthcare by providing information and tools that will lead to greater interaction between patients and their doctors”* (Valkeakari 2008). It further stipulates that healthcare professionals will require

permission from patients for access to their personal health records which provides a novel means for healthcare professionals to provide care and interact with patients.

The Health Informatics Management and Systems Society (HIMSS) in a position paper in 2007 sought to elaborate on the Markle Foundation's definition and defines an electronic Personal Health Record as follows: *"An electronic Personal Health Record ("ePHR") is a universally accessible, layperson comprehensible, lifelong tool for managing relevant health information, promoting health maintenance and assisting with chronic disease management via an interactive, common data set of electronic health information and e-health tools. The ePHR is owned, managed, and shared by the individual or his or her legal proxy(s) and must be secure to protect the privacy and confidentiality of the health information it contains. It is not a legal record unless so defined and is subject to various legal limitations"* (Health Information Management and Systems Society 2007).

The emphasis on the interactive nature of an electronic Personal Health Record and the use of a common data set for health information would appear to seek to progress the definition to provide greater mobility and accuracy of health information. This definition also stresses the ownership of the record as being that of the patient thus stressing the patient centredness of the record. This supports the findings of the Institute of Medicine Report 2001 which stressed the need for healthcare provision to be more patient centred as opposed to provider organisation centred (Institute of Medicine (a) 2001).

The openEHR foundation (openEHR) is an international organisation that seeks to support healthcare through the use of ICT. openEHR's definition of a personal health record is based on the International Standards Organisation (ISO) Draft Standard for Electronic Healthcare Records ISO/TR 20514 which defines an Electronic Healthcare Record for Integrated Care (ICEHR) as *"a repository of information regarding the health status of a subject of care in computer processable form, stored and transmitted securely, and accessible by multiple authorised users. It has a standardised or 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"* (International Standards Organisation 2005). Standard ISO/TR 5014 further describes a "Health Record" as *"a repository of information regarding the health of a subject of care"* (International Standards Organisation 2005). These definitions do not take into account the actual content or ownership of the record but concentrate solely on the structural function of the record i.e. a container for information. This clearly defines a personal health record in a manner that differentiates the record from the system that was used to generate it and thus introduces the concept of a health record as an independent

entity which acts as a container for patient information and how that information may be shared with other EHR systems. This may seem abstract to most, however, the importance of developing the mindset that a patient's health record is a separate entity from the systems that are used to manipulate and store patients' information is an important development to ensuring that future models of healthcare concentrate on the patient as opposed to the system(s) used to provide healthcare. This is an important distinction that differentiates EHRs and PHRs. An EHR can be viewed as a record generated and managed by the healthcare professional, whereas a PHR is owned and controlled by the patient despite the fact that the information therein may be generated by the healthcare professional providing care to the patient using a bespoke EHR system. This adoption of the Personal Health Records was supported by HIMSS at its symposium on PHRs in 2006 (Tang, Ash, Bates, Overhage & Sands 2006).

The Australian Government has mandated the National E-Health Transition Authority (NEHTA) to develop and implement Electronic Health Records for citizens called a "personally controlled electronic healthcare record" (PCEHR) based on the principal that the record *"enables the secure sharing of health information between an individual's healthcare providers, while enabling the individual to control who can access their PCEHR"* (National E-Health Transition Authority 2011).

In England and Scotland the Summary Care Record (SCR) and the Emergency Care Summary (ECS) respectively are being implemented for patients to assist in Out of Hours and Accident and Emergency department care where access to the record is controlled by the patient. No specific definition is available for these records. However, one of the predominant governing principles of the SCR and ECS is that they are generated with the patient's consent and are also accessible to the patient through the internet and healthcare professionals can only access the record with the explicit consent of the patient. The record is expected to allow patients take a greater role in the management of their own healthcare.

In Ireland the Health Information Quality Authority has defined a personal health record as 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"* (Health Information Quality Authority 2011b). However, this definition in its terseness does not explore issues of interoperability or the legal status of the record. This is probably a reflection of the fact that in Ireland the introduction of a Personal Health Record has not been fully scoped to date.

To try and bring together a single definition for a personal health record would seem to be an impossible task, due to the various emphases of different organisations on its purpose and

functionality. For example, the ownership of the record is a core attribute of the personal health record based on the Markle Foundation, Finnish Government, HIMSS and HIQA definitions whereas, the interoperability of the information with other record systems would appear to be the core attribute of a PHR based on openEHR and ISO definitions. Despite the above differences in emphasis, it is clear from all of the above definitions that it is the patient who should own and control the record. This theme of patient centredness is further discussed in Section 2.4.

As previously mentioned in Section 2.2, proprietary Personal Health Records are already in existence such as Microsoft Vault where the patient may upload their personal health information through the internet. In other cases, patients may simply have the information stored in paper format, on a USB, or other storage media. However, the usefulness of unformatted, patient generated records has been questioned as they may be prone to data error due to lack of accuracy and integrity and also may lack clinical subjectivity (Tang, Ash, Bates, Overhage & Sands 2006). This perceived lack of reliability of patient generated data may be a reflection of the medico-legal risk of healthcare professionals basing clinical decisions on data and information that may not be objective and be of questionable integrity. In 2005 the American Medical Informatics Association (AMIA) concluded that going forward PHR's will be complex records incorporating patient data, clinical data and will be integrated with Electronic Health Records systems leading to a level of complexity greater than that of a standalone, non integrated Personal Health Records such as those stored on bespoke healthcare professional's Electronic Patient Record systems (Tang, Ash, Bates, Overhage & Sands 2006).

Figure 1 is taken from the report of a symposium hosted by American Medical Informatics Association to explore ways in which Personal Health Records could be promoted. This figure illustrates the potential complexity of interoperable, interconnected PHRs compared to standalone PHRs which are PHRs that may be created using web based applications but do not connect with other systems and also compared to tethered PHRs which are based on data stored on a specific healthcare providers EHR systems that may not be connected to other systems.

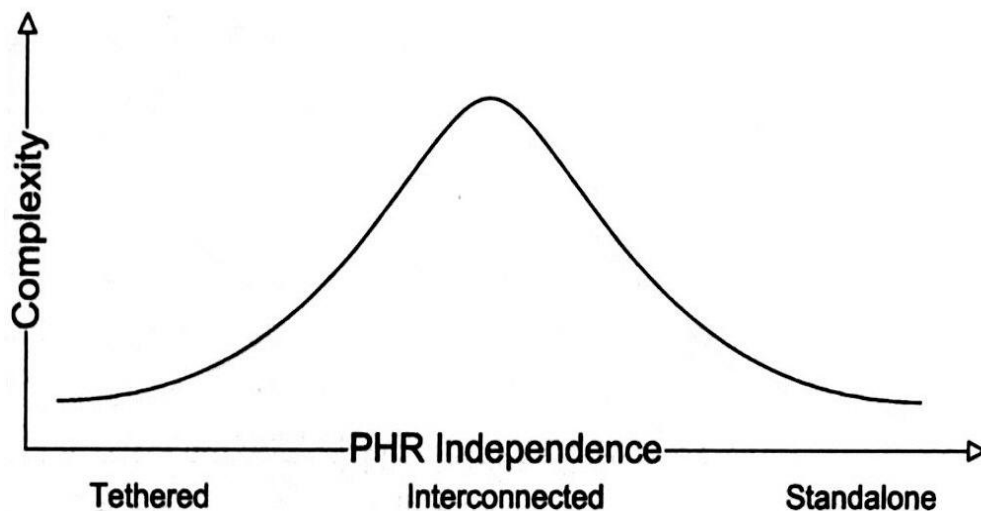


Figure 1. Complexity of approaches to PHRs (Tang, Ash, Bates, Overhage & Sands 2006)

A systematic review of the impact of eHealth technology has found large variations in the functionality, purpose, use and accessibility of Electronic Health Records including Personal Health Records, e.g. who has access, what is stored, for how long, for what purpose and who uses them (Black et al. 2011). This clearly indicates that one person's understanding of the concept of a Personal Health Record may be perceived as an electronic healthcare record by others and that there is much confusion and variation into what is the function of Personal Health Records, leading to differences in design and information to be held on the record.

However, it can be concluded that a PHR in its simplest form is a repository for patient health information that is owned and controlled by the patient. The amount of information and the length of time information is stored on the PHR appears to be subject to the scope of implementation and functionality of a particular PHR and how it will interact with existing EHR systems.

Based on the variation in the definitions and functionality of Patient Health Records, it would be imperative that prior to implementing a Personal Health Record in Ireland that would focus on the Patient Held Prescribing Record, a clear definition of the scope, purpose, functionality, ownership and access to the record should be undertaken in the first instance.

Based on the above evidence, a Personal Health Record should be developed with the following core principles;

- In Ireland, a clear definition of the scope, purpose and functionality of PHRs should be undertaken prior to implementation
- PHRs should be owned and controlled by the Patient (EHR is owned and controlled by the healthcare professional and is often dependent on EHR system)
- Information on PHRs should be generated by healthcare professionals with patient consent to optimise data integrity and objectivity
- PHRs should be interoperable with EHR systems to allow portability of data and facilitate continuity of care

As reported by Tang in 2006, there is much debate as to whether patients should have the facility to upload their own information e.g. over the counter medication. This would need to be considered in consultation with stakeholders including patients prior to implementing a Patient Held Prescribing Record.

2.4 Establishing the need for Personal Health Records

2.4.1 Patient Safety

As discussed in the introduction, significant information gaps exist in the patients' journeys through the healthcare system in many countries which may result in delays to patient treatment or medication errors. In Ireland the Department of Health and Children's National Health Information Strategy proposed a phased implementation of electronic healthcare records in Ireland where it stated *"It will include much of the data derived from operational clinical systems that are needed to support many of the information requirements of this Strategy. This includes the sharing of clinical information across multi-disciplinary care environments that transcend traditional service delivery boundaries. It has potential to support safer care delivery"* (Department of Health and Children 2004).

The Markle Foundation 2004 Report, "Connecting Americans to their Healthcare" concluded that Personal Health Records provide a tool for patients to *"bridge gaps"* between healthcare professionals who are not in contact with each other and may improve the quality, timeliness and safety of care (Markle Foundation 2004). The USA's Institute of Medicine published a report in 2006 as part of its "Quality Chasm" series entitled "Preventing Medication Errors" which estimated that over one and a half million preventable adverse drug events occur each year, which could be avoided if healthcare professionals had complete medication information for their patients (Institute

of Medicine (b) 2006). It recommends that all patients should have a single medication record that all healthcare professionals would refer to and that medication would be reconciled against this record (Institute of Medicine (b) 2006). This recommendation was followed through by the Madden Commission in Ireland in 2008 as discussed in the introduction. The Institute of Medicine further recommended that all medication should be on this record including over the counter medicines and dietary supplements. In Holland, market research carried out by the company TNS-NIPO, revealed that approximately 800,000 adults perceived that they had been subject to treatment errors due to inadequate medication information and 86% agreed that this type of error could be reduced using an electronic patient record (European Commission 2006).

An EU Commission report on Quality and Safety in Healthcare, found that EU Member States expressed the view that the use of patient summaries would reduce the impact of the fragmentation in care pathways and allow for more patient involvement in their healthcare (European Commission 2006). The stakeholder group that was consulted as part of the research for the report concluded that three use case scenarios would benefit from electronic patient summaries: firstly in the case where there is a single acute case (e.g. presentation to an Accident and Emergency Department); secondly in a normal patient case which is a routine interaction between the patient and the healthcare professional and finally in a chronic use case where a care plan for chronic disease is being implemented.

In order to find a solution to information gaps that present in the patient's journey through the care pathway in the United Kingdom, the NHS is implementing the Summary Care Record (SCR) in England and the Emergency Care Summary (ECS) in Scotland. The SCR is a centrally held Personal Health Record that is a summary of the patient's medication, allergies, adverse reactions and other health information deemed relevant by the patient's General Practitioner (GP). The information in the SCR is sourced from the GP Electronic Patient Record System. The NHS has assumed universal consent from patients in relation to the generation of the SCR, however; patients may choose to opt out of the service by giving written notification to the NHS. Healthcare Professionals providing care to patients will have access to the SCR only with the patient's consent. The NHS' main aim in introducing the SCR is to improve the safety, quality and efficiency of patient care. In relation to the benefits to the patient, the NHS believes that the record will improve patient care by enabling access to patient information by Out of Hours GP services, Emergency Departments and hospital pharmacists on patient admission. The NHS specifically states that *"SCRs will support better, safer prescribing of medication for patients by providing up to date information on a patient's allergies, previous adverse reactions and medications"* (NHS (a) 2012). In Northern Ireland and Wales, health

services are currently investigating introducing Emergency Care Records based on the Emergency Care Summary Model in Scotland.

Information deficits encountered or not known while providing care to patients have also been recognised as a problem by the Australian Government which set up NEHTA to improve the quality and efficiency of Australian health services. The main role of NEHTA is to improve the collection and safe exchange of health information between healthcare providers. NEHTA is now overseeing the implementation of a “personally controlled electronic healthcare record” (PCEHR). NEHTA has asserted that the PCEHR will result in *“access to consolidated information about an individual’s medicines, leading to safer and more effective medication management and reductions in avoidable medication-related adverse events”* (National E-Health Transition Authority 2011).

Research conducted on behalf of the European commission identified that in many European countries, one of the most important developments in eHealth in recent years has been the implementation of electronic health records at national, regional and local levels (European Commission 2006). Similarly, the Institute of Medicine in the US advised that moving from a paper to an electronic-based patient record system would be the single step that would most improve patient safety (Institute of Medicine (c) 2001).

With the increasing prominence of chronic disease in the general population (Balanda Kevin P., Barron Steve, Fahy Lorraine 2010), care is often provided by many different professionals and this may result in the patient’s information being stored in many disparate Electronic Patient Record systems or paper based systems, often at different sites. The fragmentation of information and lack of access thereof often results in less than optimal care being provided to patients and impedes patient care (Tang, Ash, Bates, Overhage & Sands 2006).

In 2009, the American Academy of Pediatrics proposed the use of electronic Personal Health Records to prevent duplication and delays in services to patients as they would be in possession of information that will facilitate clinicians in providing them with timely care be it in an emergency or routine situation within the healthcare system (AAP 2009).

Integrating the Health Enterprise (IHE) is an organisation comprised of healthcare professionals and ICT industry that promotes the sharing of healthcare information between disparate computer systems. It concludes that using data from reliable data sources such as Electronic Healthcare Records for input into the PHR *“prevents gaps in memory or detail that can be clinically relevant”* (IHE 2012).

It can therefore be concluded that there is considerable agreement among governments, non government organisations, health service providers, healthcare professionals and academic organisations that Personal Health Records have an important role to play in improving patient safety through bridging information gaps that currently exist in many healthcare scenarios allowing clinicians to have access to critical up to date information on patients in their care.

2.4.2 Knowledgeable Patients are empowered patients?

In this section, we explore the evolution of thinking in relation to how healthcare should be delivered in relation to allowing patients greater access to their health information and how this may contribute to improved healthcare delivery.

During the past decade much research and many reports have been published in relation to the principles of healthcare delivery. One core principle that has emerged is that of the need for placing the patient at the centre of the healthcare delivery model as opposed to the organisation centred nature of many healthcare systems. “To Err is Human” was a seminal report by the Institute of Medicine in 2001 which sought to investigate the principle reasons for incidents of harm being caused to patients within healthcare systems in the USA and to suggest how patient safety could be improved (Institute of Medicine (a) 2001). This report was followed up by another report by the Institute, “Crossing the Quality Chasm: A New Health System for the Twenty First Century”, which built on the recommendations on patient safety to set an agenda for change in healthcare delivery models (Institute of Medicine (c) 2001). These seminal reports recommended that the chief focus of the delivery of healthcare should be patient centred as opposed to organisation centred. The views expressed on patient centredness of healthcare delivery in these reports were also reflected in the Irish Government’s 2001 report “Primary Care: a New Direction” (Department of Health and Children (a) 2001).

The principle of patient centredness has come to be accepted by many Governments and healthcare organisations following many reports investigating incidents of patients being harmed during the healthcare process. The concept of placing the citizen at the centre of healthcare has evolved to a school of thought that the patient should be empowered with more knowledge about their healthcare and treatment. The justification for this greater availability of knowledge for the citizen has its foundation in patient safety; however; it has also been proposed that a more knowledgeable patient will have improved communication with their healthcare professionals. The Markle Foundation 2004 Report concluded that Personal Health Records can improve communication between patients and healthcare professionals (Markle Foundation 2004). In 2005, the American Medical Informatics Association proposed one of the benefits of PHRs is that they have the potential

to lower communication barriers between patients and physicians and also increases patients' knowledge about their conditions (Tang, Ash, Bates, Overhage & Sands 2006). Research into diabetes care has suggested that patients should be empowered with knowledge in order to manage their diabetes more effectively and also to communicate effectively with their healthcare professionals and that this may be achieved using Personal Health Records (Ma, Warren, Phillips & Stanek 2006). Empowerment has been defined as *"helping patients discover and develop the inherent capacity to be responsible for one's own life"* (Funnell 2004). In 2006, the EU Commission expressed the view that the use of patient summaries would allow for more patient involvement in their healthcare (European Commission 2006). Research in Germany has suggested that *"Establishing EHRs as a patient- centered approach will involve the patient more deeply in the care process as he becomes responsible for keeping and recording his own health data and for making the right data available to the right persons at the right point in time"* (Knaup, Bott, Kohl, Lovis & Garde 2007).

The Report of the Commission on Patient Safety and Quality Assurance in Ireland in 2008 proposed a vision for healthcare governance that would be based on *"Knowledgeable patients receiving safe and effective care from skilled professionals in appropriate environments with assessed outcomes"* (Madden Commission 2008) and that one of the key principles underlying this vision should be patient centredness and patient/family involvement in healthcare. The Report also recommended that *"patients should be offered full access to information relating to their care"* (Madden Commission 2008). Research conducted on behalf of the Health Information Quality Authority in 2010 indicated that 60% of people would like to be more actively involved in decisions on their healthcare (Health Information Quality Authority 2010c). In 2008 the Finnish Government outlined its concept and roadmap for implementation of electronic health services for Finnish citizens, which would be implemented *"in a citizen centred way"* (Valkeakari 2008) to include various types of information services which would be *"used to support citizen's decision-making in health -related matters as well as interaction and information flow between professionals"* (Valkeakari 2008).

In the USA, the American Academy of Pediatrics issued a policy in 2009 supporting the development and use of Personal Health Records and stated that they *"may be part of a comprehensive strategy to empower patients to understand the care they are receiving while fostering a closer collaboration with their health care team"* (AAP 2009).

In 2011, the Australian Government has proposed that through improved access to their health information, patients will be enabled to more actively participate in their healthcare (National E-Health Transition Authority 2011).

Patients in England will be able to view their own Summary Care Record on the Internet using the “Healthspace” website. The NHS asserts that the result for patients is *“giving them control over their health record and greater empowerment over their health and wellbeing. It also enables them to feel confident to travel, safe in the knowledge that they could show their SCR to a clinician if needed”*(NHS (a) 2012).

Despite the popular view that patient health records will “empower” the patient, improving their knowledge of the medical process and improving communication between patients and healthcare professionals (Tang, Ash, Bates, Overhage & Sands 2006), there appears to be little evidence that they improve clinical outcomes (Black et al. 2011). It may improve the patient’s journey through the healthcare system by better enabling them to share their health information with healthcare professionals who may not have access to it. This may indicate that patients who have their health information available when consulting healthcare professionals are less likely to suffer harm due to information deficits and thus patient safety is improved. If this is a benefit of PHRs, it is quite difficult to measure. The lack of evidence of evidence for improved health outcomes and the difficulty in measuring benefits of PHRs is explored further in section 2.6.3.

2.5 Information held in a Personal Health Record

The Markle Foundation is of the view that *“the value of the PHR is ultimately proportionate to the value of the information it holds”* (Markle Foundation 2004). It also stresses the need for a common minimum data set for PHRs in the first instance that will serve to show the usefulness of PHRs beyond that of simply being a container for information but also for the PHR being a source of clinically significant information that can be shared across the spectrum of the patient’s journey. Obviously the function for which a PHR is developed will dictate the information that will eventually be included in the record and may go beyond a common data set; for example a PHR for diabetes might contain the information recommended in the common data set and also perhaps a history of the patient’s blood glucose levels and Hb1Ac readings. The Markle Foundation recommends that the starting point for a common data set for PHRs should be the common data set for the Continuity of Care Record (CCR) which was originally developed to facilitate sharing of electronic healthcare and administrative information on patients between computer systems. The CCR is an American Society for Testing and Materials (ASTM) recognised standard-Specification for Continuity of Care Record (ASTM 2012) and has been used by Microsoft HealthVault in its implementations of Electronic Healthcare Records. The CCR is not intended as an archive of a patient’s health information but as a source of the most up to date information on the patient that will facilitate their next encounter with a healthcare professional. The CCR contains seventeen sections; however,

the standard does not dictate that all seventeen sections need to be complete for the record to be valid. The seventeen sections are outlined in Table 1 below (ASTM 2012)

Table 1 ASTM Continuity of Care Record

ASTM Continuity of Care Record- Summary of Sections	
Patient demographics	Insurance information
Advance directives	Problems/diagnoses
Allergies and alerts	Medication list (prescription and over the counter)
Immunisations	Family history
Social History	Vital signs
Results	Procedures
Encounters	Medical equipment
Health care providers	Plan of care
Functional status	

The advantage of the CCR Standard in PHRs is that it allows for both structured and coded elements and also free text which would facilitate patients in uploading their own data and information to the record.

The European Commission has conducted significant research into eHealth. In a survey of EU Member States in 2006, it was established that in EU states where either electronic or patient summaries were in existence, summaries typically contained the following information; patient history, allergies, active problems, test results, and medications. More specifically, the content of a particular national summary largely depended on the context of use and the intended purpose of the summary (European Commission 2006). The report recommended that research would be required to define the data required in relation to the proposed purpose and context of use of the specific summary. From the literature reviewed, it is apparent that there is no international consensus on what information should be held on Personal Health Records. This is largely due to the differing purposes and functionality of the various records in existence. Therefore, in an Irish context it would be important that research should be carried out to define a minimum dataset for a Patient Held Prescribing Record. In Chapter Four, the information held on Personal Health Records from the various countries studied will be outlined and in Section 5.8 issues relating to sourcing and control of information in the record are discussed.

2.6 Obstacles and Enablers to the introduction of Personal Health Records

This section examines international evidence in relation to the factors that can enable or impede the implementation of Personal Health Records. From this international evidence, the Irish context is examined and suggestions are provided as to what may be required to be put in place to enable the implementation of a Patient Held Prescribing Record in Ireland.

2.6.1 Identifiers

The implementation of any Information Technology (IT) system requires the organisation and structuring of the various data elements and information, so that it can be clearly presented to the user and also be manipulated to update the information. In an eHealth system such as a Patient Health Record System, the primary information required is that to uniquely identify the patient. Once a patient can be uniquely identified, links to their personal health information such as medication, allergies, healthcare professionals and medical conditions can be structured within the system. In Ireland there exists no legal framework to allow for the unique identification of patients, healthcare professionals or healthcare organisations that would be in compliance with Data Protection legislation to protect the privacy and confidentiality rights of patients. At the time of writing of this dissertation, the Irish Government is preparing legislation to allow for the introduction of a system of health identifiers in Ireland. The need for a system of unique identification in Ireland has been set out in the National Health Information Strategy (Department of Health and Children 2004) and the Report of the Commission on Patient Safety and Quality Assurance (Madden Commission 2008). The Health Information Quality Authority in Ireland has recognised the lack of such identifiers as a significant obstacle to the introduction of Information Technology in the Irish healthcare system (Health Information Quality Authority 2011b). These reports have stressed that such identifiers are required to enable improved quality and safety of patient care by facilitating shared care and transfer of patient information between primary and secondary care and any other healthcare setting where care is given to patients.

The introduction of such a system of identifiers will provide a legal framework to protect patient confidentiality and control access to patient's information on a need to know basis. The issue of patient consent is also another matter that requires consideration and clarification. In England, consent of the patient is assumed unless the patient specifically request to opt out of the use of a Summary Care Record (NHS Care Records Service 2012). Such requirements are being anticipated by HIQA in Ireland which is developing health information governance standards to ensure the secure and ethical use of patient information (Health Information Quality Authority 2010)

The lack of unique identifiers for patients, healthcare professionals and healthcare providers is a significant obstacle that must be overcome in order to develop a Patient Held Prescribing Record in Ireland.

2.6.2 Health Information and Interoperability Standards

A standalone Personal Health Record as previously mentioned in Section 1 can act as an information repository for patients and their healthcare professionals and may be in paper or electronic form. This record can be carried personally by the patient and shared with their healthcare professional to allow for a more successful encounter in that the healthcare professional will have the most up to date information at his/her disposal thus allowing for more informed clinical decisions which will optimise patient care. Where a PHR is stored electronically either on a smart card or on a web application, in order for the healthcare professional to gain access, the information needs to be in a format that his/her Electronic Patient Record System can view, interpret and interrogate. In other words, the PHR needs to be portable and have meaning for the user. This is the basis of interoperability which has two distinct forms which have been defined by the International Standards Organisation (ISO). Functional interoperability is defined as *“the ability of two or more systems to exchange information (so that it is human readable by the receiver)”* (International Standards Organisation 2005) and semantic interoperability which is defined as *“the ability for information shared by systems to be understood at the level of formally defined domain concepts (so that information is computer processable by the receiving system)”* (International Standards Organisation 2005).

The Healthcare Information and Management Systems Society (Health Information Management and Systems Society (b) 2005) proposed the following definition for interoperability; *“Interoperability means the ability of health information systems to work together within and across organizational boundaries in order to advance the effective delivery of healthcare for individuals and communities”* (Health Information Management and Systems Society (b) 2005). HIMSS recognised that its definition only deals with the goal and not the practical achievement of interoperability. To address this deficit, HIMSS also proposed six dimensions that would need to be considered for interoperability to be achieved. These dimensions are; uniform movement of healthcare data, uniform presentation of healthcare data, uniform safeguarding data security and integrity, uniform protection of patient confidentiality and uniform assurance of a common degree of system service quality (Health Information Management and Systems Society (b) 2005). Although all of the above factors are critical, two of the above are most relevant in the context of this dissertation, namely the uniform presentation of health care data which equates to semantic interoperability and the uniform movement of healthcare data which pertains to functional interoperability. Uniform

presentation of information requires that the information that is moved from one system to another must be equally relevant and comprehensible by users of the sending and receiving system. For example, laboratory results from one system will be presented in the same manner that will provide users at both ends the ability to interpret and analyse the data correctly and consistently. This is the basis of health information standards such as and LOINC® (Logical Observations Identifiers Names and Codes) used to uniquely identify clinical observations and laboratory data (LOINC 2012) and SNOMED Clinical Terms® (SNOMED CT) which is a set of standards that allows for the standardisation of clinical information to enable electronic exchange and interoperability of that information (IHTSDO 2009). The uniform movement of healthcare data requires that messages used to transport healthcare information will be sent and received in the same structure and that the information sent will be the information received. This transport of healthcare information from one system to another requires that a structure is used as an envelope for the message and that within a particular type of message the correct information will be held consistently in the correct place. HL7 v2.x and HL7 v3 with Clinical Document Architecture (CDA) are example of such messaging standards (HL7 2012). It has been estimated that healthcare information exchange and interoperability if fully implemented in healthcare in the USA could result in savings of \$77.8 billion per annum (Walker et al. 2005).

The EU Commission in agreement with Member States has formed the view that the introduction of patient summaries in EU states would be the most appropriate way of establishing cross border eHealth interoperability which would facilitate the movement of citizens across the EU within the healthcare context (European Commission 2006), stating that interoperability is a *“means to contribute to the goal, of seamless transfer of information between healthcare systems in order to satisfy a clinical purpose”*. As part of its recommendations to the EU Commission the eHealth working group on interoperability recommended that the Commission collaborate closely with international standard development organisations such as SNOMED CT® and HL7 to explore if existing standards for documents and terminology could be incorporated into the roadmap for achieving interoperability across EU health systems.

In 2008, the Commission on Patient Safety and Quality Assurance in Ireland stressed the critical need for health information and interoperability standards in the healthcare system in Ireland.

Recommendations 7.51 and 7.52 below outline the importance of standards

R7.51 Madden Report *“There must be a standards-based approach to HIT developments that will be led by HIQA. These standards should apply in areas such as clinical terms, coding and classification as well as messaging and electronic health record. Such standards are necessary requirements for the*

effective interoperability of HIT systems, i.e. the ability to share information that has a consistently understood meaning and interpretation wherever and by whomever it is accessed, and this approach will enable reliability, performance, security and interoperability” (Madden Commission 2008).

R7.52 Madden Report *“The health system must commit itself to the full implementation of an appropriate standards-based electronic health record, with appropriate sharing of information within and between providers so that critical information about the care of patients is available at the point of care. This should include the sharing of critical clinical information between the public and private sectors” (Madden Commission 2008).*

The concept of sharing information across healthcare professionals within and across organisations is critical to facilitating the movement of information with the patient which was discussed in Chapter 1. This concept was outlined with great clarity in a review of EHRs by the International Medical Informatics Association (IMIA) in 2007. This paper proposed that in order to achieve full semantic interoperability, standards would be required for basic data types, messages and services, system architecture, clinical terminologies and scope and functionality (Knaup, Bott, Kohl, Lovis & Garde 2007). The concept of current systems existing as islands not connected to other islands explains the current state of affairs in Ireland with disparate systems often operating in isolation.

A critical standard for a Patient Held Prescribing Record in Ireland would be a common system of identification of medicines. Pharmacy data by its nature is quite structured compared to some other health data, however; in Ireland there is currently no common system for the unique identification of medicines. Currently, EPR systems in Ireland use proprietary drug files and vocabularies. This was also the system that prevailed in the UK where the NHS introduced the dm+d system which provides for unique identification of medicines and medical devices. The dm+d system is an extension of SNOMED CT® which is an International Health Terminology Standards Development Organisation (IHTSDO) standard (NHS Connecting for Health 2012). This unique system of identification allows for interoperability between systems using disparate drug files by linking their drug names to dm+d codes. Similarly in the USA, a system called Rx Norm is used to uniquely identify medicines. This standard is maintained by the National Institutes of Health, National Library of Medicine and is also a SNOMED CT® standard (National Library of Medicine 2012).

The Health Information Quality Authority has indicated the requirement for health information and interoperability standards in its Recommendations for Unique Health Identifiers in 2011. It stated that within the Irish context of ICT in healthcare *“Some of the recognised deficits include the lack of a system of unique identifiers for individuals, health professionals and organisations.....the legal*

impediment to the use of digital signatures in the context of eHealth applications, and the absence of a coherent set of national standards including communication and terminological systems for example, coding and terminology” (Health Information Quality Authority 2011b). At the time of writing of this dissertation, HIQA had completed a consultation on *“developing National eHealth Interoperability Standards for Ireland”* (Health Information Quality Authority 2011a) and has investigated the use of SNOMED CT® as a clinical terminology standard as it supports full semantic interoperability, in relation to messaging standards it would appear that the most common standard currently in use in Ireland is HL7 v2.x. In Ireland, HIQA has published a General Practice Messaging Standard based on HL7 standards to facilitate two way communication between hospital and general practice systems (Health Information Quality Authority 2010a). Whatever standards are to be used in Ireland is outside the scope of this dissertation; however, for a Personal Health Record such as a Patient Held Prescribing Record to be introduced in Ireland that would facilitate the improvement of the patient’s journey through the health system, it will be imperative that eHealth interoperability standards should be introduced.

2.6.3 Realising the Benefits of eHealth

In relation to Government policy, the EU EHR IMPACT Report carried out an evaluation of EHR pilot projects in the European Union and concluded from a high level that EHR projects need to be implemented in close co-operation with users including patients and health professionals and that a national strategy should be in place setting out clear long term and short term objectives that will be backed up with patience and long term commitment. The report also concluded that there is a need for strong change management leadership and a strategy to monitor costs and benefits (Dobrev, Alexander: Jones, Tom: Kersting, Anne: Artmann, Jorg: Stroetmann, Karl: Stroetmann 2008). Given the current climate of economic austerity that prevails in most EU countries, government decisions to invest in eHealth programmes are under greater scrutiny and investment decisions require a robust business case. The development of a business case for eHealth programmes has been complicated by the lack of robust methodology to outline savings and benefits that may accrue as a result and often the savings might not be achieved for several years (KA Stroetmann, Jones & Dobrev 2006).

This lack of evidence for cost benefits arising from patient safety initiatives has also been highlighted by the Commission of Patient Safety and Quality Assurance (Madden Commission 2008). Many national ICT programmes have been subject to controversy due to significant budget overspends and lack of adherence to timelines.

A Systematic Review of the impact of eHealth strategies concluded that little evidence exists to support the arguments made in relation to improved patient outcomes and other benefits of eHealth, including the use of EHRs in all their forms (Black et al. 2011). This has been an issue that has caused much concern internationally with many countries investing substantial resources into eHealth programmes on the belief that patient outcomes will improve and that there will be an economic benefit. However; while concluding that there is little evidence for the benefits of eHealth, Black et al stress that the lack of evidence in itself is not an indicator of lack of benefits.

The perceived partial success or failure of programmes can be attributed to many factors, many of which are difficult to measure e.g. socio-technical and cultural factors. However, there is increasing evidence to suggest that the lack of evidence of benefits from eHealth programmes may be due to the difficulty in measuring output in the health sector. This has been reflected in a study by the US Congressional Budget Office which stated that *“no aspect of health ICT entails as much uncertainty as the magnitude of its potential benefits”* (OECD Health Policy Studies 2008). This lack of certainty about the benefits of ICT programmes in healthcare has led to a rethinking by Governments on investment in eHealth programmes. In recognition of this issue, the EU commissioned a report to develop a methodology to measure expected impact from eHealth programmes in the context of EHR, interoperability and ePrescribing, to include both financial and socio-technical factors (Dobrev, Alexander: Jones, Tom: Kersting, Anne: Artmann, Jorg: Stroetmann, Karl: Stroetmann 2008).

In England, the National Programme for IT (NPFIT) has been subject to much scrutiny and controversy due to perceived budget overspends and lack of progress. The NPFIT programme was a top down approach to the implementation of ICT in the NHS. Part of the rollout of the national programme was the introduction of the Summary Care Record (SCR) which is currently being rolled out in many NHS Primary Care Trusts. As part of the introduction of the SCR, a Benefits Management programme has also been introduced to ensure that *“the desired business change and outcomes of a programme are identified, defined and measured”* (NHS (a) 2012). The Benefit Management Strategy seeks to measure benefits which can result in cost savings or “non cash releasing” or “quality benefits” savings which relate to improved patient safety or satisfaction and other strategic goals such as reducing inequality within the healthcare system (Hawkins, Roberts & Devoto 2009). In 2008 the Finnish Government’s Saini Report on electronic healthcare services evaluated the results from pilot studies on the introduction of local personal electronic health care programmes using the EHR IMPACT methodology and identified many non-financial benefits (European Commission 2011). An example of such an intangible benefit was that citizens acquired and received better quality and easy to understand information about their own health and illnesses

leading to better understanding of their own health status which in turn resulted in their taking greater responsibility for their own health and also improved communication between physicians and patients (Valkeakari 2008).

In many cases investment in major eHealth projects have proven to provide financial and other benefits. However, in many cases the investment is required to be made by organisations that will not directly benefit. This is especially the case in the USA where there is a two tiered public/private mix of healthcare provision. In addition to the fact that non financial benefits may accrue directly to patients by improved access and better care, other potential benefits such as reduced adverse events and their associated financial costs may accrue to the private healthcare system as opposed to the public healthcare system which would be expected to provide the investment in eHealth (OECD Health Policy Studies 2008). Ireland currently has a two tiered system of healthcare, however; it is now national policy that a universal system of healthcare will be put in place by 2016. This may result in a greater incentive to invest in IT in healthcare where a unified system will be the sole beneficiary of that investment.

It can therefore be concluded that there needs to be more research and attention paid to the value and expected return on investment in eHealth programmes such as the implementation of a Patient Held Prescribing Record. Many methods for achieving this have been postulated such as Benefits Realisation which is used by the NHS in the UK and the EU eHealth Impact Report methodology. In any such evaluation it is important that not only financial impacts should be measured but also less tangible benefits such as patient education and empowerment, social factors such as reduction in inequality and improved healthcare professional-patient communication.

2.6.4 Stakeholder engagement

In order for a Patient Held Prescribing Record to be successfully implemented it is important that key stakeholders are involved to ensure buy-in at an early stage and also to ensure resolution of conflicts between varying centres of influence prior to roll out. Stakeholders will be from disparate groups including patient advocacy organisations, EPR system vendors and developers, healthcare professional representative organisations and regulatory bodies. Research has shown that stakeholders involvement is a key success factor to success in eHealth projects (European Commission 2011) (KA Stroetmann, Jones & Dobrev 2006). As part of its consultation on developing national eHealth interoperability standards in Ireland, HIQA has indicated it intends to set up an eHealth Standards Advisory Group made up of stakeholders (Health Information Quality Authority 2011a). In relation to patient attitudes to Personal Health Records, research has indicated a high

level of patient acceptance and satisfaction with PHRs (Tang, Ash, Bates, Overhage & Sands 2006), especially among those with chronic diseases.

2.6.5 Governance and Administrative Support for eHealth initiatives

In Ireland the establishment of HIQA has been a key enabler in advancing the integration of ICT into healthcare as it is legally charged with setting standards of care and health information standards in Ireland and monitoring these standards. However; implementation of standards is largely the responsibility of healthcare providers whether private or public. eHealth initiatives in Ireland are also largely driven by the healthcare providers who are from the public, voluntary or private sectors often to fulfil a need specific for their particular organisation. This variety of governance and funding of organisations in Irish healthcare has resulted in fragmentation of information and use of disparate EPR systems as mentioned in Chapter One. In order for national eHealth initiatives to be implemented that would benefit all patients and all healthcare providers, there needs to be an overall supporting administrative structure that would drive and implement eHealth initiatives. Such structures have been put in place in many countries e.g. Gematik (Society for Telematic Applications of the Health Card) in Germany, ASIP (Agence pour les Systèmes d'Information de santé Partagés) in France, NEHTA in Australia and the National Institute for Health and Welfare in Finland. The EU Commission's Final European Progress Report on eHealth strategies has concluded that *"Although they are not a sufficient condition for success, it seems they are a necessary ingredient"* (European Commission 2011).

2.7 Conclusion

At the outset of this review of the State of the Art, an exploration of the following key factors was outlined;

- The evolution of Personal Health Records, various definitions, purposes and functionalities
- The need for Personal Health Records and how they have become regarded as an important tool in optimising patient care from a patient safety perspective
- The current thinking that empowering patients with knowledge about their condition may improve healthcare and how Personal Health Records may be used to achieve this
- The current state of art in relation to the health information that should be included in a Personal Health Record
- An examination from an Irish context as to what are the obstacles and enablers to the introduction to Personal Health Records and how lessons can be learned from international research conducted in this area

From the research conducted, it can be concluded that there is no agreed international definition of Personal Health Records, therefore in Ireland it will be necessary to define what we mean by a Personal Health Record within the context of a Patient Held Prescribing Record, taking into account the scope, purpose and functionality of such a record. There is international agreement that PHRs should be owned and under the control of the patient and should be interoperable with EHR systems which will promote continuity of care. To optimise data integrity and accuracy, healthcare professionals should generate and update information on the PHR on the patient's behalf.

The core function of a Personal Health Record should be to improve patient safety and optimise patient care reducing delays in service provision and mitigating medication error, in particular when patients are moving from one care environment to another. There is a school of thought that also suggests that empowering the patient with knowledge of their own healthcare may improve their understanding of their illness and improve communication with their healthcare professionals. However; despite the claims for improved patient safety and empowerment, there is little evidence to support the argument that PHRs improve patient outcomes. This lack of evidence in itself is not an indication of lack of benefits. It is therefore necessary that a robust means of measurement of benefits of eHealth would be adopted in Ireland; such methods include Benefits Management Strategies as used in the NHS in England and the EU EHR Impact methodology. The information that should be held on the record will be directly related to the purpose and function of the record.

There are significant obstacles in Ireland to the introduction of a Personal Health Record, however; some work is underway which will enable its introduction. In order to gather together the obstacles and enablers for a Personal Health Record from this review of the State of the Art to a meaningful conclusion, Table 2 below outlines the main findings of this study of the State of the Art, while also outlining proposed enabling actions in an Irish context that would facilitate the implementation of a Personal Health Record in relation to patient medication.

Table 2. Proposed actions for introduction of a Patient Medication Record in Ireland

Issue	Current Status	Enabling Action
National and Administrative support structure for eHealth	Currently none in place, each sector provides its own governance and administration and technical support for eHealth	A public body should be charged to drive and implement eHealth initiatives in Ireland
Unique Identifiers for Patients, Healthcare providers and Organisations	No legal framework in Ireland	Enactment of Health Information Bill
Information Governance Standards	HIQA currently developing these standards	Requires enactment of Health Information Bill
Health Information & Interoperability Standards	GP Messaging Standard in place. Other standards being developed	Full implementation of national eHealth interoperability standards in Ireland
Benefits Management and Realisation in eHealth	No national methodology	Consider adopting Benefits Management Strategy or EHR IMPACT Methodology in Ireland
Stakeholder engagement	HIQA setting up eHealth Standards Advisory Group	Continued stakeholder engagement in eHealth initiatives
Definition and scope of a Patient Held Prescribing Record	None	Based on international evidence and national patient safety priorities, define and scope Patient Medication Record
Develop a unique medicines identification system for Ireland	Will first require national Health Information Standards	Consider SNOMED CT® or other suitable standard as the basis for a national standard

Finland is currently undertaking a bottom up development of its eHealth services which it hopes will standardise existing services and technical standards based on a national architecture for health services. The EU EHR IMPACT study conducted research into the Finnish approach to the development of its eHealth services and concluded that for all countries;

“1. Policymakers should create an enabling framework and context.

2. Development should be a never-ending story.

3. The right approach is the one that fits the specific needs and the context.

4. The right strategic goal is better healthcare, not cash.

5. Interoperability and engagement are requirements for success” (Dobrev, Alexander: Jones, Tom: Kersting, Anne: Artmann, Jorg: Stroetmann, Karl: Stroetmann 2008)

3 Chapter Three: Methodology

3.1 Introduction

This chapter outlines the methodology used to answer the research question, also outlining the reasons why a qualitative approach was used. Certain case studies were chosen to provide insight into the research question and the criteria for choosing certain cases over others is explained. As a mixture of data sources were used during the research, an explanation of how the resulting data was analysed is outlined. As with all research and methodologies, there will be limitations which are outlined to assist the reader in interpreting the research findings.

3.2 Choice of Methodology

The research question that was chosen for this dissertation was “What are the Obstacles and Enablers to implementing a Patient Held Prescribing Record in Ireland?” An Electronic Healthcare Record such as a Patient Held Prescribing Record may be judged to be a phenomenon i.e. an existence of a particular fact or situation. In order to gain an insight into the phenomenon of such a record an understanding of the phenomenon was required. As phenomena such as EHRs do not easily submit to measurement it was decided that qualitative research should be used as it allows for the research of problems that require “an exploration and understanding of a central phenomenon” (J. W. Cresswell 2002). To quote Albert Einstein

“Not everything that can be counted counts and not everything that counts can be counted”.

Ireland currently lags behind many other countries in relation to implementation of eHealth, partly due to the negative economic conditions that prevail (Health Information Quality Authority 2011a). While this may seem to put Ireland at a disadvantage it also affords it the opportunity to learn lessons from other countries that have greater penetration of eHealth within their healthcare systems. As the national implementation of a national Personal Health Record involves complex stakeholder involvement and socio-technical issues, it was felt that the case studies involving several countries would facilitate a holistic approach to reveal the complex interdependencies and issues involved in such a project/phenomenon and why certain outcomes resulted (Denscombe 2010).

Another advantage of the case study approach is that it allows for the use of multiple sources of evidence, for example literature review, interviews, Government reports and publications and grey literature which provides for a richer understanding of the phenomenon being investigated (McAuley, Pham, Tugwell & Moher 2000). The case study approach is also used by the EU Commission’s eHealth Strategies studies to examine impact of ICT investment in healthcare. In support of this approach, it has been stated that *“An advantage of case studies is the high level of specificity and details that can be achieved, enabling concrete conclusions and lessons to be*

drawn”(Dobrev, Alexander: Jones, Tom: Kersting, Anne: Artmann, Jorg: Stroetmann, Karl: Stroetmann 2008). Along with existing literature, it was decided that where possible, to also conduct semi-structured interviews with information sources in the countries being studied. Structured interviews were deemed not to be suitable as this would have restricted the questioning to a fixed list of questions some of which might not have been relevant to a particular informant. Semi-structured interviews allowed for flexibility in terms of the questions asked and in accordance with the particularities of the national system in place in the informant’s country being taken into account. This would allow for richer information and facilitate a greater understanding of the complexities involved. Ethics approval was sought and received from the School of Computer Science and Statistics, Trinity College Dublin to conduct the interviews. Where semi-structured interviews were not possible, a list of questions was sent to the information sources. Lists of the questions used are included in Appendices 1 to 4 of this dissertation.

3.3 Role of Literature Review

Having decided on the methodology of using case studies the next step was to identify and select the cases. The main themes explored during the literature review were definitions of Personal Health Records, patient safety and empowerment, information held on personal medication records and obstacles and enablers to the implementation of personal health records including, unique identifiers, interoperability standards, evaluating the impact of the record, stakeholder engagement and administrative issues. The literature review revealed that several countries had implemented or were currently attempting to implement personal medication records albeit with varying flavours thereof. Among the countries identified were England, Scotland, the Netherlands, Finland, France and Australia.

3.4 Selection criteria for case study

In order to control the scope of the research and in recognition of the limited timeframe within which the research was to be conducted it was decided to apply certain selection criteria in order to limit the number of cases and to concentrate on the cases which would be most likely to provide the most robust information and data that would be most relevant to Ireland.

Firstly, it was decided to restrict the case studies to European Union countries as Data Protection laws in EU countries emanate from the EU Directive 95/46 and follow similar core principles. Secondly, a decision needed to be made in relation to the availability of data sources and information that would be available in English. Thirdly, the availability of stakeholders who would be willing to participate in the research and would agree to be interviewed or provide information needed to be ascertained. Fourthly, consideration was given to the origin of the medication record,

i.e. was the record generated using pharmacy system dispensed prescription data or GP system prescribed data. Fifthly, it was decided to select cases that would reflect different patient consent models which would provide for a greater understanding of data protection and patient confidence issues. Finally, consideration was given to the perceived success and stage of implementation of the national record as success/failure and delays might give some insight into the obstacles and enablers for the implementation of such a record in the Irish context. Table 3 below outlines the results of the selection process.

Table 3 Selection criteria for Case study

Criteria	France	Netherlands	Scotland	England	Finland	Australia
EU country	✓	✓	✓	✓	✓	X
Availability of information in English	✓	✓	✓	✓	✓	✓
Availability of interviewees	✓	✓	✓	X	X	X
GP/Pharmacy data used to generate record	Pharmacy	Pharmacy	GP	GP	Pharmacy	GP
Consent Model	Explicit	Combined Implied/ Explicit Consent model	Combined Implied/ Explicit Consent model	Combined Implied/ Explicit Consent model	Combined Implied/ Explicit Consent model	Combined Implied/ Explicit Consent model
Successful/ Partially Successful/At Planning stage	Successful	Partially Successful	Successful	Partially Successful	At Planning stage	At Planning stage

It was decided based on the above criteria to use the Dossier Pharmaceutique in France, the EMD record in the Netherlands and the Emergency Care Summary in Scotland as the cases to be studied.

As the research progressed it came to light that the differing consent models used in the three countries may possibly have an effect on the success or otherwise of the implementation of the

record. It was therefore decided to seek the advice of the Data Protection Commission in Ireland to ascertain what would need to be done from a legal perspective in Ireland to enable the implementation of a Patient Held Prescribing Record which would be consistent with Data Protection legislation.

3.5 Data Collection

Data collection consisted of combined use of the knowledge base generated from the literature review identifying seminal reports from the Governments relating to the case studies and also EU Commission reports. A more detailed overview of the data collection technique is outlined for each case study in the next chapter. The sourcing of interviewees is also outlined in the individual cases studies and experience base by interviewing those on the ground in the countries studied. This method of data collection was also used by Barjis in exploring the history and context and complexity of the Dutch Electronic Medical Record (EMD) (Barjis 2010).

3.5.1 Interviews

At the selection stage contact had been made with key stakeholders in the countries listed in Table 3 above to ascertain the availability and willingness of stakeholders in those countries to participate in the research and agree to being interviewed. Successful responses were received from following:

- the Ordre National des Pharmaciens in France which is the state regulatory body for pharmacy in France which was legally charged with the roll out of the Dossier Pharmaceutique
- SIR Institute for Pharmacy Practice Research, Utrecht University, the Netherlands
- Principal Pharmaceutical Officer, Scottish Government
- Data Protection Commission, Ireland

Each interviewee was provided with an information sheet summarising the research proposal. Two interviews were conducted face to face, while information on the other two countries was received by email as answers to the questions outlined in Appendices 2 and 3. The face to face interviews were recorded with the interviewees' permission. The audio recordings from the face to face interviews were transcribed. Field notes were also made during and immediately subsequent to the interviews. Subsequent to the interviews, key points were clarified by email in some instances to ensure accuracy of the transcript. Original questions asked of each interviewee are included in Appendices 1 to 4.

3.6 Limitations of the Research methodology

The use of case studies has been known to give cause for scepticism in relation to how to generalise and come to conclusions from an in depth analysis of several cases (Denscombe 2010). This issue has also been raised by the EU Commission in outlining the limitations of its case study approach in assessing the socio-technical impact of ICT investment in healthcare. The EU Commission acknowledges that applying generalised findings from one case to another does raise certain questions as it is not possible to apply similar constraints in the design methodology for each case being studied (Dobrev, Alexander: Jones, Tom: Kersting, Anne: Artmann, Jorg: Stroetmann, Karl: Stroetmann 2008). Healthcare systems vary between countries (including the ones used in this research) and as a result it can be difficult to draw conclusions as to the success and failure factors attributed in one country and seek to apply them to another.

Another difficulty with the methodology in this instance is that in France, unlike the Netherlands and Scotland, there has been no independent evaluation of the Dossier Pharmaceutique. The Ordre National des Pharmaciens (ONP) has commissioned an independent evaluation of it. However, the ONP was the main implementing organisation and therefore one cannot rule out the potential for bias under these circumstances.

4 Chapter Four: Research

In this chapter, an in depth study of the summary records in use in France and Scotland is presented and an analysis is also made of the proposed EMD record in the Netherlands. The final section of this chapter explores data protection issues in relation to the implementation of a Patient Held Prescribing Record which were discussed in an interview with the Deputy Data Protection Commissioner in Ireland.

In each case study, the data collection technique used for each case is first outlined including literature sources and interviews. Data collection consisted of knowledge base from the literature and experience base from semi-structured interviews and information provided in response to questions listed in Appendices 1 to 4. This is similar to the method used by Barjis et al (Barjis 2010), consolidating the literature with the interviews and information received to provide a richer knowledge base.

In each case study that follows, a brief history of the development of the particular record being studied is given, followed by a discussion on the current state of affairs in each country and finally the views of the implementing bodies into the success or otherwise of the project is outlined where such exists.

4.1 Case Study France

4.1.1 Data collection

The main data source for this case study was an interview with the Ordre National des Pharmaciens (ONP) where the Chief Technology Officer, Vice President and Chief Policy Officer agreed to be interviewed. The Dossier Pharmaceutique (DP) has not yet been externally evaluated although this exercise is underway by the External Evaluation Committee of the ONP. A list of the questions used during the interview is included in Appendix 1.

4.1.2 Brief History of the Dossier Pharmaceutique

The DP is a professional record developed by the Ordre National des Pharmaciens in the interest of patients to ensure that pharmacists have access to information on all medication dispensed to a patient regardless of which pharmacy has dispensed the medication. It allows pharmacists to then check for drug interactions, duplication in treatment and promote continuity of care for patients (Ordre National des Pharmaciens, 2012).

The concept for the Dossier Pharmaceutique came from a 2004 law enacted by the French Parliament stating that patients should be empowered to contribute to improving their own health and to allow improved flow of patient health information between healthcare professionals and patients.

The Dossier Pharmaceutique project started in 2005 and was part of a professional initiative by the ONP which is the state body responsible for the regulation of pharmacists and pharmacies in France. Several key issues influenced the development of the DP as it was recognised that these issues were key contributors to the incidence of adverse events and/or drug interactions namely;

- Patient mobility- i.e. patients not using same pharmacy on a regular basis
- Polypharmacy: Growing number of elderly patients on large numbers of medicines
- Narrow therapeutic range of certain medicines whose use increases the risk of adverse events
- Increasing use of self medication by patients

There was recognition by the ONP of the need to gather all medication related information for a patient into a single electronic healthcare record (EHR). Article L 111-23 enacted in 2006 of the French public health code provided the legal basis for the DP and established the ONP as the body responsible for its implementation. The DP was initially set up as a community pharmacy initiative.

In relation to governance of the DP programme, the ONP implemented a clear separation between itself and the operation of the DP. A separate steering committee in the ONP and a Health IT

division which deals with investment decisions and operations was set up. External advisory, ethics and evaluation committees with input from patient organisations and other state healthcare agencies were also set up. Among the agencies involved in these external committees are the HAS (Haute Autorité de Santé, the French National Health Service), AFSSAPS (Agence Française de Sécurité Sanitaire des Produits de Santé, the French medicines and medical devices regulatory agency), ASIP (Agence des Systèmes d'Information Partagé de Santé, the French Government agency responsible for eHealth and the national EHR programme), patient organisations, Cour des Comptes (the national audit agency) and the French Parliament.

In 2006 six departments (subset of regions) in France were chosen to pilot the DP. The pilot project was divided into two stages, from May 2007 to the end of 2008 which was the initial phase for proof of concept. Once proof of concept was deemed successful, the French Data Protection Agency gave the go ahead for a national roll out in December 2008. Also in December 2008, the French Health Minister issued a decree outlining the legal basis for the information to be held on the DP, patient consent and opt out regulations and data protection issues in relation to consent for children. At the start of the project, there were no mandatory health information or interoperability standards in place in France. In order to ensure a maximum uptake by pharmacists of the DP programme, it was decided to use existing infrastructure, pharmacy management systems and drug identification systems which would also maximise pharmacy-computer vendor co-operation. As a result, messaging and drug identification standards that are used are proprietary. The drug dictionary used is called le Club Inter Pharmaceutique (CIP), a proprietary logistics file held centrally or locally on pharmacy systems. CIP also provide pharmacies with drug interaction software which checks for drug interactions and duplication in therapy.

To access public health services including pharmacy services, patients in France must be in possession of a Carte Vitale, which contains information on their unique health identifier and other demographic information. When a patient presents to a pharmacy with a prescription, they must present their Carte Vitale to the pharmacist. During the dispensing of a prescription, the pharmacy system sends a query to the DP central database to see if the patient has a DP, and where the patient has none the pharmacist can then offer to set up a DP on the patient's behalf with his/her consent. Where the patient has previously consented to the generation of a DP on their behalf, the next time they go to their usual pharmacy or another pharmacy, the Carte Vitale will prompt the pharmacy system to request data from the DP central database for all medicines dispensed in the last 4 months to the patient regardless of the pharmacies where the medicines were dispensed. The

DP will only show the fact that a particular medicine was dispensed to that particular patient on a particular date and will not identify the pharmacy.

This allows the pharmacist to check for possible drug interactions or incompatibilities for the patient of the current prescription with medicines dispensed or purchased from another pharmacy in the past four months. This would not have been possible prior to the introduction of the DP.

Interactions are logged centrally on the DP central database for analysis by the external evaluation committee. In some cases, interactions are logged for a medicine being currently prescribed with a medicine that was dispensed 4 months ago which the patient is no longer taking. The patient's DP is updated on the DP central database after each prescription has been dispensed. Under French legislation, patients may request to have their DP cancelled or request the pharmacist not to include certain medicines on their DP. Medicines purchased over the counter (OTC medicines) can also be uploaded by the pharmacist to the DP on the patient's behalf, however; this is often not possible as patients may not have their Carte Vitale with them when purchasing OTC medicines.

The ONP has indicated that four months of medicines data was decided upon as the norm as it is thought that this will provide an accurate up to date representation of the patient's current medication.

Patients do not have access to their own DP and it has been called a "professional held patient record" and therefore is not strictly speaking a personal health record. The ONP however, have said that allowing patient access to their medication data may be introduced in the future.

4.1.3 Current State of Affairs in France

The DP programme as already mentioned commenced national roll out in late 2008. To date it has cost €30 million (€5 million provided by Government), maintenance costs are €4 million equivalent to 30c per DP per annum. The project has been delivered within budget and on time. In relation to promotion of the DP, there is a limited national budget which resulted in the promotion of patient uptake of the DP being mostly undertaken by pharmacists directly talking to patients. There are 23,000 community pharmacies and 4,000 hospital pharmacies in France.

The ONP estimates that 3 million people visit a pharmacy in France every day. By January 2012, 94% of all community pharmacies in France had connected to the DP service.

Table 4 Dossier Pharmaceutique Key Statistics as of 29-1-2012

	Total	Week prior to 29-1-2012
Community Pharmacies with DP access	94%	
Number of DPs	18,462,872	
Number of DPs for patients under 20 years of age	3,654,927	
Number of DPs for patients over 60 years of age	5,856,235	
Number of active DPs	15,338,562	
Patient's refusing DP	17%	
DPs cancelled on patient request	27,128	
DPs cancelled due to 3 years inactivity	343,177	
DPs including Over the Counter Medicines	2,902,595	
DPs set up in last week		142,173
Weekly occurrence of DP information shared between pharmacies		1,469,683

Considering that the population of France based on 2011 figures was 62.6 million (Eurostat 2010), the proportion of the French population with a DP is 29.5% and approximately 1.5 million patients use their DP every week. A figure of interest is the fact that there is a 17% rate of refusal for setting up a DP which may be due to the fact that there was no significant national publicity campaign such as that undertaken in Scotland (see Section 4.3.2).

The ONP concentrated on community pharmacy initially in the introduction of the DP but it was anticipated that hospitals would eventually participate. As of 31 January 2012, only 30 of the 4,000 hospital pharmacies had connected to DP, as many hospitals had expected that ASIP should pay them to connect to the DP. A new Drug Safety law published on 29-December-2011 should accelerate hospital participation in DP programme which will be phase 2 of DP project. Phase 2 has now commenced and will initially concentrate on making available patient DP information at hospital admission or attendance at Accident and Emergency Departments. It is hoped that the use by hospitals of the DP will facilitate a reduction of adverse events due to information gaps between secondary and primary care. Due to the perceived success of DP, the National Council of Physicians is now looking at getting involved in DP programme.

In 2013, it is hoped to introduce an update to pharmacy system software to allow the pharmacist to log mitigating actions taken to prevent drug interactions and to indicate where the interaction is not relevant as the patient is longer taking one of the medicines. For this reason, statistics on drug interactions are not currently being published as it would be a misrepresentation of the actual level of drug interaction detected.

Initial research of patients shows a 91% satisfaction rating with the DP with women and people over 60 years of age showing strongest support.

The ONP sees the main benefit of the DP program as facilitating information sharing between pharmacies and thus reducing information gaps which promote patient safety. A scientific study measuring the benefits is currently being undertaken by the external evaluation committee.

The infrastructure that has been established by the DP whereby almost all pharmacies in France are now connected to a central database has allowed the ONP to add on other applications to the DP Programme. The first application that has been introduced is a batch recall service which facilitates urgent messages being sent to pharmacies in real time. Further extensions to the functionality of the DP program are planned which include;

- Addition of a patient's vaccination summary, however; this will require more than 4 months data
- Real time drug safety-drug alerts etc
- Real time monitoring of prescribing e.g. for new drugs, however, data will not be used for commercial purposes
- As opposed to national pharmacy electronic reimbursement system where data takes a considerable amount of time (3-6 months) to be consolidated, the DP database operates in real time and may be used for nationwide real time drug usage statistics
- Anti-counterfeiting

4.1.4 Success factors

The ONP have noted certain key factors which it believes have contributed to the perceived success of the DP;

- Pharmacist motivation to contribute to patient safety
- Focus on real time drug safety
- Dedicated resources and funding
- Software vendors' early commitment and the use of existing infrastructure for identification and authentication and use of existing pharmacy system and pharmacy interaction software
- Attention paid at early stage to security and data privacy, along with close co-operation with patient organisations
- Multiple Stakeholder involvement. HAS, AFSSAPS, ASIP, French Parliament, patient organisation. Cour des Comptes and the Health Ministry.

The ONP's vision for the future of the DP is to;

“Reinforce pharmacists mission on end to end drug safety, bring DP to hospitals, extend data scope to provide patients with a better service, contribute to world leading scientific studies”

4.2 Case study: the Netherlands

4.2.1 Data collection

The Netherlands has been at the forefront in the introduction of Electronic Medical Records and the Dutch Government has promoted the development of eHealth initiatives since the mid 1990's. However, many systems were developed in isolation and more recently since 2002 following the establishment of NICTIZ, the National IT Institute for Healthcare, there has been a desire to integrate the various records in existence into an interoperable national healthcare infrastructure (Barjis 2010). As the Dutch Government has been a champion of eHealth for a considerable time, there are rich sources of information on the evolution of eHealth in the Netherlands. Data sources used include the Government's report of 2006 on ICT in Dutch Healthcare (Ministry of Health Welfare and Sport 2006), eHealth Strategies review of the Dutch national eHealth Infrastructure (European Commission 2010), the Dutch White Paper of Pharmacy which is a policy document of the main pharmacy representative body in the Netherlands (Bouvy, Dessing & Duchateau 2011), and research conducted into the history of eHealth in the Netherlands (Barjis 2010). Finally information was received from the Professor of Pharmacy Practice and Research in the University of Utrecht in the Netherlands based on the questions listed in Appendix 2.

4.2.2 History of the Dutch National EHR project

In recognising the need for the accessibility by healthcare professionals to accurate and up to date information on patients that would facilitate the safe provision of healthcare, the Dutch Government in 1996 decided that the introduction of an Electronic Medical Record (EPD) was required (Barjis 2010). It was decided that the introduction of an Electronic Medication Record (EMD) and an Electronic General Practitioner's Record (WDH) would be the first steps in the realisation of a fully fledged national Electronic Healthcare Record (Ministry of Health Welfare and Sport 2006). The implementation and integration of these two records was prioritised following research that revealed up to 90,000 patients were admitted to hospital each year as a result of avoidable medication error, representing 2.5% of all hospital admissions at a cost of €300 million per year (Ministry of Health Welfare and Sport 2006). It was the intention of the Dutch Government that the initial introduction of the EMD and WDH would provide a scalable implementation of the EPD with new applications being added in time. The Dutch Government established the National IT Institute for Healthcare (NICTIZ) in 2002 as an independent agency whose role was to design and implement the architecture and health information standards for the national Electronic Healthcare Record (EPD) (Barjis 2010). In 2003, the Central Information Point for Healthcare Professionals (CIBG) was established as an executive agency within the Ministry for Health, Welfare and Sport to provide for the unique identification and authentication of healthcare providers that would be using the EPD.

All healthcare providers were issued “UZI” cards which were unique chip cards with accompanying log in and passwords which would provide authentication for healthcare professionals accessing an integrated national EHR. The Dutch national EHR infrastructure is called AORTA and comprises of several key components:

- A system of unique identifiers for citizens/patients (BSN), for healthcare professionals (UZI) and for health insurers (UZOVl).
- The National Switch Point (LSP)
- Local Care organisation information systems
- Security and Authorisation using Public Key Infrastructure (PKI)
- Messaging Standards based on HL7 version 3

(Ministry of Health Welfare and Sport 2006)

This AORTA infrastructure is intended to facilitate the electronic exchange of data from and between local systems in GP surgeries and pharmacies and will be available on a twenty four hour basis via the National Switch Point which holds a reference index of what information on a patient (using the BSN as a reference) is stored on which local system. Local systems connected to the LSP must comply with strict standards for security. When a healthcare professional requests the most recent information for a patient, the National Switch Point (LSP) identifies which local system has the most recent information for that patient (using the BSN as a reference) and will provide the requested information to the healthcare professional based on his/her level of authorisation (using the UZI as a reference). A record of the data being requested, the patient and the healthcare provider requesting the information is logged by the LSP for auditing purposes. The AORTA infrastructure uses HL7 version 3 as a messaging standard (Nictiz 2008).

The proposed Dutch national EHR can be regarded as a virtual EPR, in that the LSP collects information requested by a healthcare professional from information systems where the most up to date information has been originally generated and allows the requesting healthcare professional or requesting system to use the data locally. Thus there is no central database that acts as a repository for all patient information as the LSP and national AORTA infrastructure allows for the most recent up to date information stored on local systems to be accessed remotely. This has the advantage of there not being a requirement to constantly update information to a central database with information from local systems as the information is kept up to date and integrity is maintained at source.

4.2.3 History of Regional networks – OZIS and GP/Pharmacy System co-vendors

Prior to and in parallel with the development of the Dutch National EHR, GPs and pharmacies had been exchanging patient medication information electronically at a regional level using the OZIS network. OZIS (Open Zorg Informatie Systeem, translated to English is the Open Care Information System) is a protocol that has been used in Dutch Healthcare since 2001 (Stoop, Bal & Berg 2007).

Its introduction was aimed at allowing GPs and pharmacies to share patient medication information, allowing for checking of drug interactions with medication previously dispensed in another pharmacy or where the patient had been prescribed medication by a different GP. This was deemed especially relevant in out of hours situations where the patient's usual pharmacy or GP surgery is closed and they use another pharmacy or another GP surgery that is part of a regional rota system for Out of Hours care (Stoop, Bal & Berg 2007). There were four main stakeholders involved at the start of the OZIS programme in relation to pharmacy, the Dutch Government (which provided funding in 1998), the KNMP (the main pharmacy representative body), local healthcare organisations and the main pharmacy computer system vendors. All parties came to the table with competing internal and external interests to found the OZIS foundation which was an independent foundation which sought to find a solution to the electronic sharing of patient medication information at a regional level. OZIS uses the MEDEUR standard of messaging which is Dutch national adaptation of the United Nations EDIFACT standard for the electronic interchange of structured data between independent computerized information systems (United Nations Economic Commission for Europe 2012).

It was not possible to ascertain from the literature what information is shared between GPs and pharmacies, however; contacts made in the Netherlands revealed that the following information for the previous four months for a patient is shared using the OZIS protocol;

- Prescriber information including- name, address, UZI number, telephone number
- Patient information including- name, address, date of birth, gender, BSN, insurance number
- Drug information- name of drug, strength, amount prescribed, dose, MEDEUR code
- Contra-indications and medical intolerances

It is understood that it is hoped to expand this information to include drug indication, dose changes and reasons thereof, discontinuation of medication and reasons thereof and clinical laboratory values (e.g. renal function and electrolytes) that are of relevance to monitoring of drug therapy. The process for determination of the content of the information to be exchanged is managed by the OZIS foundation and is based on consensus being achieved between the various stakeholders involved and their respective requirements. The electronic sharing of patient information using the OZIS

protocol is governed by the Medical Treatment Act (WGBO, Wet op de Geneeskundige Behandelovereenkomst) and the Personal Data Protection Act (WBP, Wet Bescherming Persoonsgegevens) (European Commission 2010) which ensure that it is the patient's choice as to who gets to see his/her health information.

By 2006 the records of 11 million out of 16 million Dutch citizens were interchangeable between local pharmacies and GP surgeries on a regional basis (Huisman 2006). The OZIS network is not a national network but a regional network within cities and their hinterlands of a population of approximately 150,000. The OZIS network has also facilitated ePrescribing at a regional level.

4.2.4 Current State of Affairs in the Netherlands

Much of the national infrastructure required to implement the national EHR is now in place in the Netherlands. However, the project has run in to significant legal obstacles in relation to the proposed Government legislation which would make it mandatory for all healthcare professionals to use the national EHR system. In 2008 the Dutch Government enacted a law making it mandatory for use of the BSN as the patient identifier and also requiring all healthcare providers to connect to the LSP and share patient information with other providers under the Medical Treatment Act and the Personal Data Protection Act. However, while this law required healthcare providers to connect to the LSP but it did not make it mandatory for them to use the LSP for sharing patient information (European Commission 2010). The current government proposal would have made it mandatory for all healthcare professionals to use the national EHR system and to allow access to all health data relating to their patients via the LSP.

At present, the OZIS protocol complies with the 2008 legislation which ensures that it is the patient's choice as to who gets to see his/her health information. The current government proposal seeks to make mandatory that the pharmacies and GPs and all healthcare providers would use the LSP for sharing patient information as opposed to the OZIS protocol which would also require that before a healthcare professional could access a patient's record, the patient's explicit consent would be required. Despite this requirement, patient organisations raised their concerns in relation to the security of patient data and the controls that would be in place to prevent unauthorised access as local systems would now be opened up. The current legislative proposal would also require patients to explicitly opt out of the national EHR system if they did not wish their data to be available to be shared. Concerns were also raised by patient organisations in relation to the security arrangements to be put in place that would allow citizens access to their own data via the "eNIK" card (European Commission 2010). The Dutch Senate took on board the patient concerns and blocked the legislation in 2010. As a result, the further roll out of the national EHR has been stalled since that

date. Currently where a patient's GP and pharmacy use the same computer system vendor, it is possible for patients to log on to a secure website and view their current medication and request repeat prescriptions.

There also has been significant resistance from GPs and pharmacists in relation to the implementation of the national EHR. It must be borne in mind that many pharmacists and GPs have been sharing patient information at regional level for many years. While under the 2008 legislation, connection to the LSP was made mandatory, use of it was not and as a result many GPs and pharmacists continued to use the regional OZIS networks for sharing information as they were of the view that most of the requirements for sharing of patient information were achieved using the regional networks already in place and that imposing a national EHR system to replace it would be expensive, not an improvement and therefore not necessary (Barjis 2010).

Evaluation of Dutch national eHealth infrastructure would appear to be on an ad hoc basis with certain applications being evaluated in isolation from the overall national EHR programme and often audited by disparate agencies such as the Ministry of Health, Welfare and Sport, the National Health Inspectorate and the Dutch Data Protection Authority (European Commission 2010), there is no dedicated evaluation organisation in the context of the national EHR programme.

4.3 Case Study Scotland: Emergency Care Summary

4.3.1 Data Collection

The initial scoping of a Care Summary Record in Scotland began in 2002; however, the introduction of a new contract for GPs in 2004 that released GPs from 24 hour commitment to patients expedited the development of the Emergency Care Summary (ECS) which was rolled out in 2006. The Scottish Government in the last decade has published two eHealth strategy reports setting out a roadmap for the development of eHealth in Scotland. As the ECS has now been in existence for six years, much research has been conducted into its impact both from a socio-technical and economic perspective. The resulting reports were published by the Scottish Government, European Commission eHealth Strategies and NHS Scotland. Much of the data sourced in the case study that follows is from these sources. The Chief Pharmaceutical Officer to the Scottish Government also provided significant information based on questions sent (see Appendix 3) which yielded very rich data.

4.3.2 Brief History of the Emergency Care Summary

In Scotland the Emergency Care Summary was introduced as a result of the transfer in 2004 of Out of Hours services from GPs to local health boards. Prior to 2004, GPs were responsible for the 24 hour care of their patients, in 2004 a new General Medical Services contract allowed GPs to opt out of this 24 hour commitment. Out of Hours care of patients then became the responsibility of local health boards and the service is accessed by patients through the NHS24 phone service where trained nurses and physicians triage patients and if required refer them to a local Out of Hours clinic or the local Accident and Emergency department. The introduction of the ECS was primarily to facilitate the availability of information from the patient's GP system to NHS24, Out of Hours clinics and Accident and Emergency Departments (Jones, Dobrev, K. A. Stroetmann, Cameron, et al. 2008).

Initial planning for the Emergency Care Summary (ECS) began in 2002 when consultation with stakeholders was commenced and piloting began in 2004. Following successful piloting the ECS was introduced nationally in 2006 which coincided with a national publicity campaign to introduce the ECS. Leaflets were posted to all households in Scotland to familiarise patients with the ECS and to outline the consent model for patients (NHS Scotland 2006) (Jones, Dobrev, K. A. Stroetmann, Cameron & Morris 2008). The ECS is an electronic summary of patient demographic and health information including allergies and GP prescribed medications, to provide up to date information about patients for authorised healthcare professionals in situations where patients are availing of services where their GP surgery is closed, e.g. The Scottish national health call centre NHS24, Out of Hours (OOH) services and Accident and Emergency (A & E) departments. The ECS is generated by GP systems and involves the transfer twice daily of the most up to date information on patients from

the GP Practice systems to the ECS database. Thus information is generated at source and updated automatically every 12 hours to the central ECS database ensuring the most up to date information on patients is available. The following data is included in the ECS (Jones, Dobrev, K. A. Stroetmann, Cameron & Morris 2008);

- Unique health identifier (Community Health Index)
- Name and surname
- Address including postcode
- Telephone number (up to three allowed)
- GP Practice
- Allergies and adverse reactions
- Current repeat prescriptions (in last year) and acute prescriptions issued in last month

The model of consent consists of two stages. The first stage is implied consent where it is assumed by the NHS that patients have consented to their GP generating an ECS on their behalf. If patients do not wish to have an ECS they must explicitly opt out by writing to the NHS. The opt out rate as of 2008 was 0.02% (Jones et al. 2009). Secondly, at each encounter with a patient, authorised healthcare professionals must seek explicit consent from the patient to view their ECS. GPs may only include information on allergies and prescribed medication on the ECS, if they wish to include any other information; they must seek explicit consent from the patient. Patients also may view their ECS online.

The ECS database is a Microsoft SQL Server database which has associated web applications such as Active Server Pages (ASP) and Visual Basic Script which allows for interoperability with software used by the various parts of the health service where healthcare professionals are authorised to access the ECS e.g. NHS24, Accident and Emergency Departments and GP Out of Hours services (Jones et al. 2009). Data is exported from GP systems to the ECS using standard XML messaging and is viewable by NHS24, Out of Hours and A & E systems. The service can be accessed by a web service integrated within existing applications or as a standalone web application. In Scotland, the dm+d drug dictionary described in Section 2.6.2 is used to uniquely identify medication information. This is achieved by mapping local drug dictionaries that are used in GP systems to dm+d codes or by using the dm+d dictionary as the drug dictionary on the local GP system. Allergy information on patients is READ coded into the GP system prior to export to the ECS. READ codes are a UK Government standard for clinical terminology which can be cross mapped to international ICD 10 disease terminology system and SNOMED CT® (NHS (a) 2012).

The implementation of the ECS was incremental in that Out of Hours services were the first services to use it in 2006, followed by NHS24 in 2008 and A & E services which have shown a slower uptake due to the IT infrastructure within departments. Each local health board was responsible for roll out of the ECS in its area and piloting of the ECS was advised prior to full adoption in order to encourage healthcare professionals to get used to using the system. This allowed for the healthcare professionals to take ownership of local implementation projects (Jones, Dobrev, K. A. Stroetmann, Cameron & Morris 2008).

In relation to security, access to the ECS is via the NHS's N3 secure broadband, user control is based on authorisation and password and access may only be obtained with the explicit consent of the patient. Where explicit consent cannot be given, incapacitated adults and children may be covered by the principle of proxy under Scottish Law and where a proxy cannot be contacted, it is recommended that consent is not required where it is deemed in the patient's best interests. The ECS is read only and the data therein cannot be manipulated. Regular audits and reviews of access are conducted by the ECS management team to ensure only proper and authorised use is made of the ECS (Jones, Dobrev, K. A. Stroetmann, Cameron & Morris 2008).

Stakeholder involvement was achieved through consultation with representative organisations of doctors, nurses, ambulance staff and Out of Hours service staff. All of these stakeholders were given the opportunity to take on a clinical leadership role in the project. Patient groups were also involved in the consultation process and the Scottish Consumer Council organised focus groups which showed a high level of support for sharing of health information with healthcare professionals that would result in quicker and safer care (Jones, Dobrev, K. A. Stroetmann, Cameron & Morris 2008). The involvement of stakeholders at an early stage in the development of the ECS is seen to be a key contributor to its success.

Other parts of the NHS have expressed their wish to receive access to the ECS in order facilitate improved workflow and to optimise patient safety, including community pharmacies, hospital pharmacists on patient admission to hospital and the ambulance service (Jones, Dobrev, K. A. Stroetmann, Cameron & Morris 2008).

4.3.3 Current State of Affairs in Scotland

By 2008 over 98% of GP practices participated in ECS project with 98% of Scottish population having an ECS with 1.3 million ECS records having medication information stored (Jones, Dobrev, K. A. Stroetmann, Cameron & Morris 2008). Information received from the Office of the Principal Pharmaceutical Officer of the Scottish Government indicates that 99.98% of citizens have an ECS with 50% having medication information on the ECS (see Table 5 below).

An analysis of benefits of ECS estimated that 77% of benefits were non financial and 23% resulted from redeployed finance i.e. money saved that was used for efficiency gains. The main benefits however, are non financial and have been cited as increased patient safety, time saving for staff seeking information not available at point of care and mitigation of risk in patient care. It has been estimated that 40% of the overall benefits have accrued to the health service, 40% to patients and 20% to health care professionals (Jones et al. 2009). In relation to the financial benefits when measured against costs, it has been shown that increased use of the ECS resulted in increased financial benefits. In 2006, the annual financial cost of the ECS was approximately £6 million and the annual benefits were estimated at under £1m, by 2010 it has been estimated that annual cost would be under £2 million as opposed to annual benefits estimated at £6 million (Jones et al. 2009). It is estimated that cumulative benefits will outstrip cumulative costs by 2012.

Information received from the Scottish Government as part of the research has revealed that up to 80% of access to the ECS is by NHS24 and Out of Hours services with 10% of access being from Accident and Emergency Departments. This figure was not expected as it would have been expected that A & E and out of hours services would require to access the ECS more (Jones et al. 2009). A theory has been postulated that this low level of requirement of access by A & E may be an indicator of the success of the ECS as its existence allows for more effective triage of patients by NHS24 and Out of Hour's services which may have led to less referral of patients to A & E. No firm evidence exists to support this theory and this may be a topic worthy of future research. More statistics on the ECS are set out in Table 5 below;

Table 5 Key Statistics for the Emergency Care summary May 2012

Key Statistics for Scottish Emergency Care Summary May 2012	
GP Practices generating Emergency Care Summary	100%
Number of Emergency Care Summary Records	5.5 million
Percent of population opting out of ECS	0.02%
Percentage of ECS Records with medication summary	50%
Monthly access to ECS Records	220,000
Incidence of access to ECS since its introduction in 2006	>10 million
Percentage of total access by NHS24 service	55%
Percentage of total access Out of Hours Services	25%
Percentage of total access by Accident & Emergency Departments	10%
Percentage of total access by Hospital Pharmacy & others	10%

The Scottish Government has noted the success of the ECS and as part of its ongoing eHealth strategy. It hopes to build on this success by using the ECS to develop other health records such as the Key Information Summary (KIS) which will facilitate nursing and palliative care and mental health and electronic patient records for long term conditions. Information that will be added to the ECS to develop these records may include prescriptions issued by dentists, nurse prescribers and pharmacist prescribers, diagnostic test results and over the counter medication (Jones, Dobrev, K. A. Stroetmann, Cameron & Morris 2008). It is currently proposed that the KIS will consist of four sections to include diagnosis and co- morbidities, free text for GPs, guardianship and power of attorney information and living will information e.g. “do not resuscitate” requests (Barr 2012).

4.3.4 Success factors

The key factors that have contributed to the success of the ECS have been assessed using the EHR impact methodology and also by NHS Scotland. The following factors have been identified;

- Ensuring patient safety is the key driver of the ECS project
- The patient consent model ensured that a patient’s record should not be accessed without the patient’s explicit consent

- Patient education and involvement through the 2006 information campaign was critical
- Early and continued stakeholder engagement
- Robust security and auditing of access is required
- Using existing IT infrastructure is more likely to result in success e.g. Use of existing GP IT system infrastructure and facilitating interoperability between disparate systems
- Incremental implementation is more likely to mitigate risk of failure. This requires patience
- Allowing Interoperability is critical to success (Cameron 2008)

As a result of the success of the Scottish model of the Emergency Care Summary, the NHS in Wales and Northern Ireland are adopting the Scottish model for their implementation of patient care summaries.

4.4 Data Protection issues

4.4.1 Data Collection

After conducting research into the medication records that are in use in France and Scotland and proposed in the Netherlands, it became apparent that some of the critical issues contributing to the success or otherwise of the records were related to patient consent, security, and confidentiality and patient confidence issues. It was also necessary to investigate the legal and other provisions that would need to be in place in Ireland to ensure that any proposed Patient Held Prescribing Record would be consistent with Data Protection legislation. The assistance of the Data Protection Commission was sought and an interview was conducted with the Deputy Data Protection Commissioner in April 2012. The interview revealed critical issues that need consideration both from a legal perspective but also from a patient confidence perspective which are discussed in the following sections. An outline of the issues discussed is outlined in an email to the Data Protection Commission in Appendix 4.

4.4.2 Legal provisions under current legislation

Under current Data Protection legislation in Ireland there are specific provisions for the sharing of personal health data on patients for the specific purpose of “preserving the life” of the data subject. However, in relation to a record such as a Patient Held Prescribing Record that would be shared for a more broad based medical purpose as opposed to a specific life preserving situation, the legal situation is less clear. The use of such a record for a broad based purpose would ideally involve patient consent in order to be fully compliant with Data Protection legislation. Also there is no current legal provision that would allow the pre-seeding of such a Patient Held Prescribing Record database from current records held on existing GP and/or Pharmacy Practice Management Systems. In Ireland, there are also no unique health identifiers for patients, healthcare professionals and healthcare institutions. This represents an obstacle which would effectively prevent patient information being linked up into a Patient Held Prescribing Record from disparate data sources such as GP and Pharmacy Practice Systems.

Ireland has a two-tiered healthcare system with multiple providers of care in the private, public and voluntary sectors. Each healthcare provider acts as “data controller” of patient health information in their own particular organisation or sector. Under current Data Protection legislation, the data controller is the person legally responsible for the control and content of the patient data (Data Protection Commission 2003), e.g. where the healthcare is provided in the public system, the Health Service Executive is the data controller, where healthcare is provided by the voluntary sector on behalf of the public sector, the board of the voluntary body providing the healthcare is the data controller. Similarly, where care is being provided in the private setting such as a private consultant

clinic, private GP Practice or private pharmacy, the individual consultant, GP or pharmacy owner are legally the “data controllers” under Data Protection legislation. In order to process personal data which includes the sharing of data, data controllers require the explicit consent of patients. Therefore, under Irish Data Protection legislation, the sharing of personal health information between disparate healthcare providers and healthcare organisations on a general basis would be outside Data Protection Act’s specific provisions of the preservation of life and thus is not specifically provided for in current legislation. There are certain exceptions to these provisions which exist in the current healthcare system in Ireland insofar as patients with entitlements to free or partially subsidised healthcare provided by the Health Service Executive consent to the sharing of their information for administrative and financial reimbursement purposes only, however; there is no legal provision for the sharing of personal health information for any other reason.

4.4.3 Enabling legislation

The first and most critical step to enable the setting up of a Patient Held Prescribing Record would be the establishment of a system for unique health identifiers for patients, healthcare professionals and healthcare provider institutions/organisations. This has been discussed in detail in Section 2.6.1 and is further investigated in Section 5.3 of this dissertation and would allow for the unique identification of patients and their related health data that could be shared across organisations or healthcare providers. This is currently proposed in the Health Information Bill which is part of the current government’s legislative programme.

Due to the disparate nature of healthcare delivery within the Irish healthcare system and the multiplicity of data controllers, there is a need for enabling legislation that would provide for the setting up of a national Electronic Healthcare Record whose function would be the optimisation of patient safety in the provision of healthcare. Such enabling legislation may allow for the Minister for Health and Children or an agency acting on his/her behalf to act as the custodian a national Electronic Healthcare Record and also act as the data controller for the information held therein. Once such enabling legislation would have been established, it would then be possible to set up the basic infrastructure of a national Electronic Healthcare Record to include patient demographic information. Further secondary legislation could then outline the specifics in relation to the purpose and content of the record and outline the patient consent model that would be adopted.

This could then facilitate for a situation that going forward it would be possible for information in such a record to be shared for specific purposes in line with the stated purpose of the enabling legislation with the patient’s consent. The existence of a national data controller would facilitate the population of a national Electronic Healthcare Record such as a Patient Held Prescribing Record with

relevant patient health information going forward; however; the patient's explicit consent would be required to allow for retrospective information to be added to the record. This could be achieved by healthcare professionals obtaining the explicit consent of patients in interactions with patients subsequent to the establishment of the record and would be facilitated by using the patient's unique health identifier to link the different fragments of the retrospective information.

4.4.4 Patient Consent Model

The success and uptake of a national Electronic Healthcare Record would greatly depend on a robust model of patient consent being introduced. On examination of the models of consent used in France, the Netherlands and Scotland, the opinion expressed by the Data Protection Commission was that the model used in Scotland would probably be a good fit for the Irish situation as it appears to provide for a high level of patient confidence and trust based on the lower level of opt out by patients from the record when compared with the French situation. This may perhaps be due to the large scale of the national campaign undertaken in Scotland in 2006 where all households were informed by posted leaflets of the Scottish Government's intent to introduce the Emergency Care Summary, explaining its purpose and also outlining the consent model and how patients could opt out if they so wished (NHS Scotland 2006). The Scottish model assumed the patient's consent to the setting up of an Emergency Care Summary on his/her behalf. While this assumption of consent appears to have disempowered the citizen during that step, there is the argument that the national information campaign was of such a scale that the position could be held that nobody could have missed it. Also, under the Scottish model the patient is then given the opportunity to opt out of the generation of the ECS on their behalf and is then re-empowered by the fact that their explicit consent must be sought from the healthcare professional to access their ECS. The publicity campaign in France appeared to be more limited to interaction with patients at pharmacy level and this may account for a higher opt out rate and may also be due the cultural differences between different countries in relation to data protection issues.

The proposed Dutch model of consent was similar to the Scottish model, however; the manner in which the EMD was to be introduced as part of the national EHR implementation may have resulted in a loss of public confidence as opposed to the actual consent model that was proposed.

4.4.5 Security

In addition to enabling the setting up of a national EHR, primary legislation would also need to make provision for enabling mechanisms for the Minister for Health to make regulations that would also provide for the security arrangements that would legally apply to use of the EHR. Such provisions would need to include legal entitlements of healthcare professionals to access the record and under which circumstances e.g. patient consent and also provisions for where the patient may not be in a

position to provide consent. Robust logging in, authentication of access and audit also would be required to ensure that the record would only be used for means it is intended. Such a robust governance system around the record will be essential if patients are to have confidence in the security and confidentiality of their information. It would also be vital that the record should be as complete and accurate as possible to optimise patient safety. This differs from the situation that pertains in France where patients are allowed to request that certain medications do not appear on their record and this may put their safety at risk as a result. This issue is further discussed in the Research Findings chapter (Chapter 5).

In relation to the nature and scope of a national Electronic Healthcare Record that would be developed in Ireland, the view was expressed by the Data Protection Commission that starting with a summary record similar to a Patient Held Prescribing Record would be the best approach. The concept of a cradle to grave record while much vaunted over recent decades is probably unrealistic. A summary record would in the first instance provide the means to link episodes of patient care which may optimise treatment. Patients might also have concern about cradle to grave model. It was stressed that in the Irish context it would be vitally important that in implementing a national Electronic Healthcare Record, a patient centred approach would be critical and that the core function of the record would be for the benefit of patients, a view that should constantly be publically reinforced and iterated.

5 Chapter Five: The Research Findings

5.1 Introduction

The first section of this chapter outlines the method used to analyse the data and the development of themes which explore the similarities and differences between the records researched in the case studies. In the following sections, the major themes are then explored in more detail to identify obstacles and enablers that exist and how lessons may be learnt and applied in an Irish context.

5.2 Analysis of the data

The research question asked in this dissertation is “What are the Obstacles and Enablers to the implementation of a Patient Held Prescribing Record in Ireland?” Transcribed interviews, field notes and case studies were analysed and coded to identify recurring similarities in text and descriptive segments. Similar codes were then further distilled into similar groups to identify major similarities in context which were then sorted into themes (J. W. Cresswell 2002). Themes had also been identified in the literature review and while it is often argued that the literature review in itself is not part of the data collection in qualitative research, it may be used at the conclusion of a study to support or dispel some of the findings in the study (J. W. Cresswell 2002).

Based on analysis of the case studies, interviews and field notes outlined above, the author developed several themes which allowed for the collation of the various individual complexities surrounding the records studied to be brought together under several thematic headings which are outlined below:

- The need for Unique Health Identifiers
- The purpose and scope of the Record
- Patient trust and confidence issues
- Stakeholder involvement
- Ownership/main implementer of the project
- Content and source of information in the record
- Health information and interoperability standards used
- Costs and Benefits

From an initial analysis of the case studies, Table 6 below was prepared to give a broad comparative overview of the various records studied based on the themes developed.

Table 6. Comparison of Records from Case Studies

	Emergency Care Summary	Dossier Pharmaceutique	EMD
Purpose of Record	Patient Safety	Patient Safety	Patient Safety
Scope of Record	Use for out of hours care by NHS24, A & E departments and GP Out of Hours clinics	Pharmacy only	National Healthcare System
Patient access to record	Y	N	Y (proposed)
GP/Pharmacy generated	GP	Pharmacy	Pharmacy
Open interoperability standards	Y (dm+d- Snomed CT®, eXML, READ Codes)	N (Proprietary)	Y (Snomed CT® and HL7 proposed)
Hospital access	Y	Y (being implemented)	Y (proposed)
Messaging Standard used	eXML	Proprietary	HL7 proposed
Length of retrospective information stored	Last 12 months of prescribed repeat medication + last 30 days acute medication	Last 4 months of medication dispensed	Last 4 months of medication dispensed
Consent Model	Mixed model of assumed and explicit consent	Explicit patient consent	Mixed model of assumed and explicit consent
Independent Custodian Agency for Record	Y	Y	Y
Benefits Management/Impact Assessment Strategy	Y	Being developed	Multi-agency approach- no single evaluation agency
Stakeholder engagement	Y	Y	Y
Opt out rate	0.02%	17%	n/a

The sections that follow explore these themes in more detail to explore obstacles and enablers that exist within the Irish context were a similar record to be considered for implementation.

5.3 The need for Unique Health Identifiers

As discussed in the Literature Review section, there is currently no unique health identifier for individuals in the Irish healthcare system. This has been recognised by the Health Information Quality Authority as the *“the single most important deficiency in the health information infrastructure in Ireland”* (Health Information Quality Authority 2009). This deficiency has also been highlighted by the Department of Health and Children (Department of Health and Children 2004) and the Commission on Patient Safety and Quality Assurance (Madden Commission 2008).

While a Patient Held Prescribing Record should be under the control of the individual to which it pertains, it is likely that the information that will be held in such a record will be generated by healthcare professionals. It will therefore be important that there will be an audit trail of who has added information to the record and on which date, this will ensure the integrity and accuracy of the record. It will also be critical to ensure that patients will have a high level of confidence that their information will be secure and that the confidentiality of their information will be maintained; therefore a robust governance system will need to be in place that would allow for auditing of access to the record. To ensure that there will be traceability of who added information on what date and also to allow for audit of access to the record, there will also need to be a system of unique identification of healthcare professionals and the organisations where they work. The Health Information Quality Authority following public consultation published its *“Recommendations for Health Identifiers for Healthcare Practitioners and Organisations”* in 2011 (Health Information Quality Authority 2011b) which made recommendations for the identifiers to be used and the governance arrangements that would apply to their introduction and use.

At the time of writing of this dissertation, it is understood that the Department of Health is finalising the heads of the Health Information Bill which will facilitate the introduction of the unique health identifiers for individuals and unique identifiers for healthcare practitioners and organisations. The enactment of this proposed legislation will be a key enabler to the implementation of a Personal Held Prescribing Record in Ireland.

5.4 Purpose and Scope of the Record

The primary purpose of any healthcare system should be to ensure patient safety at all times. The records that exist or are proposed in the countries studied, while having similar functionality, were introduced to achieve different objectives while also facilitating patient safety as the overall goal.

As discussed in the case study in Scotland the Emergency Care Summary was introduced as a result of the transfer in 2004 of Out of Hours services from GPs to local health boards. The purpose of the ECS was to allow for the patient's up to date GP information to be made available to NHS24, Out of Hours clinics and Accident & Emergency staff. This scope of the record was strictly controlled in that only those parts of the NHS were initially allowed access based on consultation with stakeholders such as healthcare professionals and patients through engagement with the Scottish Consumer Council (Jones, Dobrev, K. A. Stroetmann, Cameron & Morris 2008). The Scottish Government has adopted a national eHealth Strategy which aims to focus on how eHealth can facilitate healthcare professionals in designing new and existing services to improve patient outcomes (Scottish Government 2011). Thus the focus is not on the technology or infrastructure themselves but on the needs of patients and how technology may assist in realising improved services and patient outcomes. Thus the ECS was an initiative designed to overcome a particular problem i.e. the availability of patient information in Out of Hours care.

The Dossier Pharmaceutique in France was introduced by the Ordre National des Pharmaciens as a patient safety initiative in response to legislation that sought to empower patients to contribute to improving their own health and to allow improved flow of patient health information between healthcare professionals and patients. The view of the ONP was that there was a need to gather all medication related information for a patient into a single electronic healthcare record to reduce the risk of incidence of adverse events that may be due to patient mobility e.g. Patients not using same pharmacy on a regular basis, the growing number of elderly patients on large numbers of medicines and the increasing use of self medication by patients. Thus the purpose of the DP was to improve patient safety and the initial scope of the record was to facilitate this improved safety where the patients engaged with different pharmacies. Again the scope of the record was strictly controlled in that only pharmacies would have access to the information where the patient had consented to the record being generated.

In the Netherlands, the Dutch Government recognised the need to improve patient safety and decided to establish a national EHR (EPD) of which the EMD (Electronic Medication Record) and the EWD (Electronic General Practitioner Record) would be the starting point. The first step towards realising a national EHR was to first put in place a national infrastructure which would then allow for

certain applications to be added on an incremental basis e.g. making the EWD available to Out of Hours Services and making the EMD available to pharmacies, hospitals and Out of Hours services (Ministry of Health Welfare and Sport 2006). However, there is no single strategy document on eHealth in the Netherlands (European Commission 2010) and therefore it is not possible to ascertain the core purpose of the EMD i.e. is it to improve patient safety in the first instance or is it part of the critical path towards the realisation of a national EHR which in itself would improve patient safety? The scope of the record therefore was much broader in that it would not only fulfil the need for sharing of patient information between healthcare professionals but it would also form a building block for a national EHR (EPD). This in itself caused much concern amongst healthcare professionals as it was felt that the Government was imposing a national system that would replace regional systems which already facilitated the sharing of patient information between healthcare professionals. This would appear to be a key contributing factor in the lack of progress in rolling out the EWD, EMD and subsequently the EPD.

It is evident from the above that the approach taken may contribute to the success or otherwise of a project. The Scottish and French approaches appear to be more bottom up in that the records were introduced and designed to respond to clearly defined specific patient needs. The ECS and DP have been successful in so far as they are now operational and fulfilling specific needs. While some may question the success of the DP due to the 17% opt out rate, the ONP nonetheless consider it to be successful, judgement on the success or otherwise has yet to be independently evaluated. The ECS and DP have also proven to be scalable and adaptable in that the original scope of both records is now being broadened and other functionalities and purposes being fulfilled by expansion of the records. Other agencies and healthcare professionals are now seeking access to the patient information in the records as they see the value of the availability of that information. For example, in Scotland the ambulance service and community pharmacies are now seeking access to the ECS to improve patient safety and the ECS Programme Board is considering extending it to incorporate nursing care and palliative care plans, hospital prescriptions, test results and vaccinations (Jones, Dobrev, K. A. Stroetmann, Cameron & Morris 2008). Similarly in France, physician representative organisations have expressed interest in having access to the DP and the ONP has already added a batch recall service to the DP, it is also rolling out the DP into hospital pharmacy and is considering adding in vaccination summaries as part of the record.

The evidence from Scotland and France support the argument that in introducing a record such as a Patient Held Prescribing Record, the primary focus should be on increasing patient safety through improved sharing of patient information that pertains to a specific patient need e.g. Out of Hours

care and where patients do not necessarily use the same doctor or pharmacist through their continuum of care. Based on this approach, it would appear likely that outcomes are improved. Building on the success of the initial projects as originally scoped, it may be possible to add further scope and functionality to the record that would fulfil other specific patient needs.

This is supported by the EU EHR IMPACT study which states that *“the right approach is the one that fits the specific needs and the context”* and *“development should be a never-ending story”* (Dobrev, Alexander: Jones, Tom: Kersting, Anne: Artmann, Jorg: Stroetmann, Karl: Stroetmann 2008).

Taking into consideration the above, it will be important that in the Irish context, the purpose and scope of the record should be clearly defined prior to design and implementation.

5.5 Patient Trust and Confidence issues

5.5.1 Consent Model

In Section 4.4, the issues of patient consent, confidence and trust were discussed in relation to Data Protection Legislation and privacy issues. Research from the case studies seems to indicate that the patient consent model and governance arrangements that would be put in place are critical to the success of the record. The Scottish model of consent is a two step model involving implied consent/opt out to the generation of the ECS and then patient permission being required on every occasion the ECS is accessed. The Scottish Government launched a nationwide publicity campaign to introduce the ECS with a patient information leaflet being delivered to every household in Scotland prior to the roll out of the ECS. This model would appear to be sufficiently robust to dispel any fears patients may have on the privacy and confidentiality of their records. This is evident from the low level of opt out from the ECS in Scotland which is 0.02% compared to 17% in France. In Ireland, the Health Information Quality Authority conducted a poll in 2008 which indicated that 96% of people would like the right to be informed as to who has access to their medical record (Health Information Quality Authority 2008). This is further evidence that the Scottish model of the healthcare professional requiring consent prior to viewing the ECS would be a good fit for Ireland.

Evidence from research also points to an expectation among patients that healthcare professionals were already sharing their health information. Results from focus groups in Scotland that were conducted by the Scottish Consumer Council prior to the roll out of the ECS indicated that patients had already assumed that information was being shared (Jones, Dobrev, K. A. Stroetmann, Cameron & Morris 2008). Research in the USA also shows a high level of satisfaction among patients with Personal Health Records (Tang, Ash, Bates, Overhage & Sands 2006). More interestingly, research conducted in Ireland on behalf of the Health Information Quality Authority shows that 71% of those

polled believed that health information linkage is already occurring (Health Information Quality Authority 2008).

5.5.2 Information Governance

To ensure continued public confidence in the security of their information, over and above the provisions for consent, a shared care record will require robust governance arrangements in relation to security of the data and access to the data. The view of the Data Protection Commission is that such a robust governance system should be put in place with significant criminal conviction provisions included in any regulations in relation to illegal access to the record. A trusted agency that would act as custodian of the record and data controller of the information would be required in Ireland. The establishment of a single custodian agency would also serve to overcome the problem of sharing information across the private, public and voluntary sectors as outlined in Section 4.4.3. Such an agency could be the same agency proposed as the national competence centre for eHealth as outlined in Section 5.7 below, however; such an agency should not be a healthcare provider organisation. Patients must have absolute confidence that their health information will only be use to optimise and improve the safety of their care. If this is not the case, there will likely be a large percentage of patients who would opt out of such a record. Evidence from Germany suggests that patients, GPs and data security experts were concerned about data security in relation to the proposed national eHealth card (Tuffs 2010). The co-existence of eligibility information and health information raised concern among patient groups. As previously discussed in Section 4.4.2, the HSE Primary Care Reimbursement Service collects prescription information in relation to patients that are eligible for State subvention in relation to cost of medicines. It also has a role is in determining patient eligibility for State subvention and manages the reimbursement of pharmacies and GPs for services provided. These roles have the potential to create conflict between the HSE, patients and healthcare professionals. Therefore a separate agency independent of healthcare provider organisations would be in a better position to act as custodian for patient health information.

5.6 Stakeholder Involvement

Experiences from the cases studied would indicate that early stakeholder involvement and engagement is critical. This was recognised by all three countries studied.

In France stakeholder engagement involved several external public bodies that were involved in the area of healthcare regulation, the national audit agency, the French parliament and patient organisations. As the scope of the record was quite narrow in that it would only involve sharing of

information between pharmacies, there was no requirement for involvement of GP and nursing organisations.

Similarly in Scotland the scope of the record was to facilitate sharing of patient information between GPs and Out of Hours care services which meant there was no requirement for involvement of pharmacists and other healthcare professionals other than GPs and nurses. In Scotland the ECS Programme board was of the view that all patients in Scotland should also be considered stakeholders i.e. 5.1 million people. In order to engage with such a large body, focus groups were arranged under the aegis of the Scottish Consumer Council in order to independently ascertain patient views to the sharing of their health information. Stakeholder engagement in Scotland would seem to have been very effective and involved continuous engagement from the project design stage to final implementation. For example, local health boards were allowed to roll out the ECS at their own pace so that the users of the record could be part of the implementation process and therefore take greater ownership of the project. It has been estimated that in rolling out the ECS in Scotland, 50% of the costs were due to doctors' time in the engagement process with 10% being spent on IT (Jones, Dobrev, K. A. Stroetmann, Cameron & Morris 2008).

In the Netherlands, the scope of the record was to be much broader and therefore there was the requirement to engage with a larger group of stakeholders and which resulted in challenges in relation to how differing opinions and positions of varying stakeholders could be co-ordinated and streamlined (Barjis 2010). The project in the Netherlands involved the building blocks for the national EHR (EPD) and patients had concerns about the privacy of their data in relation to how pharmacy and GP systems would be required to share information and also in relation to the security of access to their personal health data. This had the effect of patients raising concerns in relation to the legislation that would have made it compulsory for GPs and pharmacies to use the national EHR infrastructure. Similarly, pharmacists and GPs objected to the speed of roll out of the national EHR (EPD) (Barjis 2010) and it was recognised by the eHealth Strategies Report for the EU Commission that *"At present, there seems to be a lack of clear incentives and short-term added value for key stakeholders, especially HCPs"* (European Commission 2010). As the scope of the Dutch project was so vast and the fact that the perceived purpose of the EMD was to be part of the EPD as opposed to fulfilling a specific need for patients in relation to their engagement with pharmacy and GP services, it would appear the stakeholder engagement did not achieve its goals. The incremental approach adopted by Scotland and France would appear to allow for better outcomes.

In Ireland, HIQA has already engaged with stakeholders in relation to the development of eHealth interoperability standards that will be introduced into the health sector (Health Information Quality

Authority 2011a). Ongoing consultation and engagement with stakeholders will be necessary if eHealth programmes in Ireland are to be successful.

5.7 Ownership/main implementer of the project

A recurring theme from the research was that in order to implement an eHealth project on a national basis there is a requirement for strong change management, project management and leadership in order to achieve success. In France, the ONP worked with ASIP (Agence pour les Systèmes d'Information de santé Partagés) which is the agency responsible for eHealth in France in order to implement the DP. In the Netherlands, the Government set up NICTIZ in 2002 which is responsible for the national implementation of ICT in healthcare. In Scotland, NHS Scotland set up an independent ECS Programme Board to oversee implementation of the ECS. Such structures have also been put in place in Germany (Gematik-Society for Telematic Applications of the Health Card) in Australia (NEHTA) and in Finland (National Institute for Health and Welfare). Such organisations may be viewed as national competence centres for eHealth.

These agencies also have an executive function in relation to planning, finance, piloting and roll out of eHealth initiatives and are independent of national healthcare provider organisations. In Ireland, the Health Information Quality Authority (HIQA) may be viewed as a national competence centre in that it has a statutory role in developing information and other standards in healthcare in Ireland and also in the monitoring of compliance with those standards. However; HIQA does not have an executive function in relation to the planning and roll out of eHealth projects. In order to ensure the success of a national programme such as a Patient Held Prescribing Record that would allow involvement of the private, public and voluntary sectors where healthcare is provided, a national executive agency would be required to implement the project. This may overcome the current fragmentation that exists in relation to Electronic Patient Records in Ireland where separate organisations have EPRs, however; the information is not shareable due to each organisation taking its own approach to implementing EPR systems. As discussed in Section 2.6, the EU Commission's eHealth Strategies Final Report recommended that the existence of such an agency would be necessary to ensure success (European Commission 2011).

5.8 Content and source of information in the record

5.8.1 Information held on the record

As discussed in Section 2.5, the content of a summary care record will largely depend on its intended purpose. An analysis of the content of the records in France, Scotland and the Netherlands is set out in Table 7 below.

Table 7. Summary of Information in Records studied

Information contained in record	Emergency Care Summary	Dossier Pharmaceutique	EMD
	Scotland	France	Netherlands
Unique Health identifier	✓	✓	✓
Patient name, surname	✓	✓	✓
Patient Address	✓	✓	✓
Prescriber	?	?	✓
Allergies	✓	X	✓
Medication	✓	✓	✓
Period of Medication	Last 12 months of repeat prescriptions + last 30 days acute prescriptions	Last 4 months	Last 4 months
Interoperable Health Information	Y	N	Y

From the above table, it is evident that patient demographics and identification are in all records. Medication is also present in the French and Dutch records relating to the last four months of medicines dispensed. In Scotland, the records holds information on all active repeat prescriptions for the last year and current acute medication prescribed in the last month.

As a Patient Held Prescribing Record should be a summary record that would facilitate a safer, less delayed patient journey through the healthcare system preventing the occurrence of drug interactions, inappropriate therapy, adverse events and duplication in therapy, the record should be as accurate and complete as possible.

In Scotland the information is generated from GP Practice Systems, in France and the Netherlands, it is generated from pharmacy systems. This raises a question as to which source should be used in Ireland to generate and update the record. This will largely depend on the scope and purpose of the record. Consideration also needs to be given to the reliability of the information e.g. if a doctor prescribes a certain medication, the patient may not necessarily choose to have the prescription dispensed. Even where a prescription has been dispensed, the patient may not necessarily be taking the medication. In Scotland, only the GP can add information to the ECS by inputting information to

his/her own GP Practice Management system. Where the patient has used Out of Hours or Accident and Emergency services and has been prescribed medication, a report is sent back to the patient's GP who then must input the data into his/her Practice Management system. Thus there exists the possibility of a significant time lag before the patient's ECS is updated as there are two steps to the ECS being updated after the patient has used the Out of Hours services, i.e. the time taken for the report to be sent to the GP and the time it takes for the GP to manually update the Practice Management System. This is similar to the workflow that exists in Ireland in relation to Out of Hours care.

There may be an argument for using pharmacy dispensed medication data as opposed to prescription issuance data as patients when they are issued a prescription be it in the GP surgery, Out of Hours service or Accident and Emergency Department must visit a community pharmacy to have their prescription dispensed. They also may choose not to have the prescription dispensed. Thus a central database that would be updated using pharmacy dispensed medication data may mitigate the risk of time lags and also give a clear indication of the medication the patient is actually taking. Prior to the design and implementation of a Patient Held Prescribing Record, more research will be required to identify which will be the most accurate and up to date source for the information in the record. Another issue to be considered is where potential drug interactions/duplication of therapy is not identified at the point of prescribing. In the event of a pharmacist detecting the potential interaction, under Irish law, he/she must contact the prescriber to issue a new prescription for a safer medicine and/or cancel the prescription for the item that would possibly have caused an interaction/duplication in therapy. Where the GP/ Out of Hours prescribers are not contactable, pharmacists have the discretion not to dispense the medicine where in their view; it is in the best interests of the patient. Thus, by using GP/Out of Hours or Accident and Emergency generated data, information on the Patient Held Prescribing Record could possibly contain information that is incorrect where the required deletion or cancelled prescription has not been executed.

5.8.2 Control of information on the record

In France patients can request to redact their record, this may happen for example where the patient has been prescribed medication for a perceived embarrassing illness. There is a risk that such redaction may lead to negative outcomes and compromise patient safety as clinical decisions are being made by doctors and pharmacists based on incomplete information. The Data Protection Commission expressed concern that the record could be curated by the patient as it may compromise patient safety and suggested this could be overcome by having the security arrangements around access to the record being strictly controlled and only allowing those with

authority to use the record under similar “break the glass” provisions that would have to be put in place where patients are unconscious and their consent was not obtainable. Such access could have stricter audit provisions than would pertain to normal patient consent scenarios.

5.8.3 Patient Information systems in Ireland

The vast majority of GP and Pharmacy Practices in Ireland use Electronic Patient Information Systems. In 2010, there were 2740 GPs with contracts to provide services on behalf of the Health Service Executive (HSE Primary Care Reimbursement Service 2010) and as of 21st May 2012 there were 2671 GPs using the Healthlink service which is a web-based messaging service for the secure transmission of patient information between hospitals and GPs (Healthlink 2012). In order for a pharmacy in Ireland to have a licence from the Pharmaceutical Society of Ireland, they must have a Patient Management System and 78.6% of pharmacies in 2010 had access to the internet (Pharmaceutical Society of Ireland 2011). Thus in Ireland the vast majority of GPs and pharmacies use Patient Management Systems and are also connected to the internet. Also, GP and pharmacy systems are in many cases connected to the Government Virtual Private Network to allow for communication of financial and administrative information on patient interactions. More recently, pharmacies providing flu vaccination services now must electronically notify the HSE of patient vaccinations. Security arrangements involve Public Key Infrastructure to ensure that the data being shared is encrypted and cannot be intercepted. Thus there is an existing IT infrastructure that is a significant available resource that could be used to facilitate a Patient Held Prescribing Record.

The situation in relation to the use of Electronic Patient Information Systems in hospitals in Ireland however is not as straightforward. The Commission on Patient Safety and Quality Assurance found that patient records in many areas of care are paper based and where IT systems exist, the information is collected more for financial or administrative purposes as opposed to having a clinical purpose (Madden Commission 2008). In hospitals much of the patient’s health information is held on the patient chart in paper format with the exception of radiological information. Medication is often ordered at ward level as opposed to at patient level which reflects a system that is currently organisation centred as opposed to patient centred. Prescriptions in most hospitals are written on to charts or kardexes and pharmacy orders are generated based on cumulative ward requirements. Where sufficient manpower exists, a pharmacist double checks the patient charts for possible drug interactions, duplication and potential adverse events. Similarly, on discharge, prescriptions are often manually generated from the patient chart or kardex. Thus within the Irish hospital context, the lack of suitable Electronic Patient Information Systems at both ward and pharmacy level, would appear to be an obstacle to the Patient Held Prescribing Record being updated using hospital patient information infrastructure. This in itself will limit the potential to implement medicines

reconciliation on hospital discharge as recommended by the Madden Report. In order for patients and hospitals to benefit fully from a Patient Held Prescribing Record there would need to be a reengineering of the processes used to prescribe, supply, dispense and administer medication to patients. This is an obstacle to the implementation of a Patient Held Prescribing Record.

5.9 Health Information and Interoperability Standards

For information to be shared it must be viewable by and have meaning for both the person who generates the information and for others who will access the information. The issue of health information standards and interoperability were discussed in detail in section 2.6.2. In Ireland, health information standards that facilitate interoperability have been introduced e.g. HL7 messaging standards used in GP messaging between GP practices and hospitals through the Healthlink service. The Health Information Quality Authority has concluded a consultation on the development of eHealth interoperability standards in Ireland. The introduction of such standards will also be necessary for the future introduction of ePrescribing and Electronic Transfer of Prescriptions. Thus by implementing these standards, some of the essential functionality required in implementing ePrescribing, Electronic Transfer of Prescriptions and a Patient Held Prescribing Record will have been enabled.

5.10 Costs and Benefits

5.10.1 Current situation in Ireland

As outlined in Section 2.5.3 the issue of who pays and who benefits from eHealth projects such as a Patient Held Prescribing Record is fraught with complexity. A Patient Held Prescribing Record in Ireland that would be truly patient centred would require a national roll out and buy in from all providers and payers of healthcare be they public, private or voluntary. Such an initiative would therefore require central planning and funding. In Scotland the NHS is the main payer for provision of healthcare and local health boards are the main providers of healthcare. Thus there is central funding and financial payment for healthcare and the NHS and patients are the main beneficiaries of the Emergency Care Summary. In Ireland, however; healthcare is funded publicly, privately and through health insurance and therefore the picture is less clear as to whom benefits would accrue. This was noted by the OECD where it states that in many cases the benefits (be they financial or non-financial) do not necessarily accrue to the main investor in the project with patients, healthcare providers often reaping the majority of the benefits (OECD Health Policy Studies 2008). Thus in Ireland under the current model of healthcare provision, if the State was to invest in the implementation of a Patient Held Prescribing Record, the State itself may not necessarily receive the majority of the benefits that may accrue. The current Government in Ireland is proposing to undertake major reforms to the funding of healthcare in Ireland in the coming years. The model of

funding that will be introduced will potentially have a significant impact on how future national eHealth projects such as the implementation of a Patient Held Prescribing Record will be funded. The model of funding will also be critical to who will benefit from such a project.

5.10.2 Measuring costs and benefits

In Section 2.6.3, the complexity of measuring the benefits of eHealth projects has been outlined. In order to measure the success or otherwise of a Patient Held Prescribing Record, it would be imperative that in the first instance a clear definition of the scope and purpose of the record is in place. A clear view of all stakeholder initial expectations is also critical so that a benefits management strategy can be implemented to benchmark the success or otherwise of the record against these expectations. Any benefits management strategy should also be based on evidenced based methods such as the EHR IMPACT methodology taking into account not only financial impacts but also less tangible benefits such as patient education and empowerment, social factors such as reduction in inequality and improved healthcare professional-patient communication.

It can therefore be concluded that there needs to be more research and attention paid to the value and expected return on investment in eHealth programmes such as the implementation of a Patient Held Prescribing Record. This is a complex area that is worthy of ongoing research.

5.10.3 Evidence of cost benefit analysis

In the three records studied only the Emergency Care Summary in Scotland has been evaluated in relation to the financial and non financial benefits that will accrue. The ONP in France will be commissioning an external evaluation of the Dossier Pharmaceutique, however, at the time of writing of this dissertation, the evaluation was not complete. In relation to the Netherlands, the EMD has not yet been introduced and therefore no evaluation of the record has been possible. In Scotland, extensive research has been carried out into the cost and benefits of the Emergency Care Summary.

An analysis based on the EU EHR Impact methodology of the cost and benefits of the ECS in the period from roll out of the ECS to 2010 showed that NHS Scotland paid 95% of the costs, the remaining 5% being paid by the Scottish Executive as part of the national information campaign. Over the same period it was estimated that 37% of the benefits accrued to citizens and the remainder of 74% accrued to NHS Scotland through a reduction in risk exposure (Jones, Dobrev, K. A. Stroetmann, Cameron & Morris 2008). Interestingly 77% of the benefits are non financial and 23% are financial through the redeployment of existing resources. An analysis of the cumulative net benefits (i.e. after cumulative costs have been deducted) indicates after 2012, the ECS will show a net benefit which is expected to increase with increased access by healthcare professionals. This

cumulative net benefit will occur 4 years after full implementation to NHS24, Out of Hours and A & E services and ten years after initial planning began. This is broadly in line with findings from a 2006 EU Commission Report “eHealth- Is it worth it” which studied ten eHealth projects and found that the average time for total benefits to exceed total costs to be five years (KA Stroetmann, Jones & Dobrev 2006).

It can therefore be concluded that in implementing an eHealth project such as a Patient Held Prescribing Record that there should be a realistic expectation of the timeframe required for the expected cumulative net benefits, as well as absolute clarity in relation to what exactly the benefits are.

6 Chapter Six: Conclusion

The primary objective of this research was to investigate the possibility of introducing a Personal Health Record in Ireland that would include an up to date profile of the patient's medication. This record, which for the purpose of this research has been entitled the Patient Held Prescribing Record, would be under the control of the patient in that he/she would control who has access to it. The record could potentially fill information gaps that patients and healthcare professionals currently encounter between Primary and Secondary Care and also where they are using Out of Hours Services or a pharmacy other than their usual pharmacy. The filling of these information gaps has the potential to result in less delay in the patient's journey through the healthcare system and mitigate the risk caused by such gaps in information. The research question asked was "What are the Obstacles and Enablers to the introduction of a Patient Held Prescribing Record in Ireland?"

6.1 Research Summary

Initial research indicated that some countries in Europe have attempted to introduce Personal Health Records, proprietary records have also been introduced in the USA by some health insurance companies, and in Australia the Government is also currently introducing a Personally Controlled Electronic Healthcare Record. The literature review was conducted into Personal Health Records in the context of existing records that are primarily used to carry up to date medication information. The review revealed that Personal Health Records have come to be regarded as an important tool in empowering patients to take ownership of their health information and how this can be used to optimise patient safety. Following on from the Literature Review it was decided to conduct case studies into the summary records that exist in France and Scotland and proposed in the Netherlands. The purpose of the case studies was to investigate the approach taken in those countries, why a certain approach was taken and how lessons could be learned and applied in the Irish context to the introduction of a Patient Held Prescribing Record.

6.2 Summary of findings

The following section summarises the main findings of the research also taking into account the findings from the Literature Review.

The lack of unique health identifiers for patients, healthcare professionals and healthcare provider organisations is a key obstacle to the introduction of a Patient Held Prescribing Record in Ireland. However, at the time of writing of this dissertation, the current Government is proposing to enact the Health Information Bill which will provide a legal framework for the introduction of unique health identifiers and possibly also provide the legal framework for the setting up on Electronic Health Records in Ireland.

The purpose and scope of a Patient Held Prescribing Record will need to be clearly defined prior to its introduction. Evidence from other countries indicates that the approach taken may contribute to the success or otherwise of such a project. The primary purpose of such a record should be to improve patient safety scoped to particular situation(s). Experience from Scotland and France indicates that the focus should not be on the technology or infrastructure themselves but primarily on the needs of patients and how technology may assist in realising improved services and patient outcomes. The scope of the record should initially focus on a particular problem i.e. information gaps and how the record may improve the availability of information at certain points in the healthcare system. Once rolled out successfully the record may then be expanded to fulfil other functions and provide solutions in other areas as has occurred in Scotland and France.

The Patient Held Prescribing Record should be under the control of the patient in that the patient will always have control over who may access it. A consent model similar to that which operates in Scotland may be the best approach in the Irish context, in that implied consent to generate the record will be assumed, patients will then have the option to opt out of the record. If the patient chooses not to opt out, each time a healthcare professional seeks to view the record they will need to obtain the patient's specific consent. Robust governance arrangements should be put in place to ensure that there is strict audit of access to the record, this will be essential to maintain public confidence in the security and confidentiality of their health information. A national "trust centre" that would act as the data controller for the record would be required to ensure that the record could be used across the various public, private and voluntary agencies providing healthcare in Ireland.

The national trust centre should be an agency independent of a healthcare provider or a healthcare administrative organisation, to ensure public confidence is maintained. Such organisations may in some cases determine patient eligibility for treatment or subvention and these roles may conflict

with a trusted agency role in the preservation of the confidentiality of patient information and optimising patient safety.

In order to ensure the success of a national eHealth programme such as a Patient Held Prescribing Record that would allow involvement of the private, public and voluntary sectors where healthcare is provided a national executive agency would be required to implement the project. This may overcome the current fragmentation that there is in relation to Electronic Patient Records in Ireland where separate organisations have EPRs however, the information is not shareable due to each organisation taking its own approach to implementing EPR systems. The EU Commission's eHealth Strategies Final Report recommended that such an agency may be necessary to ensure success (European Commission 2011).

Evidence from the case studies would indicate that early stakeholder involvement and engagement is critical. The incremental approach adopted by Scotland and France would appear to allow for better outcomes. In Ireland, HIQA has already engaged with stakeholders in relation to eHealth Interoperability Standards that will be introduced into the health sector. Ongoing consultation and engagement with stakeholders will be necessary if eHealth programmes in Ireland are to be successful. The approach already taken in Ireland should enable success of such programmes.

The scope and purpose of the Patient Held Prescribing Record will largely dictate the information that will be included in the record. However, to ensure continuity of care in the Irish context the following information, at a minimum should be included in the record; patient demographic details, patient unique identifier, allergies and medication information from the last four months to include date prescribed or dispensed. In the interests of their own safety, patients should not be given the option to redact or curate their own record, however; extra safeguards can be put in place to ensure that only those with the patient's consent can have access to sensitive information.

Information held on the record should conform to any health information and interoperability standards that will be introduced by the Health Information Quality Authority. This will ensure that the information on the record will be portable between disparate Electronic Patient Information Systems in the future and will allow for the scalability and adaptability of the record going forward. The Health Information Quality Authority in Ireland has commenced the process for the introduction of such standards which will be a key enabler to the introduction of a Patient Held Prescribing Record. The ability of systems to generate and interpret a Patient Held Prescribing Record may also be an important step on the road to the introduction of Electronic Prescribing and the Electronic Transfer of Prescriptions in Ireland. However, in relation to ePrescribing, significant legal obstacles

exist as digital signatures are not allowed in prescribing. This may have negative implications for implementing a system for identifying and authentication of prescribers and dispensers in the case where they would be updating a Patient Held Prescribing Record. This prohibition of digital signatures is set out in the Medicinal Products (Prescription and Control of Supply) Regulations (S.I. 540/2003) which require that a prescription *“be in ink and be signed by the person issuing it with his usual signature and be dated by him”* (Office of the Attorney General 2003). In order that a system of unique identification of healthcare professionals could be used in prescribing, dispensing and the generation of a Patient Held Prescribing Record, a review of the current prescription legislation will be required.

A Benefits Management Strategy will need to be developed to ensure that the success or otherwise of the record can be measured and benchmarked against initial expectations. Any benefits management strategy should be based on evidenced based methods such as the EHR IMPACT methodology taking into account not only financial impact but also less tangible benefits such as patient education and empowerment, social factors such as reduction in inequality and improved healthcare professional-patient communication. The expected timeframe for a return on investment would also need to be realistic. Evidence from the EU Commission studies show that it takes on average five years from the date of implementation for cumulative net benefits to outstrip cumulative costs.

6.3 Recommendations for future research

Ireland is at a crossroads in relation to the future of eHealth. The publication of the Health Information Bill and the investigation by HIQA of eHealth Interoperability Standards will be significant landmarks in Ireland’s journey to introducing eHealth. It will be imperative from a fiscal context to have a robust Benefits Management Strategy in place to ensure that eHealth projects will give the State and related organisations a return on investment, research into to how this has been achieved in other jurisdictions exists, however, the lessons learned from abroad need to be taken into account and applied into an Irish context based on the regulatory, cultural, fiscal and legal frameworks that exist in Ireland.

Prior to a Patient Held Prescribing Record being introduced in Ireland, a decision will need to be made whether to use pharmacy or GP system data to generate the record. Factors that will need to be considered might include integrity, concurrency and accuracy of the data and the ability of EPR systems to generate the data. Research should also be conducted into the various processes that occur in the Irish hospital system in relation to how patient data is generated, stored and shared. While under current circumstances a Patient Held Prescribing Record could potentially be updated

from community systems such as those that exist in pharmacies and GP practices that would allow for medication information to be provided on hospital admission, the disparity of information practices in Irish hospitals would greatly limit the availability of current patient information on hospital discharge. Therefore, under current processes, medicines reconciliation would be facilitated on hospital admission but not on hospital discharge. Medicines Reconciliation was a key recommendation of the Commission of Patient Safety and Quality Assurance in 2008.

A Patient Held Prescribing Record may facilitate the development of a future national Electronic Health Record and may provide the opportunity for the development of a national database of patients e.g. key demographic information, medicines information and allergies. Evidence from Scotland and France has shown that the record if properly implemented may prove scalable and adaptable to include other functionalities. The introduction of a unique health identifier for individuals may also allow for the linking of information held on the Patient Held Prescribing Record to other information held on patient's behalf such a laboratory and radiological information. Research into how such records may be linked up in the future would be of significant value in the path to a national Electronic Healthcare Record in Ireland.

6.4 Limitations of research findings

In addition to the limitations referred to in Section 3.6 pertaining to the research methodology used, further potential limitations may also need to be considered by the reader to the research findings. Such limitations may rest with the author's self interest as an M Sc in Health Informatics candidate in seeking to complete this dissertation. It should also be noted that the author is a pharmacist and this may exert influence on his view of the world of eHealth and how a Patient Held Prescribing Record should be implemented. It should also be noted that at the time writing of this dissertation, the author was President of the Council of the Pharmaceutical Society of Ireland which regulates the pharmacy profession in Ireland. Therefore, there may be a possibility for some bias from these other roles which the reader may wish to take into consideration.

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Appendix 1

Interview Questions for Ordre National des Pharmaciens 01-02-2012

1. What was the main motivation for the introduction of patient held records (Dossier Pharmaceutique) in France? Was it political initiative or otherwise?
2. What evidence base existed for the implementation of a patient held record (Dossier Pharmaceutique) in your country as opposed to an electronic patient record which only healthcare professionals would have access to?
3. Was a business case developed prior to implementation and if so did it include an articulation of the proposed benefits?
4. If benefits were identified prior to implementation have there been any attempts to assess whether or not they have been delivered? If so what has been the result?
5. Was the system delivered within budget and on time; if not, why?
6. How did you go about developing the implementation plan and what criteria were used? How did you go about implementation i.e. was it a big bang, was there a pilot, was it rolled out on a regional basis?
7. If you were implementing it again what if anything would you differently?
8. What information is held on the patient held record (Dossier Pharmaceutique)?
- 9.
10. What Health Information standards are applied within the record? For example for disease is it ICD10 or other, for drugs and medical devices is it SNOMED CT or other, for laboratory values is it LOINC or other?
11. What process was used to determine which information should be held on the record?
12. Is the patient held record (Dossier Pharmaceutique) designed to be interoperable across various electronic patient record systems?
13. Will the patient held record (Dossier Pharmaceutique) be part of the national Electronic Healthcare Record (EHR)?
14. If so, is there a particular system architecture standard used for the national EHR?
15. How is consent obtained from the patient to allow healthcare professionals access the record?

16. Has there been evidence of increased “patient empowerment” following the introduction of the patient held record (Dossier Pharmaceutique)?
17. How is the patient held record (Dossier Pharmaceutique) generated and updated?
18. Is the patient held record (Dossier Pharmaceutique) accessible to patients via the Internet or on the physical card or on both?
19. Is it possible for the patients to add their own information to the record?

Appendix 2

Interview Questions for the Professor of Pharmacy Practice and Research in the University of Utrecht

March 2012

1. I understand the Dutch Government's initiative to establish a national EHR has been stalled by the Dutch Senate due to Privacy concerns, is there any indication as to what those particular concerns are?
2. Had any pharmacies connected to the national EHR prior to the project being stalled in the Senate?
3. As you stated in your email that an electronic medication record with local health data exchange has been in operation for over 10 years now, is this the "OZIS network"?
4. If so is there an indication of the percentage of pharmacies and GP practices that are connected to the OZIS network?
5. Is it the Government's intention that the OZIS network will be replaced with the new national EHR and AORTA infrastructure?
6. I understand the OZIS network uses HL7 version 3 messaging standards, what drug identification standard is used? (E.g. Snomed?)
7. I read in a paper by Dr. Joseph Barjis from the Delft University of Technology that there has been much resistance over the years by pharmacists and GPs to the introduction of a national EHR incorporating the EMD and EWD. Is this resistance due to the fact that they are happy with the way things with local arrangements through the OZIS network, or are there other perhaps political issues a play here?
8. Are pharmacists generally supportive of EMD and national EHR programme?
9. In relation to the above why are they supportive/not supportive?
10. What methodology does the Dutch Government use to assess the impact of EHR programs in the Netherlands?
11. To date, has the national EHR system been delivered within budget and on time;
12. If not, what are the main reasons for the over spend, delay?
13. Is there a definitive standard for what information will be held on the EMD and if so what process was used to determine what information should be included?

14. What information is currently exchanged between pharmacies and between pharmacies and GP practices using the OZIS network?
15. I understand that under the national EHR programme, patients will be able to view their EMD record online; can they do this currently through the OZIS network?
16. How is consent obtained from the patient to allow healthcare professionals access the record?
17. Is it possible for the patients to add their own information to the record?
18. Any other information you might think is relevant?

Appendix 3

Interview Questions for the Chief Pharmaceutical Officer to the Scottish Government

April 2012

1. What are the latest usage statistics for the ECS?
 - How many ECS's are in existence?
 - What percentage of the population has an ECS?
 - What percentage of the population that has opted out of the ECS?
 - Is there any information on reasons for opt out?
 - What percentage of ECS' contain medication information
 - What is the weekly number of accesses to the ECS database?
 - Is there information on the percentage breakdown of access by Out of Hours service, A & E departments and NHS24 access of ECS?
2. I understand eLinks is used to transport the information from GP systems to the ECS database, is this a HL 7 standard and if so which version?
3. Is the medication information on the ECS free text (as it appears on the GP system) or are dm+d used? If not are there plans to use it?
4. Is the allergies and adverse events information in free text or is it coded?
5. In relation to the early development of the ECS why was it decided to use GP system data for medication information as opposed to dispensed data from pharmacy systems?
6. In relation to authorisation for access after patient consent has been obtained, how are healthcare professionals authorised? Is this through the professional regulators, NHS or both?
7. Are hospital prescriptions included in the ECS or does the GP have to update the ECS with hospital prescriptions?
8. Out of hours services cannot update the ECS, is this correct? If so, does the GP update the ECS with Out of Hours service prescription information?
9. Are there any plans to allow for the Out of Hours services and hospitals to update the ECS after patient encounters?

10. Are there any plans to expand the ECS to include hospital discharges?

11. Does community pharmacy have access to the ECS?

12. Are there any plans to expand the range of services that has access to the ECS?

If there is any other information you might deem useful, I would be grateful for it!

Appendix 4

From: Paul Fahey [faheyp1@tcd.ie]

Sent: 04/04/2012 09:38 CET

Subject: Query relating to M Sc Health Informatics Thesis

Dear [Redacted],

My name is Paul Fahey and I am in my second year of the M Sc Health Informatics programme in TCD. I am currently doing research for my thesis which asks the questions "*What are the obstacles and enablers to the implementation of a Patient Held Prescribing Record in Ireland?*". This record would facilitate the sharing of patient information between authorised healthcare professionals in relation to prescribed medicines and patient allergies and thus improve patient safety and work flow within the healthcare system. I am looking at the current situation in Scotland, France and the Netherlands as case studies and I have attached an information document to this email which better explains the context of my research.

My supervisor is Professor Jane Grimson who has suggested it would be useful to talk to you in the context of my research. From your lecture to my class last year, I understand that the current legal position would not permit the establishment of the proposed prescribing record. Therefore, I would be grateful if I could meet with you to discuss what legal and other provisions may be required to be put in place in order to ensure that the proposed electronic prescription record would be consistent with Data Protection legislation. This would be very relevant in the context of my research question.

I am a pharmacist based in Tullamore, Co. Offaly and I could meet with you in Portllington at a time that would suit you or alternatively, I could meet with you in Dublin at another time that suits.

I can be contacted at this email address.

I look forward to hearing from you.

Paul Fahey
