

Introducing electronic health records in Ireland

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Department of Computer Science

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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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Siobhan McNally

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ABBREVIATIONS

| | |
|---------|--|
| AHIC | American Health Information Community |
| AHIC | Australian Health Information Council |
| CCHIT | Certification Commission for Healthcare Information Technology |
| CIA | Central Intelligence Agency |
| COAG | Council of Australian Governments |
| CRDB | Care Record Development Board |
| CSA | Canadian Standards Association |
| DCR | Detailed Care Record |
| DI | Digital Imaging |
| DICOM | Digital Imaging and Communications in Medicine |
| DOHC | Department of Health and Children |
| eHealth | electronic health |
| EHR | Electronic health record |
| EHRi | Electronic health record infostructure |
| EHRs | Electronic health records |
| EPR | Electronic patient record |
| EMR | Electronic medical record |
| EPS | Electronic Prescriptions Service |
| GDP | Gross domestic product |
| GP | General Practitioner |
| HHS | Department of Health and Human Services (USA) |
| HIE | Health information exchange |
| HIMSS | Healthcare Information and Management Systems Society |
| HIPAA | Health Insurance Portability and Accountability Act |
| HIQA | Health Information Quality Authority |
| HISAC | Health Information Strategy Action Committee |
| HISNZ | Health Information Strategy for New Zealand |
| HISO | Health Information Standards Organization |
| HIT | Health information technology |
| HL7 | Health Level 7 |
| HL7 CDA | Health Level 7 Clinical Document Architecture |
| HL7 RIM | Health Level 7 Reference Information Model |
| HPI | Health Practitioner Index |
| IEHR | Individual Electronic Health Record |
| ID | Identifier |
| IHI | Individual health identifiers |

| | |
|-----------|--|
| IOM | Institute of Medicine |
| ISO | International Standards Organization |
| ISO/OID | International Standards Organization object identifier |
| ICT | Information communications technology |
| IT | Information technology |
| IOM | Institute of Medicine (USA) |
| LOINC | Logical Observation Identifiers Names and Codes |
| LSP | Local service provider |
| NCVHS | National Committee on Vital and Health Statistics |
| NEHTA | National E-Health Transition Authority |
| NHI | National Health Index |
| NHIG | National Health Information Group |
| NHIN | Nationwide Health Information Network` |
| NHIMAC | National Health Information Management Advisory Council |
| NHIS | National Health Information Strategy |
| NHS | National Health Service |
| NHS CfH | National Health Service Connecting for Health |
| NHS CRS | National Health Service Care Records Service |
| NLOP | NPfIT Local Ownership Programme |
| NPfIT | National Programme for Information Technology |
| NZHIS | New Zealand Health Information Service |
| ONC | Office of the National Coordinator |
| PACS | Picture Archiving and Communications Systems |
| PAS | Privacy Authentication Security |
| PAS | Patient administration systems |
| PCSA | Privacy and security conceptual architecture |
| PDS | Personal Demographics Service |
| PHI | Personal Health Information |
| PIA | Privacy Impact Assessment |
| PKI | Public key infrastructure |
| RHIN | Regional health information network |
| RHIO | Regional Health Information Organizations |
| SEHR | Shared Electronic Health Record |
| SNOMED CT | Systematized Nomenclature of medicine clinical terminology |
| SUS | Secondary Use Service |
| UHI | Unique health care identification |
| VPN | Virtual Private Network |
| WHO | World Health Organisation |

CHAPTER 1 INTRODUCTION

1.1 Background

For each patient who receives health care, health information is recorded in a medical chart. Unfortunately, it is often the case that a patient's chart is not available, or their laboratory results have not yet been entered into a paper chart. This may be due to difficulty finding the chart or because it is being used at another location. The report by the Institute of Medicine (IOM) in USA, "Crossing the Quality Chasm" called for a redesign of the health care system with a focus on health information technology (HIT) as a key means of achieving improved patient care. The report identified safety, effectiveness, patient-centeredness, timeliness, efficiency and equity, as the main aims for improved patient care, each of which could be supported by HIT (IOM, 2001).

Many acute and primary care settings use electronic medical record (EMR) systems, which differ in functionality and features. For example, some include components for ePrescribing, while others may also include clinical decision support, such as alerts, or reminders. EMR systems involve many stakeholders, including patients, clinicians/nurses, GP's and allied health staff, as well as laboratories, radiology centers, pharmacies, dentists and others. It is recognized that the contribution of electronic management of health information can improve sharing and facilitate access to complete medical histories. This has been shown internationally through national health information strategies, which acknowledge the potential of HIT and electronic health records (EHRs) to deliver safer, better quality, more efficient health care. Health information in digital form is easier and faster to analyze than in paper format. Health information in electronic form is used by more advanced HIT applications, such as, clinical decision support. The information contained in the EHR could also provide secondary uses, such as, the analysis of national health information to assist in planning future health service delivery (AMIA, 2006).

In 2004, the National Health Information Strategy of Ireland proposed introducing EHRs. This report attempts to identify what has been done, in the countries selected for research, to progress the introduction of national EHR systems. Qualitative research of the health information strategies of the countries selected for research was undertaken to identify the main prerequisites for national EHR systems. A comparison of those prerequisites was undertaken by the author.

Based on that comparison, this report attempts to identify those actions, which could now be taken, to accelerate the planned transition from the use of paper based care records to a national electronic health record system.

1.2 Objectives of the study

- To undertake a literature review of the benefits and barriers to EHRs.
- To identify and select current national EHR projects for comparison.
- To review the published information related to those projects.
- To identify common initiatives and strategies.
- To compare and contrast criteria to reveal prerequisites and trends.
- To propose the best way forward for Ireland to introduce a national EHR system based on the outcome of this research.

1.3 Thesis Structure

Chapter 2 Electronic Health Records Overview

This chapter explains the concepts and prerequisites related to national EHR systems.

Chapter 3 Literature Review

This chapter contains the results of a literature review regarding the benefits of and barriers to EHRs.

Chapter 4 Canada

This chapter outlines the current Health Information Strategy and EHR project in Canada.

Chapter 5 United States

This chapter outlines the current Health Information Strategy and EHR project in the United States.

Chapter 6 Finland

This chapter outlines the current Health Information Strategy and EHR project in Finland.

Chapter 7 Australia

This chapter outlines the current Health Information Strategy and EHR project in Australia.

Chapter 8 New Zealand

This chapter outlines the current Health Information Strategy and EHR project in the New Zealand.

Chapter 9 England

This chapter outlines the current Health Information Strategy and EHR project in England.

Chapter 10 Ireland

This chapter reviews the current Health Information Strategy and the current developments in relation to a proposed national EHR system in Ireland.

Chapter 11 Summary of Findings

This chapter presents a summary of the findings of the research. It provides a snap shot of the common criteria, which were found, related to EHR strategies in table form.

Chapter 12 Methodology

The purpose of this chapter is to consider the research topic and to demonstrate how the most appropriate research methodology was employed during the research phase.

Chapter 13 Discussion

This chapter discusses each of the common criteria found in international EHR projects identified during the course of the research. Initiatives are compared and contrasted in the light of developments in Ireland in relation to the Health Information Strategy 2004.

Chapter 14 Conclusions

This chapter contains the recommendations related to the introduction of a national EHR system in Ireland and suggests areas for future work.

1.4 Scope

This research is concerned with health information strategies and international work towards introducing national EHR systems. It is concerned with identifying those areas and activities that could impact positively on the existing framework that has been developed for Irelands transition towards a national electronic health record system.

The focus during research was to explore EHR initiatives underway currently, and the progress made, in the countries selected for research. Research was undertaken regarding standards and interoperability, which are prerequisites to integrated EHR systems. However, the research focused on identifying those standards that are being used internationally, rather than on the technical aspects of the standards. There was difficulty finding published documents relating to the technical specifications / architectures for proposed national EHR systems. Therefore such technical specifications are not included in this report. No research was conducted regarding medicine terminologies. No interviews were conducted for this research. This has been a limiting factor because there is a limited amount of published documents relating to EHR strategies internationally.

CHAPTER 2 ELECTRONIC HEALTH RECORDS OVERVIEW

2.1 Electronic Health Records (EHRs)

Berg notes "The medical record is a tool ... it does not represent the work, but feeds into it, it structures and transforms it in complex ways: it structures the communication between healthcare personnel, shapes medical decision making, and frames relations between personnel and patients" (Berg, 1998).

Electronic health records differ from electronic health record systems. Electronic health records provide electronic access to health information and the tools, such as event summaries, which organise that information. However, unlike an EHR system, they do not facilitate the sharing of a patient's health information across the various clinics or departments that a patient may attend in one or more health locations.

For the purpose of this report the definition of the EHR system proposed by the Institute of Medicine (IOM) is used. "An EHR system includes (1) a longitudinal collection of electronic health information for and about persons, where health information is defined as information pertaining to the health of an individual or health care provided to an individual; (2) immediate electronic access to person- and population-level information by authorized, and only authorized, users; (3) provision of knowledge and decision-support that enhance the quality, safety, and efficiency of patient care; and (4) support of efficient processes for health care delivery. Critical building blocks of an EHR system are the electronic health records (EHR) maintained by providers. . .and by individuals (also called personal health records)" (IOM, 2003). An example of a process for health care delivery, which can be provided by an EHR system, is provision of result management. Result management enables access by health providers to test results, and provision of order management regarding entering, storing and access to, prescriptions, lab tests etc., to reduce duplication and improve the speed at which orders are executed.

2.2 Prerequisites for EHR systems

In order to provide the above functions of the EHR system the following prerequisites for implementing a national EHR system became apparent during research and they are outlined below:

1. Governance

Governance is defined by Health Information Strategy of New Zealand (HIS-NZ) as “the set of processes that ensure that an asset or strategy is sustained for the benefit of the group of people who value it” (Health Information Strategy Steering Committee, 2005).

2. Strategy

Designing a national EHR system requires a plan, which outlines deliverables, goals and milestones and how to accomplish them. The plan also identifies leadership, sets a time frame and has a risk management strategy.

3. Collaboration

Collaboration is needed to provide a nationally co-ordinated approach. It is essential to engage and have the input of the public, the health care providers, industry and the government regarding the implementation of a national EHR system. This is especially important because the EHR could cause many changes in relation to privacy, identity management, and how health information will be used and communicated in the future. In the area of standards, collaboration is necessary to attain consensus. In the area of implementation, collaboration is needed to learn from others experiences.

4. EHR Model

There are several national and regional EHR models, which are being piloted internationally, and these are outlined in chapters 4 to 9 and discussed in Chapter 13.

5. Funding

Implementing EHR systems will entail costs. There are costs associated with change management, user training, administration, planning, standards development for interoperability, certification, unique identification and information technology and communications development and procurement.

6. Change management

Change management refers to the management of the organisational and cultural changes that occur as a result of the transition from paper based methods of working to working electronically. According to the Interoperability Framework published by NEHTA in Australia, change management “requires a combination of initiatives (government or organisational) and individual

leadership to create a momentum for change. Such initiatives focus on ensuring the controlled and evolutionary adoption of new technologies" (NEHTA, 2007).

7. Standards

Systems, which share information between multiple users, require the use of consistent standards to provide interoperability.

a) Technical interoperability

Technical interoperability refers to the ability to capture, present and reuse information from one computer source to another computer, so that both computers can reliably understand the information. It supports the exchange of data accurately and consistently. Technical interoperability is essential for the use of decision support software. Health Level 7 (HL7) is an example of a messaging standard. It contains business requirements for sending and receiving each message. Digital Imaging and Communications in Medicine (DICOM) is an example of a standard for transferring images between computer devices.

b) Data interoperability and data quality

EHRs are large integrated systems, which have multiple users. Different users may, when entering data into the EHR, have different opinions of what goes into a data field. This could prevent collection of appropriate and accurate information. By standardizing data, interoperability is improved across computer systems (Bernstein et al, 2005). A data dictionary is a list of definitions, attributes and names of data. Its purpose is to standardise definitions and ensure consistency of use. There are many industry standard data sets which can be used to improve interoperability, such as the Electronic Medical Summary Project Core Data Set (Canada), ISO / TS 18308 and HL7 Clinical Document Architecture, release 2 (CDA R2). HL7 CDA is a standard for the representation and machine processing of clinical documents in a way that makes them both human readable and machine processable. According to Dolin et al, HL7 CDA R2 is a document mark up standard that specifies the structure and semantics of a clinic document such as a discharge summary, for the purpose of exchange. CDA documents are encoded in Extensible Markup Language (XML). They derive their meaning from the HL7 Reference Information Model (RIM) and use HL7 Version 3 data types. The RIM and V3 data types provide a powerful mechanism for enabling CDA's incorporation of concepts from standard

coding systems such as Systematized Nomenclature of Medicine Clinic Terms (SNOMED) and Logical Observation Identifiers Names and Codes (LOINC) (Dolin et al, 2005).

c) Semantic interoperability

Clinical terminologies are required to precisely represent clinical health information to record care, procedures, diagnosis, medications and treatments. They also enable the consistent retrieval and analysis of records based on meaning. Systematized Nomenclature of Medicine Clinic Terms (SNOMED CT) is a systematically organized computer processable collection of medical terminology. When a common terminology standard is used, it allows patient data across the health sector to be encoded with the same coding system, thus enabling electronic health care systems to understand each others data, which provides semantic interoperability (Bernstein et al, 2005a).

8. Information Governance, Security and Privacy

Canada Health Infoway describes information governance as " ... those matters involved in handling personal information in a secure and confidential manner and in compliance with appropriate legal, ethical and quality standards" (Canada Health Infoway, 2007). Information governance is required in relation to EHR systems, because health care providers and patients will not use the EHR unless they have confidence that the EHR is being securely maintained, is private, and the data contained is accurate, complete and up to date. Information governance is a complex area because the data being shared can often be sensitive. This is particularly important in light of the large number of people who will have access to that information. As noted by Ratajczak, "the shared EHR is access based not disclosure based" (Ratajczak, 2007).

9. Unique Identifiers

Unique identifiers are essential to the development of national EHR systems. The unique identifier acts as an anchor within the EHR system. As noted by the Canadian Institute for Health information, they enable linking the correct information across the continuum of care with the correct person. Unique patient identifiers are also needed for population research. Unique identifiers deliver benefits in planning and evaluating the health system (Canadian Institute for Health Information, 2000). Unique identifiers are also needed to

identify and authenticate health care providers, health care locations, and health care applications for accurate and secure information flow.

10. Certification

Certification is a procedure by which a third party gives written assurance that a product or service conforms to certain standards or specifications. For example, that a product meets the HL7 specifications. Anderson suggests that certification of vendors applications may help to overcome the barrier of interoperability to implementation of EHRs (Anderson, 2007).

2.3 National EHR infrastructures

National EHR systems are part of national health information infrastructures. These infrastructures enable EHRs to be securely accessed and updated by carers electronically over the network.

According to a report regarding the American national health infrastructure by the National Committee on Vital and Health Statistics in America (NCVHS, 2001), a national health infrastructure is described as "... not just technologies but more importantly values, practices, relationships, laws, standards, systems and applications that support all facets of individual health, health care and public health. It encompasses tools, such as, clinical practice guidelines, educational resources for the public and health professionals, geographic information systems, health statistics at all levels of government, and many forms of communications among users".

An EHR infrastructure includes, hardware such as PDAs and sensors and PCs; a secure and private network on the internet, such as, a virtual private network (VPN) and servers. It includes software, for example, firewalls for security and software to ensure privacy. It includes data definitions, messaging standards and a shared architecture standard, which provides a means for capturing and specifying, shared EHR content (such as discharge summaries). It includes registries to manage and provide information to uniquely identify individuals. It also encompasses repositories that manage / store data related to patient care, such as, MRI scans and laboratory results. It is encapsulated by privacy, security and confidentiality policy and legislation.

CHAPTER 3 LITERATURE REVIEW

There are many benefits that can be provided by EHRs and also several barriers to their introduction and use. A literature review was conducted by the author regarding those benefits and barriers.

3.1 Perceived benefits of electronic health records

The Agency for Health Care Research and Quality (ARHQ) noted in their summary of key findings of non financially focused studies that the benefits of information technology seem to depend greatly on the quality of the implementation and the level and type of decision-support technology (ARHQ, 2006a).

1. Improved access.

EHRs can provide improved access to a patient's health care history, which facilitates increased sharing of health information. The EHR can also reduce the problems associated with paper records, such as difficulty retrieving them and storing them, as well as, the physical difficulty of combining a lot of information in a chart which may tear under the pressure. This has been confirmed by a survey carried out among 33 third year medical students in an Outpatient Clinic the USA in 2005/06. 70% reported that essential information was easier to find in the EHR. 69% reported that the EHR improved their documentation (Rouf et al, 2008).

2. Increased time saving.

Research by Koide et al, undertaken in Tokyo, found that the main benefits of the EHR were reduced patient waiting time, and enhanced explanation to patients (Koide et al, 2006).

3. Increased potential for automating and streamlining workflow.

The EHR has the potential to provide a single source of current and previous health data from multiple sources that can be used in analysis to determine effective options. A statewide survey was carried out in Alabama by Houser et al. The survey was related to perceptions regarding EHR implementation among health information management professionals. House et al found that the key factor driving EHR implementation was to improve clinical processes or workflow efficiency (Houser et al, 2008).

4. Reduction in the numbers of people attending outpatients in hospitals.
Harno et al note that EHRs enable eConsultation. They also note that eConsultation was found to reduce hospital outpatient visits by 50% in the Department of Internal Medicine at the hospital district of Helsinki and Uusimaa (Harno, 2008).
5. Improved collaboration.
EHRs can provide improved collaboration and increased availability of results at the point of care, because they have the capability to link information from different sources within the health care setting. This benefit is of great importance today because patient health care has moved from an inpatient model of delivery to collaborative care models, where multiple carers in different locations working as multidisciplinary teams require access to up to date health care information. The Institute of Medicine (IOM) in the U.S. reports that integrated health records, both within a setting and across settings and institutions, allow for improved access to patient data at the point where clinical decisions are made (IOM, 1997).
6. Improved quality of care.
The EHR was found to decrease overused health services by enhancing access to data, providing capabilities for real-time analysis of data and acting as platforms for decision support (ARHQ, 2006). Research by Bates et al also shows that access to computer-based clinical information, such as laboratory and radiology results, can reduce redundancy and improve quality (Bates et al., 1998, 1999). However, in medical group practices in the USA, EHRs were found to be only a part of a larger set of cultural and structural variables that influence quality of patient care as well as costs of care, as noted by the Agency for Healthcare Research and Quality (ARHQ) in 2005 (ARHQ, 2005).
7. Improved analysis and planning.
Better health care planning can be achieved because the information is in digital format, making it easier to analyse and interpret, which could generate important information for statistics and future health care planning (House of Commons, 2007).
8. Improved safety

Improved safety could be achieved as a result of greater adherence to guidelines. EHRs provide the infrastructure for the use of computerized physician order entry systems (CPOE). A CPOE system is a networked computer system that allows orders for medication, laboratory tests, radiology examinations and other requests to be written electronically. Eslami et al, reviewed published studies evaluating computerized physician order entry in the inpatient setting in 2006, and found that the impact of CPOE systems was positive in relation to adherence to guidelines and that on average there seemed to be a positive effect of CPOE on safety (Elsami et al, 2008).

9. Improved safety as a result of reduced adverse events.

Bates et al found electronic medical records can be used to detect the frequency of adverse events and to develop methods to reduce the number of such events (Bates et al, 2003).

10. Improved clinical decision making.

EHR systems are at the core of national computerized health information systems. Computer diagnosis is the use of computer programs which have been designed to assist the physician in solving a diagnostic problem or making a therapeutic decision. Digital information, which is provided by EHRs, is required by computer diagnosis systems. Research by Durieux et al reveals that computer-assisted diagnosis and chronic care management programs can improve clinical decision making, and adherence to clinical guidelines (Durieux et al., 2000; Evans et al., 1998).

11. Improved laboratory information processing.

It is reported that improved health information exchange, which can be provided by electronic health records, can improve laboratory information processing. A report by Kaelber et al shows that this is particularly important in relation to helping to ensure that indicated lab tests are ordered and followed up on (Kaelber et al, 2007).

3.2 Perceived barriers to electronic health records

There are several barriers to electronic health records. A literature review was undertaken in this regard and the results are documented below.

1. The technical challenges of information exchange standards.

One of the main barriers to introducing interoperable EHRs is that the necessary standards for exchanging information have not yet been fully developed. A further barrier is that there are many standards that cover different aspects of health data exchange. The difficulty is in bringing the different standards together to achieve full interoperability and meet the requirements both technical and clinical of the stakeholders. However, standards development work is ongoing internationally. Findings by Hayrinen et al, show that an interoperable infrastructure is needed for secure movement of health information and a common understanding of what is being exchanged (Hayrinen et al, 2008).

2. The technical challenges of clinical terminology standards.

In relation to consistent clinical terminology there are many challenges regarding the interpretation of clinical data that has been integrated from diverse sources. This has been confirmed by Kalra et al (Kalra et al, 2007). Van Ginneken also reports that the lack of standardization in this area impedes exchange and sharing of medical data (Van Ginneken, 2002).

3. Policy, organizational, financial challenges.

Overhage et al found that policy, organizational, and financial challenges must be addressed to facilitate the adoption of EHR systems (Overhage et al., 2002). Linder et al carried out a cross sectional survey of primary care physicians to assess clinicians' use of EHRs during patient visits and to identify perceived barriers. They found that clinicians did not use the EHR during patient visits because of social, workflow, technical and professional barriers (Linders et al, 2007).

4. Changes to work processes.

Christensen et al studied the use of EHRs by primary care physicians. They found that the physicians use of the EHRs was efficient and comprehensive but that it resulted in a transfer of administrative work from secretaries to physicians. However, they found no indications of disturbance of the clinician-patient relationship by the use of computers in the study (Christensen et al, 2008). Linders et al also found that the most common reason for not using the EHR was loss of eye contact with the patient (Linders et al, 2007). Walsh states that clinicians need to be closely involved

in ensuring that software for documenting patient encounters complements the way that clinicians work (Walsh, 2004).

5. Funding challenges.

Simon et al surveyed ambulatory care practices in Massachusetts in 2005 to measure the use of health information technology, plans for EHR adoption, and perceived barriers to adoption. They found that inadequate funding remains an important barrier to EHR adoption in ambulatory care practices in the United States (Simon SR et al, 2008). Bates found that in the U.S.A the biggest barrier to physicians using outpatient EHRs was reimbursement (Bates, 2005). Houser et al, also found that the lack of funding and resources was a barrier to EHR implementation, in a survey carried out in Alabama (Houser et al, 2008).

6. The need for certification.

Bates also noted the number of vendors and the transience of vendors to be a further barrier to implementing EHRs (Bates, 2005). However, currently in the U.S.A. there are a number of organizations such as the Certification Commission for Healthcare Information Technology (CCHIT) which work towards certification of services related to EHRs, which may hopefully improve buyer confidence in the EHR product.

7. The perceived low user confidence in the EHR.

Low user confidence may also be a barrier to EHR use. In an article published by Abdolrasulnia et al, it is asserted that policy makers should consider strategies that would enhance the confidence of users, as well as, provide financial support in areas with high concentrations of small practices in the USA (Abdolrasulnia et al, 2008).

8. The concerns regarding EHRs in relation to privacy.

These concerns stem from the fact that in the area of health much of the information used is of a sensitive nature and because when EHRs are linked over the internet, control over access to and security of the information contained could be compromised, leaving the patient unable to be certain about who is accessing their health information. The privacy concerns regarding a system of linked EHRs were noted in a report by the NSW Ministerial Advisory Committee on Privacy and Health Information (NSW Government, 2000). The report recommended introducing safeguarding

legislation related specifically to health records and information privacy in Australia. Pyper et al carried out a survey carried of 100 patients from a randomized group and concluded that patients have strong views on what they find acceptable regarding access to EHRs. Pyper et al found that further work is needed to address the legal and ethical issues of EHRs, and to evaluate their impact on patients, health professionals and service. They also found that working with patients to develop systems is essential to their success (Pyper et al, 2004).

9. Security concerns.

As noted by HISO in New Zealand, health information today is subject to a variety of threats and vulnerabilities, because of the increased use of technology and the increased sharing of health information between multiple organisations (HISO, 2008a).

In summary, this review of the benefits and barriers to EHRs shows that there is one technical barrier to electronic health records which centers on interoperability. As will be shown in the following chapters, all the countries researched have established standards bodies. These standards bodies are working nationally and internationally to remove this barrier. The remaining barriers are people oriented and set in a complex landscape of multiple users with valid views. These views are related to security, privacy and confidentiality and are currently being carefully addressed internationally. A further barrier is that there are difficulties regarding the changes to work practices and culture that the EHRs may introduce. The review of the benefits of EHRs shows electronic management and sharing of health information can result in improvements to health care quality in the future.

3.3 Selection of countries for this report

The strategies toward the implementation of national EHR systems in six countries are reviewed in the following chapters. The following countries were selected for research.

- England was selected for research because it has chosen to implement a Summary Care Record and has made the most progress of all the countries globally having established the N3 network and it is in the process of implementing the Summary Care Record. It was also chosen for research because it is using a centralized EHR model.

- New Zealand was selected for research as it has a population of similar size to the population of Ireland and has a national health information strategy. It had also made initial progress in having already established a national system of unique identifiers.
- USA was selected because it is considered to be the most technologically advanced country in the world and has a health information strategy with a goal of introducing EHRs for every American by 2014.
- Canada was selected because it has set Canada Health Infoway the specific goal of implementing electronic health records since 2001 and has funded many initiatives in this respect. To date it has utilized over 90% of its 1.6 billion Canadian dollar budget.
- Australia was selected because it has been working towards implementing its HealthOnline health information strategy since 1999.
- Finland was chosen because a unique identifier has been implemented in Finland for more than 20 years. It also has a high rate of EHR use currently.

CHAPTER 4 CANADA

4.1 Background

Each individual province or territory within Canada is responsible for the management of its own health services. The role of the federal government in health care involves the setting and administering of national principles or standards for the health care system. The total expenditure on health as a percentage of GDP in 2004 was 9.7%. Canada has a population of approximately 32.5 million. Life expectancy at birth for males is 78 and for females is 83 (WHO, 2008). Recently, the focus in the health care system has been to move towards a collaborative care model. As a result health care professionals across a variety of settings, now work as multidisciplinary teams to provide care to patients (Canada Health Infoway, 2008). Canada is composed of 10 provinces and 14 territories. Canada is the second largest country in the world after Russia with 90% of the population concentrated within 160 km of the US border (CIA, 2008).

4.2 Health Information Strategy

The goal of the current health information strategy is that by 2010, 50 percent of Canadians will have their EHR available to the authorized professionals who provide their care services, and 100% of Canadians will have this by 2016 (Canada Health Infoway, 2008).

4.3 Governance: Canada Health Infoway

Canada Health Infoway was established in 2001. Its objective is to foster and accelerate the development and adoption of electronic health information systems with compatible standards and communications technologies. According to the Infoway Corporate Business Plan 2007-2008, a shared governance model is being implemented comprising of all 14 federal, provincial and territorial governments.

4.4 Standards and certification

In 2006, Infoway created a pan Canadian standards body called the Standards Collaborative to undertake standards development, coordination and promotion, particularly in relation to EHRs. The services provided by the Standards Collaborative are national standards collaboration, education, training, conformance and maintenance services. According to the Corporate Business Plan 2008-2009,

Infoway will facilitate the use of SNOMED CT and LOINC standards in electronic health solutions (Canada Health Infoway, 2008a). The messaging standards being used are HL7 version 3. HL7 v3 CDA is being used for the Shared Health Record. IHE XDS-1 is being used to share imaging documents. The DICOM standard is being used for imaging to ensure interoperability. CeRx is the pan-Canadian standard approved as “stable for use” for ePrescribing (Canada Health Infoway, 2007b).

In relation to certification, the eHealth Collaboratory was established as an independent body that assesses EHR products and services to determine if they comply with recognized standards.

4.5 EHR Model

Canada has not chosen a single nationwide repository of clinical data. Infoway's EHR strategy is centered on a peer to peer network of interoperable health information systems, which are connected to the EHR infostructure (EHRI).

4.6 Implementation

Each jurisdiction in Canada determines its own implementation strategy. Canada Health Infoway adopts a piloted approach to projects. This means that if a pilot is successful, it is implemented in other areas. Successful initiatives are replicated nationally and best practices are shared. An example of the use of best practices and the implementation of the shared services model is the Infoway Digital Imaging (DI) Program. The DI Program allows radiology results and images to be shared among authorized physicians in different locations across Canada. A single PACS DI repository is installed in one hospital which serves as the “hub” for a regional service available to all healthcare facilities in the area. Authorized healthcare providers across Canada are then able to access this information if necessary. According to the Infoway Corporate Business Plan, change management is a key success factor in every project and accounts for between 15% and 30% of the value of each initiative (Canada Health Infoway, 2007c).

4.7 Unique Health Identifier

Canadian patients have a unique health identifier at the provincial level only. There are no national level health identifiers. Registries are systems which provide

unique identifier services for health care providers, patients and organizations that provide care. Each EHRi will maintain unique private identifiers for patients, providers and locations that are linked to external public identifiers maintained by the respective registry services.

4.71 Registries

Registries are the starting point for building the data resources for the EHR. Three registries are used in the EHRi model. They are a patient, a provider and a location registry. Each registry provides unique identification and demographic information of the actor within the health care system.

4.8 Information Governance

Canada Health Infoway is responsible for information governance (Canada Health Infoway, 2007).

4.81 Privacy and Security

Canada implements ISO/IEC 17799 "Code of Practice for Information Security Management" in many jurisdictions. Encryption technologies are used to protect against unauthorized access of private health information during storage and transmission. Digital signatures will be used on electronic documents such as ePrescribing. Audit traces will be implemented for consent over-ride and access. Access to applications will be by electronic credential (ID). An EHR privacy and security conceptual architecture (PSCA) has been implemented. The objective of the PSCA is to guide system developers and vendors when designing EHR systems, so that they comply with requirements of legislation and professional codes of conduct (Canada Health Infoway, 2006b).

The PSCA outlines 10 services that are critical to the protection of personal health information (PHI) in the EHRi. They include the encryption services, a secure audit and general security services, user identity management, user authentication service, access control service, a consent directives management service. Identity protection and an anonymisation service as well as a digital signature service are included in the PSCA (Canada Health Infoway, 2006b)

Infoway has incorporated Privacy Impact Assessments (PIAs) as part of each Infoway project. The PIAs have been developed by the Office of the Privacy Commissioner of Canada. A PIA should state how a system functions, how it will comply with privacy legislation, and it should identify privacy risks and provide strategies to mitigate those risks. The PSCA will be used while performing a PIA. Canada has 10 privacy principles from the Canadian Standards Associations Model Code for the Protection of Personal Information, also known as CAN/CSA-Q830-96, which was published as a national standard for Canada (CSA, 1996). The privacy and security requirements of the PSCA stem from the CSA model code principles. Privacy Requirement 4 (PR4) states “PR4 Privacy Impact Assessments. Organizations that share or host components that store personal health information (PHI), should assess, by means of a Privacy Impact Assessment, the risks to personal privacy associated with the implementation of the hosted components and should implement appropriate privacy controls to mitigate identified risks” (Canada Health Infoway, 2006c).

4.82 Consent

In relation to consent, Infoway’s PSCA Principle 3 states, “The knowledge and consent of the individual are required for the collection, use or disclosure of personal information except where inappropriate (Canada Health Infoway, 2006b).

4.9 Funding

Infoway co-invests approximately 75% of the eligible planning and implementation costs, with the provinces and territories funding the balance. A “gated” funding approach is being undertaken. This approach aims to manage risk by linking the reimbursement of each project to the achievement of pre-set specific milestones, deliverables, and adoption targets. For example, it is a mandatory condition for investment that certain standards are used (e.g., HL7 v3). Infoway will only provide funding if milestones and deliverables are met. Infoway leverages investment, by investing in solutions that can be replicated in other parts of Canada. It is estimated that Canada has spent 1.6 billion Canadian dollars on its overall health information infrastructure since 2000 (Canada Health Infoway, 2008b).

CHAPTER 5 UNITED STATES

5.1 Background

The Centers for Medicare and Medicaid Services estimate that, by 2010, National health expenditure in the U.S. will reach \$3 trillion and account for 17% of GDP (Centers for Medicare & Medicaid, 2000). The total expenditure on health as a percentage of GDP in 2004 was 15.2%. The USA has a population of approximately 302.8 million. In 2002, life expectancy at birth for males was 67 and for females was 71 (WHO, 2008). This was shown by research conducted in 2001, by the National Center for Health shows that the use of EHRs in the USA is increasing (NCHS, 2005). The USA has the largest and most technologically powerful economy in the world. Private individuals and business firms make most of the decisions. The federal and state governments buy needed goods and services predominantly in the private marketplace (CIA, 2008).

5.2 Health Information Strategy: 2004 and 2008

In 2004, the National Coordinator developed a Framework for Strategic Action called "The Decade of Health Information Technology: Delivering Consumer-centric and Information-rich Health Care". This framework acknowledges the roles of, and addresses the actions that need to be taken by, the federal government and the public and private health sectors to introduce HIT and EHRs in the health sector (Brailer et al, 2004). The Framework for Strategic Action outlines 12 strategies to achieve 4 major goals. These goals include a) the introduction of information tools such as EHR's into clinical practice b) interconnecting clinicians by electronically connecting clinicians to other clinicians c) using information tools to personalize care delivery and d) advancing surveillance and reporting for population health improvement (Brailer et al, 2004a).

In 2008 the Office of the National Coordinator (ONC) Co-ordinated Federal Health Information Technology Strategic Plan for 2008 to 2012 was published. The main themes are privacy and security, interoperability, IT adoption, and collaborative governance (ONC, 2008).

5.3 Governance: ONC and AHIC

In April 2004, President Bush issued Executive Order 13335, which led to the appointment of a National Coordinator and established the Office of the National

Coordinator (ONC). The task of the National Coordinator is to introduce a national network of interoperable EHRs for most Americans by 2014. To achieve this goal, the ONC coordinates and consults between federal government and the private sector, and other advisory committees. In 2005, the American Health Information Community (AHIC) was established as a federal advisory committee made up of public and private sector leaders to make recommendations to the HHS on how to accelerate adoption of interoperable electronic HIT. The AHIC has an EHR Work Group. The ONC provides management of and logistical support for the AHIC.

The Strategic Plan 2008-2012 commits the USA to a public-private, multi-stakeholder approach and it sets out strategies for the implementation of EHRs. Collaborative governance is one of the key objectives. The plan states that "The necessary planning, consensus building, priority-setting and consistent approaches to implementing policies can best be achieved through appropriate structures and mechanisms for collaborative governance. It is essential that such governance occurs across the public and private sectors and involves all individuals and organizations with a stake in health-related activities" (ONC, 2008). As a result of this, it is expected that the AHIC will be transitioned from a government advisory group to a public-private partnership based in the private sector in the autumn of this year, in order to harmonize activities in the public and private sectors (ONC, 2008).

5.4 Certification, standards and interoperability

The three main bodies involved in standards and interoperability in the U.S. are the Certification Commission for Healthcare Information Technology (CCHIT), the Health Information Technology Standards Panel (HITSP) and the AHIC. The AHIC oversees and/or endorses standards and policies on a national level. In 2004, CCHIT was created as a voluntary, private sector organization to certify HIT products to accelerate the uptake of EHRs and reduce the risk of product implementation failure in the United States. To become certified, IT vendors must meet criteria related to functionality, interoperability, security, and reliability. In 2006, Executive Order 13410, requested that healthcare programs that are administered or sponsored by the federal government in the delivery of healthcare utilize HIT systems and products that meet recognized interoperability standards (President Bush, 2006). SNOMED was adopted for EHRs in 2004 with free of charge access to SNOMED CT content and all version updates via the American

National Library of Medicine. IHE XDS-1 is certified for use for receiving imaging reports and viewing images, including ECG and radiology, and for sending / responding to a query to other providers to share imaging results. HITSP IS-01 ERH Lab and IHE XDS-Lab and HL& CDA R2 are being used to respond to a query to share laboratory results. HL7 v2.4 or HL7 v2.5.1 are certified for laboratory messaging. HL7 CDA R2 is certified for clinical documentation. HL7 2.4 for administrative and financial data has been chosen by CCHIT as the final criteria for ambulatory interoperability as of March 2007. NCPDP is being used for the transfer of data to and from the pharmacy sector and has been certified by the CCHIT for this purpose for use in ambulatory and inpatient EHRs (CCHIT, 2007).

The HITSP (HITSP, 2007) is a multi-stakeholder public private partnership body concerned with harmonization, identification and selection of standards for communicating healthcare information.

5.5 EHR Model and Infrastructure

The EHR model will be a secure and standards based “network of networks” built over the internet. These networks will be built at the local level through public / private collaboration; they will be interconnected and interoperable. The Nationwide Health Information Network (NHIN) is the proposed interoperable EHR in the U.S.A. It is expected to be operational by 2014. The NHIN will not include a national data store or centralized systems at the national level. Instead, health information exchanges will be interconnected by a shared architecture of services, adopted standards, and requirements (DHHS, 2007).

The EHR Model is made up of the following bodies and services.

1. The health information exchange (HIE). A HIE is the network and associated information technology infrastructure used by the stakeholders in the health care service to exchange patient health information. A HIE by itself can only support information exchange among members of the HIE. Only those HIEs that meet the specific requirements of the NHIN, can link to the NHIN and they are known as NHIEs (DHHS, 2007).
2. Regional Health Information Organizations (RHIO) are regarded as the building blocks of the NHIN. A RHIO is a multi-stakeholder organization that enables the exchange and use of health information, in a secure manner, for the purpose of promoting the improvement of health quality, safety, and

efficiency. The RHIO is not the network and technical infrastructure (HIMSS, 2005).

3. The NHIN is the link that will extend a HIE to other HIEs. The NHIN includes data services such as security and summary patient record exchange; consumer services; user and subject identity management services; management services (Gartner, 2007).

5.6 Implementation

Currently, 4 prototypes of the NHIN have been developed and implemented, as a result of the NHIN Prototype Architecture Project and they will be assessed. The development and implementation of these prototypes is the first of a series of cyclical steps toward achieving the NHIN by manageable increments in progress. For each of the existing 4 prototypes, each of the developers considered the NHIN as a set of distributed HIEs that work together to become the NHIN (Gartner, 2007a). The U.S.A is currently working on implementing the building blocks of standards development and certification, methods of collaboration between the public and the private sectors, and policies/legislation related to privacy and security.

5.7 Unique Identifiers

The U.S.A is not expected to implement national identifiers.

5.8 Information Governance

The development of a confidentiality, privacy and security framework is one of the objectives of the Strategic Plan 2008-2012. The Plan identifies milestones and it incorporates a timeframe for achieving them. According to the Strategic Plan, the publication for the Confidentiality, Privacy and Security Framework is set for 2008. According to a report by Gartner, the policies which exist in relation to information governance will inform the architecture by identifying specific requirements that must be met by systems designers of the NHIN. The architecture in turn will inform policy by enabling policymakers with approaches and solutions (Gartner, 2007a).

5.81 Privacy and Consent

In the USA, the Health Insurance Portability and Accountability Act of 1996 (HIPAA) states that consent to the use of your medical information is not required, if used or disclosed for medical treatment or payment purposes. HIPAA led to the HHS issuing the Standards for Privacy of Individually Identifiable Health Information. Known as the Privacy Rule. The major goal of the Privacy Rule is to allow health information to flow while protecting the individuals' health information (OCR, 2003). According to a recent letter by the NCVHS, there is no federal law or policy that specifically addresses individual control of sensitive health information over the NHIN (NCVHS, 2008). It has been recommended by the NCVHS that privacy protections be enhanced by affording individuals limited control over disclosure of sensitive health information among their health care providers via the NHIN (NCVHS, 2008a). The NCVHS recommended permitting an individual to restrict the flow of information based on predefined categories of information. However, it recommended that in an emergency situation, all health information should be made available including that which may be designated restricted by the patient, subject to an audit trail and the triggering of a review by a privacy officer. The patient must also be notified. Consideration was given to the technical solution on how to provide this additional consent and it was considered that the best option was to treat it as a design matter (NCVHS, 2008b). NCVHS recommended an open transparent public process to identify the possible categories of sensitive information to which restriction of sharing of certain health information would apply (NCVHS, 2008). Currently, HITSP is working on standards based security and privacy frameworks which will support security and privacy policies and processes at state, federal, local and healthcare enterprise level (HITSP, 2007a).

5.82 Security

As a result of HIPAA, the Security Rule became law in 2003. The primary objective of the Security Rule is to protect the confidentiality, integrity and availability of electronic individually identifiable health information. The CCHIT is a recognised certification body which has a Security Workgroup. CCHIT Final Security Criteria for 2007 for EHRs contains 48 criteria related to security which include restrictive role / group based access control (sections 1 – 4), security audit (section 5), security authentication, security documentation, security technical services, reliability back up and recovery, reliability documentation, and reliability technical services. Among other security standards, ISO/IEC 17799:2005, ISO/IEC 15408:2005-2, and HIPAA

have had an impact on the CCHIT security criteria (CCHIT, 2007a). As a result, all certified EHRs must provide very stringent security audit trails.

5.9 Funding

The most recent estimates for funding in relation to the NHIN found during this research were published in 2005. Kaushal et al based their estimates on the cost of the USA's regional networks without a central database. Included in the overall cost are cost estimates for functionality, interoperability and implementation in physician offices, hospitals, nursing facilities, home health agencies, clinical laboratories, payers and pharmacies. 2 sets of national costs were estimated, and are outlined below, based on achieving NHIN functionality in 5 years.

1) \$156 billion in capital investment was estimated as the cost of advancing from the current position to the proposed NHIN, which uses a central host and peer to peer networking. The central host would provide security and linking functions, but would not store data.

2) \$48 billion was estimated as expenditure over 5 years, if current levels of spending on IT were to remain unchanged (Kaushal et al, 2005)

CHAPTER 6 FINLAND

6.1 Background

Finland has a decentralized health care system comprised of 430 municipalities, which are each responsible for providing and developing health services for their residents. There are 20 hospital districts. Primary health care is undertaken in the municipal health centers, secondary and tertiary care is provided by hospitals, comprising regional, central and university teaching hospitals, and managed as 21 hospital districts (STAKES, 2004). Finland has a population of 5.261 million. Total expenditure on health as a percentage of GDP in 2005 was 7.5%. Life expectancy at birth for males is 76 and for females is 83 (WHO, 2008). EHRs are used as the main method for documentation (Ehealth Era, 2007). The high rate of utilization of the EPR has made information exchange between institutions possible (Ministry of Social Affairs and Health, Finland, 2007).

6.2 Strategy

In 2002, the National Program for Securing the Future of Health Care, called for a national electronic patient record by 2007 (Ehealth Era, 2007). In 2005, a plan to build a national EHR archive by 2007 was added to the national policies (Ministry of Social Affairs and Health, Finland, 2007a). Finland's national strategy is to ensure availability of information for patients regardless of time and place in both public and private health care. To achieve this objective it is undertaking the following initiatives

- A comprehensive digitization of patient data.
- The development of semantic and technical compatibility of electronic patient record systems.
- The development of the national health care infrastructure and information network solutions.
- Identification and verification solutions and use of electronic signatures.
- Maintaining online information that supports decision making.

(Ministry of Social Affairs and Health, 2007b).

The National EHR strategy is being coordinated by the Ministry of Social Affairs and Health. The National EHR strategy was published in 2004. The National EHR strategy defined the common semantic and technical structures that should be used in all EHR systems and the minimum or core set of patient data was also defined. The EHR implementation is ongoing. Finland has chosen message handling and the

use of common standards for interoperability (Ministry of Social Affairs and Health, 2007c).

6.3 Governance

The Ministry of Social Affairs and Health has the main role in eHealth policy. Expert bodies are involved in different aspects of the EHR development nationally and internationally. The main bodies are KELA (The National Insurance Agency), TEO (National Authority for Medicolegal Affairs), and STAKES (The National Research and Development Center for Welfare and Health). STAKES is responsible for the maintenance, development and coordination of classifications in patient documents and it is responsible for the code server. Health care provider identifiers and authentication are administered by TEO. KELA maintains the following health care information services, the patient record registering and directory services, the national electronic archiving of patient records, the consent management services, logging and monitoring services and the prescription database. The Ministry of Social Affairs and Health has many functions in the implementation of the national system architecture. It manages the overall steering of the process, the drafting of legislation, preparation of the central government budget, governing and preparing national guidelines, assuming responsibility for the national health care data security policy and implementation, managing communications, managing the strategic steering of information management in the social welfare and health care sectors, assuming responsibility for internal strategic cooperation (Ministry of Social Affairs and Health, Finland, 2007d).

6.4 Standards and Certification

The Ministry of Social Affairs and Health will supervise the drafting of certification requirements for health care information systems with regard to compatibility, information security and privacy protection (Ministry of Social Affairs and Health, Finland, 2007e). HL7 standards are the most commonly used communication standard in conjunction with XML. HL7 CDA R2 is used for structured data forms. According to a presentation by Dr. Paivi Hamalainen, Head of Unit for eHealth and eWelfare, the main objective of the structured data is to support data exchange via the national archive. National code server has been established which stores all the official versions of different core data elements including classifications, codes, HL7 structures, and terminology. The EHRs take their codes into their products from the server (Hamalainen, 2007). Currently the ePrescribing and patient record

archival service is being based on HL7 CDA R2 and version 3 messages. Version 2 messaging is deployed in most hospitals and healthcare centers. The DICOM standard has been used for imaging since 1999 (Ministry of Social Affairs and Health, Finland, 2007a).

6.5 EHR Model

A secure message handling service is being used to link local and regional patient record systems, the national archive and the prescription database (Ministry of Social Affairs and Health, 2007). Harno et al report that the shared EHR is a virtual EHR. Health data are generated and stored in repositories or exchanges by different health care providers. Common middleware, which is computer software that connects software components or applications running on one or more computers across networks, is used for integrating regional EHR systems. VPNs and web services are used for connectivity. A stepwise implementation of integrated regional health care services is being undertaken to facilitate information sharing (Harno et al, 2006). An example of the EHR model is the regional health information network (RHIN) in the county of Uusimaa. This RHIN integrates integrated services between primary, secondary and tertiary care. An eReferral network, an integrated EHR service between health care professionals, and PACS systems have been implemented. The eReferral between primary and secondary care offers the option of eConsultation between GP's and hospital specialists (Harno, 2008).

6.6 Implementation

There is no dedicated national health information network in Finland. Instead secure commercial communication channels, such as, VPNs are rented for health care purposes. Closed intranets based on VPN technology have been implemented in hospital regions. Secondary care hospital intranets are connected together using either a VPN or ATM channel or via the internet (Ehealth Era, 2007). Currently, restructuring is being undertaken to enable a national system. The national digital archive for patient documents will be at the heart of the ICT infrastructure for social care and health. Exchanging data between organizations will be on a national basis and not regionally. Legislation in July 2007 makes it mandatory that all organizations join the national IT architecture for health (Ehealth Era, 2007).

According to a report by Harno et al, applications are integrated across the regional infrastructure. Regional patient data repositories or exchanges provide a source of reference information for past treatment, a basis for current patient data distribution, as well as a data depository for consultation services. They also provide a common access point to health care data for the patient. Health providers access the RHIN by web browsers, and patient information contains primary care and hospital visits, critical data such as laboratory reports / results, and images, referrals and discharge letters (Harno et, 2006). A code and terminology server for interoperability is in place for RHINs and will be scaled for national use (Harno et al, 2008).

6.7 Unique Identifiers

Every citizen in Finland has an electronic ID since 1969. The Client Data Act covers the requirements for reliable patient identification.

A Public key infrastructure (PKI) system and smart card for health care professionals is planned. STAKES is responsible for maintaining the health care unit register. The national systems architecture requires all operating units to be designated with an International Standards Organization Object Identifier (ISO/OID). STAKES maintains the health care unit register and operation of the ISO/OID codes (Ministry of Social Affairs and Health, 2007).

6.8 Information Governance

The following legislation provides information governance in Finland. The Data Protection Act 1999. The Digital Signatures Act 2003. The Electronic Handling and Archiving of Electronic Health Care Records Act 2007. ePrescription Act 2007. The Act on Electronic Signatures 2003 provides the basis for using electronic signatures.

6.81 Security

Units in the health care sector are required to apply a uniform data security policy based on the ISO 27799 standard (Ministry of Social Affairs and Health, 2007).

6.82 Privacy

The Personal Data Act 1999 sets out the conditions for the exchange of patient information.

6.83 Consent

Patient records can not be accessed without the patient's informed consent.

6.9 Funding

The Ministry for Social Affairs and Health has provided EU 5 – 10 million per year for regional and cluster projects between 2004 and 2007. Central government will contribute EU 10 million to the construction and introduction of national services, such as the archive and prescription center, between 2007 and 2010 (Ministry of Social Affairs and Health, Finland, 2007a). The level of investment in ICT has been relatively low at approximately 2% of all health care expenditure (Harno et al, 2008).

CHAPTER 7 AUSTRALIA

7.1 Background

The total expenditure on health as a percentage of GDP in 2004 was 8.8%. Australia has a population of approximately 20.5 million. Life expectancy at birth in 2002 for males was 79 and for females was 84 (WHO, 2008). Australia is the 6th largest country in the world and its population is mainly concentrated along the eastern and southern coasts (CIA, 2008).

7.2 Strategy

HealthOnline is a report published in 1999 that is concerned with how information technology can be harnessed to improve the objectives of the health system as a whole. It pays particular attention to the collection, transfer and access to health information and its mission is to improve the delivery of health care through innovative and effective use of information in order to achieve improved quality of care and health outcomes.

The Council of Australian Governments (COAG) agreed that from 2006 the governments of Australia would accelerate the work on a national EHR system. As a result, Australia appears to be focusing its strategy in the following areas:

1. NEHTA has commenced work on systems for a unique health identifier, a healthcare provider identifier and agreed clinical terminologies (NEHTA, 2008).
2. NEHTA and the Office of the Privacy Commissioner are corresponding with regard to information governance in respect of electronic health information (Australian Government, 2008).
3. It has been agreed that future EHR systems receiving government funding will have to comply with the nationally agreed standards (NEHTA, 2008).
4. The importance of change management has been acknowledged by NEHTA and it is given a high priority in its Interoperability Framework (NEHTA, 2007).
5. National directories are also being created to accurately identify medicines, medical products, devices and consumables (HIMSS, 2007).

7.3 Governance

7.3.1 Governance: NHIMAC

In 1998, Australian governments created the National Health Information Management Advisory Council (NHIMAC) as a high-level body to advise Health Ministers. Multiple stakeholders are represented in NHIMAC. Its role is to provide a nationally co-ordinated approach to improving health information management, to increase synergies between jurisdictions and to reduce duplication of effort. It has the objective of maintaining strong linkages between existing and newly created health information management and information technology bodies and forums.

7.3.2 Governance: NHIG and AHIC and NEHTA

The National Health Information Group (NHIG) and the Australian Health Information Council (AHIC) are responsible for overseeing the development of a national strategic plan for health-related information management and ICT. The AHIC has an expert advisory role. NEHTA's mission is to set the standard, specification and infrastructure requirements for secure, interoperable electronic health information systems.

7.4 Standards

The National E-Health Standards Catalogue has confirmed that HL7 is the national standard for electronic messaging of health information across Australia and SNOMED CT will be the national standard used for terminology coding (NEHTA, 2007c). Australia has created a National Health Data Dictionary (NHDD). The NHDD contains meta-data standards for several health sectors and is updated regularly. Part of the objectives of the NHDD are to establish a core set of uniform definitions relating to the health services and population parameters (AHIW, 2003). One of Australia's current priorities is to develop and implement coordination between standards in the clinical and statistical domains, specifically between the terminologies of SNOMED CT and the NHDD. This will not be undertaken by NEHTA. The responsible bodies are the Health Data Standards Committee (HDSC) and the Statistical Information Management Committee, which are subcommittees within the AHIC and National Health Information Management Principle Committee (NHIMPC) (NHIMPC, 2007). NEHTA's Standards Catalogue confirms the messaging standards used are HL7 v2.3.1 for referral, discharge summary, diagnostic imaging orders and results. HL7 v2.4 and HL7 v2.3.1 are used for electronic messages for exchange of

information on drug prescription. HL7 v2.4 is used for referral, discharge, and health record messaging. NEHTA has chosen to continue to use HL7 v2. X for the short to medium term (NEHTA, 2007c).

7.5 Certification

There are several organisations which exist within Australia that provide conformance testing of eHealth specifications. These include the Australia Healthcare Messaging Laboratory and organisations associated with Standards Australia (NEHTA, 2007a).

7.6 EHR Model

The Individual Electronic Health Record (IEHR) previously known as the Shared Electronic Health Record (SEHR) is currently being proposed in Australia. The IEHR will contain selected portions of an individual's health record. The Summary Health Profile is part of the IEHR and will contain key facts and selected current and historical key health information about an individual. The IEHR will also contain event summaries, including pathology results, radiology results, referrals and discharge summaries, significant test results, and care plans. The IEHR will be an electronic message that will be used alongside existing paper records (NEHTA, 2008a). An event summary is a collection of health care information of a patient related to their ongoing care. The event summary will consist of a series of care record summaries. It will be organised into sections so that the information is useful for healthcare providers (NEHTA, 2006).

7.7 Unique Health Identifier

There is currently no national system for unique identification of Australian citizens (DOHC, 2008). However, there are currently investigations underway into the possibility of introducing national Individual Health Identifiers (IHI) for patients in Australia, in order to accurately identify them for health care purposes. It is proposed that the IHI will maintain accurate personal data for every individual accessing the Australian health care services. It will comprise of a unique identifier and record of information. The record of information will contain, a summary record, an identification record, a demographic record (NEHTA, 2007b).

7.8 Information Governance

7.81 Privacy

The Privacy Act 1988 is the main legislation which provides privacy protection for Australians. NEHTA published the Privacy Blueprint for the IEHR in July 2008 to elicit feedback from the public on privacy issues in order to develop constructive solutions to any issues. As part of its work to enable secure and private EHRs, NEHTA has developed a Privacy Management Framework. This Framework is a series of stages that the IEHR must undergo. An overview of the stages are outlined below. It is envisaged that the IEHR will transition parts of this Framework iteratively throughout its lifetime.

1. A preliminary privacy impact assessment (PIA).
2. A full privacy impact assessment prior to implementation.
3. The development of a privacy blueprint.
4. IEHR consultation Roundtables.
5. Public consultation on the IEHR (Current state).
6. Report on IEHR Privacy Blueprint Feedback.
7. IEHR PIA.

(NEHTA, 2008b)

The Privacy Blueprint identifies 6 privacy tenets, which guide NEHTA's work to ensure that privacy is incorporated into the health infrastructure and to develop strategies to ensure that privacy risks are mitigated in NEHTA initiatives (NEHTA, 2008c). In particular the first tenet is the Commitment to Privacy. "A commitment to privacy is the starting point for NEHTA initiatives involving the collection and handling of personal/health information. NEHTA recognises that

- Privacy is an integral component of a secure and interoperable e-health environment;
- It must be embedded in the design process;
- It must comply with legal requirements; and
- It should promote privacy positive approaches"

(NEHTA, 2008c).

Sensitivity labels have been proposed which would allow a patient to request that "special protection" be available for information they feel is sensitive. This is currently subject to further detailed analysis including a cost / benefit analysis.

7.82 Security

NEHTA recommends using AS/ NZS ISO/ IEC 17799:2006 Information Technology Security Techniques – Code of Practice for Information Security Management. NEHTA is developing a PKI system which issues “digital certificates” after agreed identification and registration processes have been completed. A National Authentication Service for Health (NASH) has been proposed to identify health care providers and workers and to provide them with credentials. It is expected that implementation of NASH will enable transactions carrying health information to remain private, to maintain integrity, to be traceable and to be conducted by known entities. Audit trails will also be implemented to assist accountability (NEHTA, 2008d).

7.83 Consent

Consent arrangements regarding the collection of information for enrolment in the UHI service and the creation of an IHI are outlined in the IEHR Privacy Blueprint. These consent arrangements are based on existing legislation, which may be updated in the future, specifically in relation to the IEHR. Express consent is required for the creation of their IEHR and also to access information contained in the IEHR. Consent to access only needs to be given once. Implied consent to access is necessary, once the access relationship has been established. An individual can opt out of participation in the IEHR at any time and reactivate the IEHR at a later date. Consent (either implied or express) may also be required for secondary use purposes, if the secondary use is not directly related to the primary purpose for collecting the information. Access rights and exclusion of certain information from the IEHR will be decided by the patient. Patients will have the right to have certain information marked as “privileged”. Individuals may also request an audit trail of access to their IEHR and have errors corrected (NEHTA, 2008a).

7.9 Funding

The State, Territory and Federal Governments have contributed \$132 million Australian dollars in funding to the Individual Health Identifier, the Healthcare Provider Identifier and establishing a national clinical terminology (NEHTA, 2008).

CHAPTER 8 NEW ZEALAND

8.1 Background

The health system in New Zealand is funded mainly by the government and provides health and disability services to all citizens. Over 75% of health care is publicly funded. New Zealand has a high rate of computer use in general practice. There is a high rate of use of the internet in New Zealand, which indicates that most general practices are equipped for electronic transfer of information between providers (Didham et al, 2004). The total expenditure on health as a percentage of GDP in 2004 was 8.9%. New Zealand has a population of approximately 4.14 million. Life expectancy at birth in 2002 for males was 78 and for females was 82 (WHO, 2008). The main focus of the current health information strategy for New Zealand is on primary and community care, as well as, integration between health care settings (Health Information Strategy Steering Committee, 2005).

8.2 Health Information Strategy: HISNZ

The Health Information Strategy for New Zealand (HISNZ) was established in 2005 and is the current health information strategy of New Zealand. HISNZ envisions a distributed EHR. The focus of HISNZ is on communication and connectivity in relation to using and sharing distributed information to improve health. Four of the priorities outlined by HISNZ to achieve this goal are listed below:

- Establishing a secure network for stakeholders to use to communicate;
- Putting in place national anchors such as unique identifiers;
- Creating key event summaries, which are the high level components of the EHR;
- Broadening dialogue between primary and secondary care using the key event summaries (Health Information Strategy Steering Committee, 2005a).

HISNZ targets 12 action zones. The 12 action zones are priority areas to achieve collaboration between multiple organisations. The aim of the action zones is to provide a focus for implementation planning in the sector over 3 to 5 years. The 12 action zones can be grouped into three areas as follows: the improvement of the national systems and communications infrastructure; introducing standards and availability of information around primary, community and long term care; and improving connectivity between providers such as through eReferrals, and

ePharmacy to increase collaboration. The action zones also have a role in facilitating security and privacy, common standards and governance. The strategy places a strong emphasis on governance, particularly in relation to fostering collaboration. This is because each action zone has dependencies with other action zones, for example the eReferrals action zone is dependent on the national network strategy (Health Information Strategy Steering Committee, 2005b).

8.3 Governance: HISAC

The Health Information Strategy Action Committee (HISAC) is the Ministerial Advisory Committee to the Ministry of Health. HISAC is a committee which is part of the New Zealand Health Information Service. HISAC was established to provide governance, oversight, quality assurance and leadership for the implementation of the Health Information Strategy for New Zealand (HISNZ). HISAC has 3 subcommittees. These are Infrastructure (including privacy, authentication and security), Health Information Standards, and National Collections (HISAC, 2008).

8.4 Governance of Information and Systems: NZHIS

The New Zealand Health Information Service (NZHIS) is a Business Unit group within the Ministry of Health. Its objective is to ensure effective governance of national health and disability sector information and systems. It provides policy advice, strategic leadership and direction with regards to health information services and systems to the Ministry of Health. NZHIS is the custodian of the Health Information Strategy for New Zealand (HISNZ). The main role of NZHIS is to measure and report progress on the goals and action zones of HISNZ, and to develop policy to support action zones. It also provides stewardship support by providing advice and support to HISAC regarding the implementation of the Health Information Strategy of New Zealand (HISNZ) and ensuring consistent health information standards. NZHIS has custodianship and operational responsibility for health event summaries, accessible through the national collections (NZHIS, 2006).

8.5 Standards and Certification

HISAC recommends HL7 but does not endorse a particular version of it (HISO, 2005). HISAC is currently working on endorsing SNOMED CT. The Infrastructure Committee of HISAC deals with the accreditation and oversight of vendors of network and certification services that supply or wish to supply services to the

Health and Disability Sector. It is currently working on the development of guidelines and minimum standards for the use of individual and organisational digital certifications. The Health Information Standards Organization (HISO) is a subcommittee of HISAC. HISO provides HISAC with written progress reports and any impediments to progress in relation to its work of establishing and endorsing standards. It is also works to promote the adoption of standards. HISNZ lists eight building guides as the key components and structural elements required to deliver information systems which can share information nationally. Standards are one of those building blocks and are considered by the strategy to be one of the foundations required for supporting the exchange of information (Health Information Strategy Steering Committee, 2005c).

8.6 EHR Model

Research and policy work regarding an EHR model for New Zealand is currently in the early stages. NZHIS has custodial and operational responsibility for national health event summaries on behalf of New Zealanders.

Within New Zealand's EHR model, EHRs are distributed at local, regional and national level. The most amount of detail about the patient is stored in the local systems. Key event summaries such as hospital discharge summaries are provided by regional systems. National systems provide shared data and consistent business processes to the health and disability sector of New Zealand. They also provide reference points and anchors, such as, unique identifiers. Examples of national systems are the National Health Index (NHI), the Health Practitioner Index (HPI), which is currently being developed, and existing national collections. The information, which is spread throughout many different physical information systems is linked, and can be accessed electronically using the unique identifiers (Health Information Strategy Steering Committee, 2005d).

8.7 Unique Identifiers

New Zealand has a registry called the National Health Index (NHI) for patients. The NHI number has been used in New Zealand for more than 20 years. All New Zealand born children receive their NHI number at birth and about 95% of New Zealand citizens now have their own NHI number (New Zealand Health Information Service, 2008). The NHI is an index of information associated with that unique number. The New Zealand Health Information Privacy Code 1994 places

restrictions on the creation and use of this number. According to NZHIS, the information held in the NHI includes name and address, date of birth, sex and ethnicity. This information identifies the person and ensures that a person is correctly matched with their health record (NZHIS, 2006a).

A Health Practitioners Index for practitioners is being developed.

The New Zealand Health Information Service (NZHIS) implements and manages the NHI systems and one of its purposes is to ensure that information is secure and that procedures are in place to prevent unauthorized access. National indexes require maintenance and ongoing development to ensure connectivity of data this is provided by NZHIS.

8.8 Information governance

Privacy and security are listed as one of the eight building blocks required to deliver integrated information systems to the sector. The Infrastructure Subcommittee of HISAC specifies, agrees and maintains protocols for privacy and security over ICT in the health and disability sector. Information governance legislation includes the Health Network Code of Practice, Health Information Privacy Code and the Health Intranet policy for the safe and secure electronic sharing of information.

8.81 Privacy

In 2007 New Zealand amended its Health Information Privacy Code to maintain patient trust, privacy and confidentiality. NZHIS is implementing a Privacy, Authentication and Security (PAS) Framework and Guide based on the principles of the Health Network Code of Practice and Health information Privacy Code 1994. It is intended that this will bring together existing policy and legislation and provide the sector with an established level of security and privacy (Health Information Strategy Steering Committee, 2005e).

8.82 Security

As noted by HISO, "health information today is shared between multiple organisations and people, and with the current and emerging interconnectedness and increasing use of technology, health information is exposed to a wide variety of

threats and vulnerabilities" (HISO, 2008a). In relation to health information and electronic health care systems, HISO has currently proposed an authentication and security framework standard based on ISO 17799, which is open for public comment (HISO, 2008a). This framework contains the core proposed components of governance, policies, guidelines and standards that organisations and/or products and services should comply. The framework applies to the network, applications that collect, access and exchange electronic health information, vendors of applications, other services, and users.

8.83 Consent

The New Zealand Health Privacy Code will govern decisions regarding consent.

8.9 Funding

Cost estimations for a New Zealand EHR were not found during the research process.

CHAPTER 9 ENGLAND

9.1 Background

The NHS is controlled by the government through the Department of Health. The total expenditure on health as a percentage of GDP in 2004 was 8.2%. England has a population of approximately 50.5 million. Life expectancy at birth for males is 77 and for females is 81 (WHO, 2008). In 2006, expenditure on health care in the UK was £109 billion sterling, or 8.4% GDP (ONS, 2008). England is now 6 years into the implementation of its health information strategy. Every trust in England now has a digital PACS system in operation. The Choose and Book service is partially implemented. GP2GP is live and transfers a medical record from GP to GP in GP2GP enabled practices (paper based records are still transferred). A total of 12,150 National Programme systems provide the foundations for Choose and Book, which allows patients to choose their outpatient appointment according to their own priorities (NHS, 2008).

9.2 Strategy: NPfIT

Delivering 21st century IT, Support for the NHS was published in 2002 and outlined the strategy and the scope for the National Programme for IT (NPfIT) in the NHS. NPfIT was established in 2002 as a 10 year program (Department of Health, 2002). The main focus of the NPfIT programme is the NHS Care Records Service which is being developed to provide a live, interactive NHS Care Record throughout the NHS organizations in England (Connecting for Health, 2008).

9.3 Governance: Connecting for Health

NHS Connecting for Health (NHS CfH) is the national body which holds and manages all the contracts agreed for NPfIT. It is the single national IT provider for the NHS, and it is responsible for ensuring the maintenance, development and effective delivery of the IT products and services used. NHS Connecting for Health also provides the policy focus, and shapes the strategic infrastructure to ensure integration where necessary. It sets the standards required of any local IT applications where choice is available. The centralized approach and the national procurement of systems was chosen to enable lower costs of procurement, as well as, greater potential for interoperability between systems than if a more localized approach had been undertaken (House of Commons, 2007).

9.4 Standards

NHS Connecting for Health uses SNOMED-CT as the universal coding language for the NHS (Connecting for Health, 2008a). According to the HL7 website, HL7 is the messaging standard which will be used for NPfIT. The EHR information model is based on HL7 v3 RIM.

9.5 Electronic Health Record Model

The NHS Care Records Service (NHS CRS) will create two separate EPR systems; a national Summary Care Record (SCR) which is currently being piloted, and a local Detailed Care Records (DCRs) which is still being planned and which will contain more comprehensive clinical information, and will be stored where a person is most likely to receive care. The Summary Care Record, and the Detailed Care Records, combine to produce a patient's complete NHS Care Record (House of Commons, 2007a)

Systems which make up the NHS Care Record.

Based on the information available from the House of Commons Health Committee Report the following systems make up the NHS Care Record

- The National Data Spine is a central database to store information, to link local and national IT systems, and to host national systems such as the Summary Care Record (SCR). It will hold summary information about every patient's health and care, such as, NHS number, date of birth, name and address, allergies, adverse drug reactions and major treatments.
- The N3 is used to transmit information between systems by handling the transmission of information and messages between systems and NHS locations. It provides all NHS organizations with access to a broadband connection and will underpin the systems and services being implemented by the NPfIT. The N3 a VPN.
- The Personal Demographics Service (PDS) contains the basic demographic details about every NHS patient including name, address, date of birth, NHS number and current GP. It is the central single source for SCR demographics.
- The electronic prescription service (EPS) which allows those in primary care setting to generate and transmit electronic prescriptions to an EPS where it can be downloaded by a dispenser who has upgraded their system to use the EPS.
- The NHS number which is a national unique identifier.

- The Secondary Use Service (SUS) will collect, manage and analyze electronic health data from a range of sources and will provide a single point of access to aggregated anonymous data for purposes including management, commissioning and clinical audit and research.
- The NHS CRS also includes local records systems such as Patient Administration Systems (PAS) (House of Commons, 2007a).

The Summary Care Record

The SCR is intended to provide a summary of key health information accessible by clinicians anywhere in the country. It will contain information such as, current and previous diagnosis and prescriptions, allergies, adverse reactions, drug interactions, and recent investigation results. It will incorporate new key items of a patients care over time, losing other elements as time lapses. Information held in the SCR will be extracted from existing GP records and later from other sources, and uploaded to and stored on the National Data Spine (House of Commons, 2007b).

9.6 Implementation

The first phase of the Care Records Service implementation was the early adopter programme, which began in 2007 and runs until mid 2008 when it will be evaluated (NHS, 2007b). A National Standard for Implementation (NSI) has been developed to enable a standardised approach to implementation using PRINCE 2, as a project management methodology. The NSI forms part of the National Implementation Guidance Toolkit. The aim of the NSI is to ensure that lifecycle changes, the products produced within them and the terminology used are the same (NHS, 2007c).

9.7 Unique Identifier

In 2002, NHS Numbers for Babies was introduced and allocates a lifetime NHS number for each baby at birth. The NHS Number was developed to provide unique patient identification within the NHS. It enables sharing of patient information across the NHS. It is a 10 digit number, the first 9 digits are the identifier and the 10th is a check digit used to confirm the number's validity. According to the Information Standards Board for Health and Social Care in England, the NHS number is to be used as the fundamental standard for the unique health identifier within health care in England. The proposed conformance date for this is 31st December 2009 (NHS, 2008a).

9.8 Information Governance

According to the NHS Connecting for Health website, the NHS is responsible for information governance and recommends that all organisations having an N3 connection work towards achieving and demonstrating compliance with the ISO 27000 series of standards. The objective of the ISO 27001 standard is “to provide a model for establishing, implementing, operating, monitoring, reviewing, maintaining, and improving an Information Management Security System” within the context of the NHS overall business risks. The NHS Information Governance Toolkit has been developed to assist the NHS organizations achieve the aims of information governance. The toolkit covers information governance, confidentiality and data protection, information security assurance, clinical information assurance, secondary uses assurance, and corporate information assurance (NHS, 2008b).

9.81 Confidentiality and Privacy

Confidentiality is given to patients under the UK Data Protection Act 1998. The National Information Governance Board for Health and Social Care, who reports to the Secretary of State for Health, publishes the Care Record Guarantee (NHS, 2008c). The Care Record Guarantee, revised in August 2007, sets out the standards required for confidentiality of patient records and consent to access and share records. It promises that patients will be able to request that sensitive information within their record will be kept from general view (NHS, 2007a).

9.82 Authorised access

Only authorised users will be able to access the NHS CRS. Authorised users will be issued with an NHS chip and pin smart card. The objective is to protect the patient’s confidentiality. The access will be role based and group based (e.g. what is the need for the information, administration or health care?) and this will determine the amount of access necessary for the user. Auditing of accesses will be undertaken (NHS, 2008d).

9.83 Consent

The Care Record Guarantee states that anybody has the right to limit their participation in the NHS CRS. Implied consent will be used. A care person with role

based access and a reason for that access will be allowed to access a patient's record with the patients implied consent. People can choose to limit their participation in the Summary Care Record in the following three ways. Emergency only (SCR only accessible in an emergency), partial access (some information is withheld from the SCR and a flag indicates missing data aka sealing or sealed envelopes), and no SCR (NHS, 2007a).

CHAPTER 10 IRELAND

10.1 Background

The Government, the Department of Health and Children (DOHC), and the Minister for Health and Children are responsible for health service provision in Ireland. The Health Services Executive (HSE) was established in January 2005. It has responsibility for delivering health services nationally. It had a budget of almost €12 billion in 2006 and €14.132 billion for 2008 (HSE, 2008). The HSE employs over 100,000 people (HSE, 2008a). The total expenditure on health as a percentage of GDP in 2004 was 8.2%. Ireland has a population of approximately 4.22 million. Life expectancy at birth for males is 77 and for females it is 82 (WHO, 2008). Ireland has 49 public hospitals, 16 of these are located in Dublin. Currently, the HSE has a transformation programme in operation. One of its six transformation priorities is “to develop integrated services across all stages of the care journey”. An example of significant projects in this area is the drive to develop shared care between primary care and hospital services. Other significant projects are the development of a unified national ICT infrastructure and support services; the development of clinical and administrative systems, which will involve establishing national ICT governance structures, integration with shared services and ICT staff development (HSE, 2006). As a result, in relation to medical records, the HSE identified developing a standardized agreed approach to medical records as a quality initiative that will be addressed (HSE, 2007). The National Hospitals Office (NHO) has since introduced a code of practice relating to all patient information collected, including both paper and electronic health records. This code outlines a framework for best practice in ensuring consistent, coherent healthcare records management, in both public and private healthcare facilities in Ireland (NHO, 2007). No information was available on the current rate of use of EHRs in Ireland. In an assessment of the current situation regarding the use of information and technology and other eHealth services, the National Health Information Strategy of Ireland notes that these services have been underdeveloped. It also recognizes the following barriers to retrieving appropriate health information. The diversity of systems and sources of information, the depth of analysis and the format and distribution of the information, the number of agencies which provide this information and the need for a mechanism to provide this information in its most useful and fullest form (DOHC, 2004). Currently, information collected within the health sector is generally for administration and financial purposes.

10.2 Strategy: NHIS 2001 and 2004

The 2001 health strategy report, *Primary Care a New Direction* notes “Appropriate electronic communication and electronic record systems are central to the operation of both the primary care team and the wider network of professionals. There will be considerable investment in the ICT infrastructure. This will include the development of an EHR based on a unique client number” (DOHC, 2001a).

The current Irish health information strategy is the National Health Information Strategy (NHIS) 2004. The aim of NHIS is to recommend the actions to rectify present deficiencies in health information systems and implement frameworks to ensure the best development and utilization of health information. NHIS identified the need for unique health identifiers, an information governance framework, information standards and the need to use technology to the full in the collection, processing, analysis and dissemination of health information (DOHC, 2004). It focuses specifically on health information and sharing health information. One of its main objectives is to improve access to information for all stakeholder groups. Another of its objectives is to establish health information standards which will ensure the quality and comparability of health information and enable appropriate sharing of health information within the health sector (DOHC, 2004a).

10.3 Governance: HIQA

HIQA is an independent authority that was established in 2007 and reports to the Minister for Health and Children. Action 15 of NHIS proposes that HIQA will have governance of NHIS and the introduction of EHRs. Among HIQA's objectives are supporting those delivering health and social care services through the sharing of best practice, skills and knowledge. The function of the Health Information Directorate within HIQA is outlined in the HIQA Corporate Plan as “Identifying and advising on health information deficiencies; establishing an information governance framework and setting standards for information systems; evaluating and providing information on the provision of health and social services” (HIQA, 2008).

10.4 Electronic Health Record Model

NHIS states that the electronic health care record is an evolving concept and that EHR architectural models are still in the early stages and being developed. It proposes that a national EHR will be introduced on a phased basis (DOHC, 2004b). NHIS describes the EHR as linking an individual's EPR and notes the need for

standards to be developed and applied both in relation to the content of the information itself but also in relation to its access and use (DOHC 2004c). During research a model for the proposed EHR could not be found.

10.5 Standards

The need to determine and enforce data standards on a health services wide basis to ensure ICT conformity and connectivity is stated in the NHIS. There is a focus on the availability / accessibility of health information across the health sector which requires use of consistent standards (DOHC, 2004c). Establishing health information standards is an objective of the strategy to ensure comparability of health information and enable information sharing. HIQA has been given responsibility for developing health information standards by the NHIS and this is being undertaken by the Health Information Directorate of HIQA (HIQA, 2008).

10.6 Unique Identifier

A review of the NHIS 2004 highlighted to the author the barriers to retrieving health information in Ireland that currently exist (DOHC 2004d). In particular it notes that there is no effective mechanism to pull information together on a national basis.

Currently, a unique identifier does not exist in Ireland. Patients have a number of identifiers according to the health care locations they attend. The NHIS acknowledges that unique identifiers are an essential requirement for the full implementation of EHRs (DOHC, 2004b). Currently, the Discussion Paper on the Proposed Health Information Bill puts forward options for the unique identifier which include, use of the PPS number or development of an entirely separate national identifier that is specific to the health sector and uses its own supporting infrastructure (DOHC, 2008).

10.7 Information Governance

In June 2008 a Discussion Paper on the Proposed Health Information Bill was produced by the DOHC to set out policy objectives and to facilitate informed discussion on the objectives of the proposed Health Information Bill. According to the Discussion Paper, the objectives are "to establish a legislative framework to enable information in whatever form to be used to best effect to enhance medical

care and patient safety; to facilitate the greater use of information technologies for the delivery of patient services and to underpin an effective information governance structure for the health system generally" (DOHC, 2008a). The Discussion Paper identifies the areas of electronic EHRs, unique identifiers, population registers, and use of information for medical research, as key areas in relation to considering patient privacy, confidentiality, professional and ethical codes on using and safeguarding personal health information. The Discussion Paper also questions if the proposed Health Information Bill should be a new piece of legislation dealing with all the relevant points in relation to privacy, confidentiality and security or if it should build on the legislative framework that exists in the form of the Data Protection and Freedom of Information acts, which are working well (DOHC, 2008a)

10.71 Privacy and Confidentiality

The Discussion Paper on the Proposed Health Information Bill discusses the extent to which patient consent should determine the use and disclosure of personal health information. Currently, the Data Protection Acts 1988 and 2003 protect an individual's right to privacy. These Acts also establish the protection principles that those who hold data about a person must comply with. Currently there is an option to extend the existing legislation or to create new legislation specifically related to personal health information.

CHAPTER 11 SUMMARY OF FINDINGS

In considering the question of introducing national EHRs in Ireland, there was a need to be aware of developments internationally related to EHR technologies and initiatives. In order to gain a thorough understanding of implementation projects and available technology it was essential to consider how other countries have approached the implementation of electronic health records.

The tables on the following pages are provided to summarize the prerequisites that were noted in Chapters 4 to 10. The tables show the actions and choices that have been made in relation to those prerequisites to introduce a national system of electronic health records.

Table 1: Goals and Time Frame

| Country | Goal | Time Frame |
|---------------|--|-------------------|
| Finland | To ensure availability of information for patients regardless of time and place in both public and private health care. | 5 years in 2002 |
| Canada | By 2010 at least 50% of Canadians and by 2016 100% of Canadians will have an EHR available to the authorised professionals who provide their care. | At least 10 years |
| United States | Interoperable EHR for most Americans by 2014. | At least 10 years |
| Australia | To improve quality and safety in health care by ensuring important clinical information is available in a high standard, when and where it is needed. | Unknown |
| New Zealand | A distributed EHR at local, regional and national levels. | Unknown |
| England | The NHS Care Records Service will provide an interactive NHS Care Record for every patient in England by 2010. A Summary Care Record and a Detailed Care Record are planned. | At least 10 years |
| Ireland | Development of an EHR based on a unique client number. Increased sharing and access to health information. | Unknown |

Table 2: Governance, Governing Body

| Country | Governance Model | Governing Body |
|---------------|---|---|
| Finland | Decentralised | Ministry of Social Affairs and Health (EHR strategy), STAKES, KELA, TEO |
| Canada | Shared governance, including public, private and industry stakeholders. | Canada Health Infoway |
| United States | Shared governance model led by the government and which includes public, private and industry stakeholders. | ONC and AHIC (up to 2008) |
| Australia | Shared governance model led by the government and which includes public, private and industry stakeholders. | NEHTA and NHIMAC |
| New Zealand | Shared governance model led by the government and which includes public, private and industry stakeholders. | NZHIS and HISAC |
| England | Centralised management structure. | NHS Connecting for Health |
| Ireland | Unknown | TBA |

Table 3: Strategy and EHR Model

| Country | Strategy | EHR Model |
|---------------|--|--|
| Finland | Digitization of patient data, interoperability of EHR systems and development of the national health care infrastructure, identification and verification solutions and electronic signatures. | Shared virtual EHR |
| Canada | National co-ordination of a project approach. Collaborative approach. Replicating successful initiatives and sharing best practice. | Hub and spoke repository systems based on a peer to peer network (Distributed EHR) |
| United States | National co-ordination and collaboration to introduce health networks, with a view to establishing a health "network of networks". Strong emphasis on standards for interoperability, privacy and security. | NHIN (Distributed EHR) |
| Australia | A national collaborative approach is being pursued. Currently, the IEHR is being considered. | IEHR has been proposed in 2008 |
| New Zealand | A national collaborative approach towards improving the infrastructure; introducing standards and improving connectivity. A single coordinated strategy is being pursued. Better use of information between service providers. | A distributed EHR model at local, regional and national level. |
| England | A centralised management structure and a combination of national projects. National procurement of systems. | Central Repository. A summary Care Record, a Detailed Care Record. |
| Ireland | It is planned that the EHR will be introduced on a phased basis. Strong emphasis on standards. | TBA |

Table 4: Investment, Funding Method, Procurement, Change Management

| Country | Funding | Funding Method | Procurement | Change Management |
|---------------|--|----------------|------------------------------|---|
| Finland | Unknown | | | |
| Canada | \$1.6 billion Canadian Dollars | Gated Funding | Infoway supports procurement | 15%-30% of the value of each initiative |
| United States | \$200 billion Dollars (estimated) | | | |
| Australia | 132 million dollars (UHI & clinical terminology) | | | |
| New Zealand | No information available | | | Acknowledged in NZHIS Guide G 12.1.2 |
| England | £12.4 billion sterling over 10 years | | Centralised procurement | |
| Ireland | TBA | | | Stated as necessary in NHIS, 2004 |

Table 5: Standards Body and Certification

| Country | Standards Body | Certification |
|---------------|---------------------------------------|--|
| Finland | Ministry of Social Affairs and Health | Drafting for requirements being implemented in 2007 |
| Canada | Infoway Standards Collaborative | eHealth Collaboratory |
| United States | AHIC, HITSP, CCHIT | CCHIT private sector certification. Legislation has been passed regarding interoperability standards for government healthcare programs. |
| Australia | NEHTA | Australian Health Care Messaging Laboratory provides conformance testing of eHealth specifications. |
| New Zealand | HISAC (HISO) | HISAC is currently working on certification |
| England | NHS CfH | |
| Ireland | HIQA | Recommended by the Health Information Society of Ireland |

Table 6: Standards being used

| Country | ePrescribing | EHR Messaging Standard | Imaging | Clinical drug terminology | Lab results | EHR Clinical Coding Standard |
|---------------|------------------------------------|--|------------------------|---------------------------|---------------|--|
| Finland | | HL7 CDA R2 v3 messages for ePrescribing and National Archive. HL7 v2 messages used in most hospitals and health centres | PACS | | | |
| Canada | CeRx | HL7 v3 HL7 v.3 CDA for shared health record | PACS + IHE XDS-1 | | | SNOMED CT |
| United States | NCPDP 8.1 | HL7 v2.4 OR HL7 v2.5.1 HL7 v.3 CDA for NHIN prototypes and RHIN and across government agencies. HITSP for laboratory messages. HL7/ASTM CCD for discharge medications (inpatient EHR) | IHE XDS-1 | RxNorm | HITSP IS-x | SNOMED CT |
| Australia | | HL7 v2.3.1 for referral and discharge summaries, diagnostic imaging orders and results HL7 v2.4 and HL7 v2.3.1 for electronic messages for exchange of information on drug prescription HL7 v2.4 for referral, discharge, and health record messaging. | | | | SNOMED CT |
| New Zealand | HISAC is currently working on this | HISAC recommends the use of HL7 but does not endorse a particular version of it. | | | | HISAC is currently working on endorsing SNOMED CT. |
| England | | HL7 v3 HL7 CDA R2 for the Summary Care Record | PACS | | | SNOMED CT |
| Ireland | | Recommended by HISI and NHIS 2004 | | | | SNOMED CT is being considered |

Table 7: Information Governance and Security

| Country | Information Governance | Security |
|---------------|------------------------|--|
| Finland | | ISO 27799 is being implemented |
| Canada | Infoway | ISO 27799 is being implemented |
| United States | | HIPAA legislation. CCHIT certification for security. |
| Australia | NEHTA | ISO 27799 is being implemented |
| New Zealand | | ISO 27799 is being considered |
| England | NHS CfH | Use of ISO 27000 series of standards |
| Ireland | HIQA | TBA |

Table 8: Privacy and Consent

| Country | Privacy | Consent |
|---------------|--|--|
| Finland | The Data Protection Act 1999 and other legislation exist to maintain privacy and security | Consent required to access patient data |
| Canada | Infoway Privacy Impact Assessment (PIA). PSCA. 10 Privacy Principles of CAN/CSA-Q830-96 | Depends on the jurisdiction |
| United States | HIPAA legislation. CCHIT EHR certification criteria address privacy and security | Not decided yet |
| Australia | A Privacy Management Framework incorporating a PIA has been implemented. | Voluntary participation and opt in arrangements for individuals |
| New Zealand | Privacy Management Framework has been implemented. | |
| England | NHS Care Record Guarantee. NHS Information Toolkit. | Allocated at NHS number at birth. Then there is the option to Opt out. |
| Ireland | Data Protection Acts 1998 and 2003. Proposed Health Bill | TBA |

Table 9: Operating Unit Codes and Unique Identifiers

| Country | Operating Unit Codes | Health care Provider Identifiers | Unique Identifiers |
|---------------|---------------------------|----------------------------------|---|
| Finland | ISO/OID | Implemented | All patients have an electronic ID. Health care provider identifiers exist. |
| Canada | ISO/OID | Implemented | Patient Registries, Provider Registries, Service Location Registries are being created in each jurisdiction |
| United States | TBA | TBA | TBA |
| Australia | No information available. | Being investigated | No unique identifiers currently. IHI and HPI are being investigated |
| New Zealand | No information available | Being developed | National Health Index in place for 20 years |
| England | No information available | No information available | NHS Numbers for Babies allocates a unique identifier at birth |
| Ireland | No information available | No information available | NHIS acknowledges EHR will be based on a unique identifier. Part of the Discussion Paper on the Proposed Health Information Bill. |

CHAPTER 12 METHODOLOGY

The purpose of this chapter is to consider the research topic and to demonstrate how the most appropriate research methodology was employed during the research phase. No interviews were conducted for this research.

Articles for the literature review regarding the benefits and barriers to introducing EHRs were published between 1992 and 2008. Documents accessed for the review of health information strategies and EHR projects were published between 1999 and 2008.

Initial research was undertaken between October and December 2007.

1. The first step undertaken was to electronically access public documents related to current implementations of national EHR systems and national health information strategies. In view of this, a search of electronic databases and health information portals of Canada Health Infoway, ONC, AHIC, NEHTA, NZHIS, HISAC, NHS CfH, HSE, was undertaken using the following search terms:

Electronic health record; electronic medical record; electronic patient record; electronic health record specifications; electronic health records taskforce; computer based patient record; health information technology strategy; information governance; unique identifiers; patient identifiers; electronic health record AND consent; electronic health record AND security; electronic health record AND privacy; electronic health record AND certification; electronic health record AND funding; electronic health record AND change management.

- a. The documents retrieved were reviewed to identify the prerequisites relevant to the ongoing EHR initiatives.
2. Those prerequisites were then further researched to provide the results in chapters 4 to 10.
3. These results were then summarised and put into a table to facilitate a comparison and contrast.

4. A literature review was undertaken in relation to EHRs focusing on a) the benefits and b) barriers. The following databases were accessed Science Direct, Web of Science, PubMed, and ARHQ.
5. It was decided to roughly estimate the cost of implementing a national EHR system in Ireland. Currency conversion was undertaken to convert the information on funding from the currency of the specific country into Euros. Yahoo Finance currency converter was used on 20/08/2008. A billion was taken as being 10^9 , (1,000,000,000) which is a billion shortscale as used in Canada, England and Australia.
6. A further review of research was undertaken in August 2008. This involved accessing the databases and portals of (2) above.
7. On the 6th August 2008, emails were sent to the ONC (USA), HISAC (New Zealand), NEHTA (Australia) requesting information in relation to the following:
 - a. NEHTA: Funding and certification
 - b. ONC: Funding and consent
 - c. HISAC: Funding and consent

One response was received from HISAC.

CHAPTER 13 DISCUSSION

It is interesting to note the observation of Thompson et al in relation to technology in the health care environment "Health care organisations are complex systems of which IT is only one component. There are many processes, cultural, organisational, and other changes that surround IT implementations, and the resulting benefits and difficulties, are the result of a combination of these factors" (Thompson et al, 2007).

The great effort and investment in the international EHR projects that were researched for this report indicates that national EHR systems are seen as critical to the success of health services internationally. The review of the selected international health information strategies showed the author that complex national EHR systems are evolving through phased and piloted approaches. All the national EHR system projects that were researched for this report are currently in the early stages of development and implementation. In some instances, such as, Canada and England, the specifications are finalized to a degree and implementation of a health network for the early stages of EHR systems has begun. In the USA, Australia and New Zealand, the specifications have not yet been finalized. In Finland, some regional networks have been implemented for EHR systems and work is currently underway to link these regional networks to form a national EHR network.

As mentioned in Chapter 10, the DOHC in Ireland has proposed in NHIS 2004 to introduce a national EHR system on a phased basis. In this chapter, the prerequisites for the national EHR systems, that emerged following this research, are discussed and compared to events currently taking place in Ireland, according to the research available.

13.1 Goals

As shown in Chapters 4 to 9, all of the countries studied for this research have the goal of a national EHR system that will provide:

1. Electronic sharing of health data among the authorized providers of care, at the right time, the right place and in the right format.
2. Support to collaborative care by electronically connecting multiple health care locations.

3. Improvements to quality and safety in health care by ensuring clinical information is available to the authorized people at the right time, the right place and in the right format.
4. Maintaining privacy and security of the health information contained in the EHR.
5. Improvements to national health care research and planning.

Findings on comparison and future vision

A comparison of the researched strategies and Ireland's strategy shows that Ireland shares a similar set of health information and national EHR system goals. These have been outlined in the NHIS 2004 (DOHC, 2004a). However, a goal specifically in relation to EHRs has not been stated since 2004.

13.2 Time Frame and Progress

Varying time frames for the implementation of EHR systems were found among the countries reviewed for this research. The countries were at differing stages of EHR readiness when they formed the goal of implementing national EHR systems.

- As shown in Section 6.2, Finland had already commenced some work on the prerequisites to implementing EHR systems, prior to setting the time frame for their goal in 2002 of achieving a national EHR in 5 years. Although it has not achieved this goal, in 2002, Finland had already implemented a national system for unique identification of individuals. By 2005, Finland had a high rate of EHRs in use with 96% of all primary care health centers using EHRs as the main method for documentation. Almost all of the hospital districts and 89% of private sector service providers used an EHR system at least to some extent (Ehealth Era, 2007).
- As shown Section 5.3, America chose a time frame of at least 10 years in 2004. In the US, a survey carried out in 2005 showed that the rate of implementation of EHRs in physicians practices had increased by 31% (NCHS, 2005). The introduction of technical standards and a legal and regulatory framework across the U.S.A. has facilitated an increase in the rate of use of the ePrescribing network by office based physicians. In 2007, there were 35 million electronic prescription transactions (2%) in the USA, it is estimated that this will increase to 100 million (7%) in 2008 (Surescripts, 2007). The USA is still in the early stages of implementation. At the

present time, it is working on the initial stages of an infrastructure by developing regional health information networks and certification standards for EHRs. As a result of the most recent strategic plan, the USA is currently undertaking work in relation to privacy and security frameworks, as well as, improving collaboration among the multiple stakeholders.

- As shown in Section 9.2, England set a time frame of at least 10 years in 2000. To date, in terms of progress, Section 9.1 shows that England has implemented a central database known as the Spine, and the N3 network, which is the backbone of the national EHR system and enables the Summary Care Record. It has also implemented a national PACS system. The Choose and Book service is partially implemented allowing patients to choose their outpatient appointment. Electronic medical record transfers from GP to GP (working alongside the transfer of paper based records) have been implemented.
- As shown in Section 4.2, Canada set a time frame of 10 years to implement EHRs for 50% of the population and has extended this by a further 6 years for 100% of the population. According to the Annual Report 2007-2008 from Canada Health Infoway, Canada has made significant progress in the areas of Diagnostic Imaging and Patient Registry systems which are currently at 64% and 71% implementation respectively. Provider Registry and Laboratory Imaging systems have achieved approximately 30% implementation. The interoperable EHR has achieved 7% implementation, with 47% currently being implemented. 71% of client registries have been implemented (Canada Health Infoway, 2008a).
- New Zealand has not set a time frame for the implementation of a national EHR system. As shown in Section 8.7, it currently has a unique identifier in place. In terms of progress, it is working on standards, identification for health care providers and linking local and regional systems to provide national systems. The creation of key event summaries, which are the high level components of the EHR, and broadening dialogue between primary and secondary care using the key event summaries are priorities of the current strategy, as shown in section 8.2.
- Australia has not set a time frame for implementation of a national EHR system. Regarding progress to date, as shown in Section 7.2, Australia is

working on unique identifiers, standards development and information governance in relation to an IEHR which will work alongside the paper based records.

Findings on comparison and future vision

If Ireland were to set a time frame for implementing a national EHR system, based on the information above, it would be reasonable to estimate that the time frame would be at least 10 years. This estimate is arrived at in light of the fact that Ireland does have a unique identifier in place and has only recently commenced work on the proposed Health Information Bill that must to be in place for secure and private transfer of patient information (DOHC, 2008b).

13.3 Governance Model

The countries researched for this report have shared governance models, which collaborate with public, private and industry stakeholders. National EHR systems require governance because they are large complex systems, which share and generate sensitive and critical information. As mentioned previously, governance is defined by Health Information Strategy of New Zealand (HIS-NZ) as “the set of processes that ensure that an asset or strategy is sustained for the benefit of the group of people who value it” (Health Information Strategy Steering Committee, 2005).

- Section 9.3 shows that England has a centralised management structure with one governing body, NHS Connecting for Health. NHS Connecting for Health reports that having a centralised management structure and central procurement has helped to keep costs down.
- Sections 6.1 and 6.3 outline the background and governance model for Finland. Finland has a decentralised governance model. In Finland, the Ministry of Social Affairs and Health leads the strategy and there are several governing bodies with responsibility in different areas. The health care system in Finland is decentralised.
- Sections 5.1 and 5.3 describe the background and governance structure in the USA. In the USA, the ONC and the AHIC provide advice to the government and co-ordinate between the government and the private sector. It is expected that the AHIC will soon be replaced by another body based in

the private sector, which will help to implement its current strategy of collaboration with industry. This is because the USA has a market led economy where private individuals and business firms make most of the decisions and the federal and state governments buy needed goods and services predominantly in the private market place (CIA, 2008).

- Chapter 8 shows that in New Zealand, there is one governing body, NZHIS, with a full time group manager. HISAC is a business unit group within the structure of NZHIS. The role of NZHIS is to measure and report on the goals and action zones of the health information strategy. It has custodial and operational responsibility for national health event summaries (health records) and, it implements and manages the national health index systems (unique identification) including their security and connectivity. HISAC provides governance, oversight, quality assurance and leadership for the implementation of the NZHIS. It is also concerned with standards, certification, privacy and security.

- In 2004, in Australia, Boston Consulting Group identified fragmented governance as an obstacle to progress in health IM&ICT and proposed a full time new independent body, established for a finite period of time, with the characteristics listed below (BCG, 2004).
 1. Full time team with full time change manager as CEO.
 2. Takes accountability for delivering against timelines.
 3. Proactively interacts and manages stakeholders to maximize the prospect of gaining agreement.
 4. Able to coordinate across projects on an ongoing basis.
 5. Able to review progress of teams and adjust resource allocation on an ongoing basis.
 6. Able to follow through on key decisions to drive implementation.(BCG, 2004)

As mentioned in Chapter 7, NEHTA was formed in 2005 and it is the governing body for the Australian eHealth and EHR systems through provision of standards and infrastructure. NHIMAC advises government, and the AHIC has an expert advisory role.

- As mentioned in Chapter 4, Canada Health Infoway is the governance body for the health information strategy in Canada and has similar characteristics to those outlined by BCG above. It has a shared governance model composed of representatives from the federation of countries which form Canada.

Findings on comparison and future vision

In Section 10.3, it was shown that the NHIS 2004 indicates that HIQA has a central role in the implementation of the NHIS. Action 15 states that HIQA will facilitate the incremental transition to EHRs through the primary and secondary domains. However, the NHIS 2004 does not identify a body related specifically to the implementation of a national EHR system in Ireland. The introduction of EHRs in Ireland could benefit from having a body, such as an EHR Work Group. In order to prevent fragmented governance, it would be beneficial if the EHR Work Group was part of HIQA. This is because as noted above HIQA has been given responsibility for facilitating the transition to EHRs and it is also responsible for standards development.

13.4 Strategy

As shown in chapters 4 to 9, all countries are working towards the same goals through nationally coordinated, phased and piloted strategies. Based on the research undertaken, the strategies generally have the following features.

1. A nationally coordinated and collaborative approach to identify the needs of, and unify the efforts of all the stakeholders involved in health care.
2. The strategies are scalable and flexible, allowing room for revision over time, because neither technology nor the health sectors are static.
3. The strategies use a standards based approach to assist in establishing interoperability.
4. The development of a privacy, consent and security framework.
5. Government funding. There are differences in the strategies in relation to funding, which are outlined in section 13.7.
6. Selection of an EHR model. There are differences in the strategies related to the EHR model, which are outlined in section 13.6.

7. Work in relation to uniquely identifying individuals.
8. Work in relation to uniquely identifying health care providers and locations.
9. Development of a central database and physical network such as a VPN (England). Or, development of regional networks using a VPN to facilitate a shared services model. In such a model one hospital works as the "hub" for a regional service available to all healthcare providers in the area.
10. Improving information flows via the development of critical health information summaries, which are most likely to be useful, such as eDischarge Summaries, national event summaries, GP2GP, and eReferrals.
11. A strategy related to a secure and reliable network.

Findings on comparison and future vision

As shown in Section 10.4, the NHIS 2004 states that EHRs will be introduced on a phased basis. Ireland is currently working on a privacy, security and consent legal framework and the introduction of a unique identifier for health information purposes. Standards development has been addressed in NHIS 2004. However, the author notes that an EHR model, details regarding implementation, details about unique identification of health care providers and location have not been addressed in NHIS 2004. Based on the research undertaken, the author suggests that these should be addressed because they would work towards enabling critical clinical information flows between health care providers.

13.5 Implementation

Based on the overall research undertaken, it is apparent to the author that implementation should integrate information technology, information governance issues, and agreed standards. England appears to have established its information governance framework to some degree. Canada, New Zealand, the USA, and Australia are currently working on the issues related to information governance. The apparent strategies for implementation are outlined below.

1. Canada is adopting a phased approach to implementation. It is focusing the initial EHR implementations in locations where they are most likely to be successful. It has identified that success is more likely in those locations that

have ICT already in place and a strong organizational commitment to implementing the EHRs. It is implementing a 'gated' funding approach. Part of its implementation strategy is to replicate successful initiatives.

2. Finland has implemented regional hospital networks with a high rate of EHR usage and it is now proposing to join the regional networks with the national archive. The intention is to establish a national network.
3. As mentioned in Chapter 10, England has adopted a phased and piloted approach, with centralised procurement of systems and services. It has just finished the first planned phase of its implementation. It has introduced formal implementation guides to assist the NHS organisations in the transition to electronic management of health information.
4. The USA, which is still at the early stages national EHR implementation, is following a project prototype approach and has placed a strong emphasis on certification of products and services that will lead to interoperability and meet security requirements.
5. New Zealand is also in the early stages of implementation. As shown in Section 8.2, New Zealand is focusing on collaboration between multiple organisations and information flows using key event summaries.
6. Section 7.2 outlines the work Australia is currently undertaking to develop its national EHR system. Part of its planned implementation for the near future is the linking of clinical and statistical domains, as shown in section 7.4.

Findings on comparison and future vision

During research, it was noted by the author, that it can be beneficial to follow a stepwise and phased approach. For example, it offers the potential to enable harnessing future technological developments. It could leverage knowledge from previous pilots or trials internationally, thus reducing costs of repeating errors. It could help to manage complexity by focusing on achieving milestones. It provides the option to replicate successful implementations in one area in other areas. Schabetsberger et al have written regarding the introduction of electronic discharge letters to replace paper letters at the Innsbruck University Hospital. They note that a stepwise approach was taken to the introduction of the electronic discharge

letters at the hospital, with the electronic discharge letters leading to the introduction of a patient-centred shared electronic health record over a period of 5 years. They highlight that one of the advantages gained through the stepwise approach was that the results and experiences learnt from the initial steps can be used to streamline the later steps (Schabetsberger et al, 2006). Finland and New Zealand have also adopted a step-wise approach to implementation.

In Section 10.4, it was shown that in Ireland, the NHIS 2004 indicates that EHRs will be introduced on a phased basis throughout the primary and secondary care domains. No information was available on a proposed national EHR system model in Ireland. Based on the information collated for this research, the author suggests that in view of this, it could be beneficial to follow Canada's example by initially, undertaking an assessment of the current situation regarding

1. The systems currently being used and EHR usage rates.
2. The number and types of health service delivery settings.
3. The origins of the data.
4. The expected volumes of health service delivery events that would require EHR sharing.
5. The technology hardware and software already in use in those settings.

The author also suggests that it would be beneficial to develop a conceptual architecture. This would provide a snap shot of high level services, such as a national database, if a centralised model was chosen, or repositories and registries, if a distributed model was chosen. The conceptual architecture could explain the work processes involved, what data is in the system, what communication is required, and define key standards which will be required.

The research undertaken for this report revealed that Finland, England and America have introduced ePrescription networks. In sections, 8.2 and 7.6, it was shown that New Zealand and Australia are working towards introducing event summaries to improve electronic health information flows between carer organisations. As noted in Chapter 7, an event summary is a collection of health care information of a patient related to their ongoing care. The event summary can consist of a series of care record summaries. It has been shown by Bolton et al, that the hospital discharge summary is needed for follow up care of the patient when discharged, and therefore it is an essential document for communication with GPs as it provides

them with clinical and administrative information (Bolton et al, 1998). Castleden et al, also note that the health data cited as being of prime importance includes admission and discharge diagnosis, investigation, dates of admission and discharge, discharge medication (Castleden et al, 1992).

The author suggests that if Ireland were to undertake a stepwise implementation, an option during the first phase of implementation would be to implement a pilot which could use key event summaries, such as eDischarge Summaries and eReferrals. A further option would be to develop and implement an ePrescription network. As noted by NZHIS, such an approach would close key information gaps and provide faster communication of essential information (NZHIS, 2005d). The author suggests that a pilot EHR could be implemented to test the completeness and correctness of the interoperability standards, protocols and security features. Although the research undertaken showed that only one country had developed implementation guides, the author suggests that this would be beneficial to do in Ireland.

13.6 Funding

Funding information was available in respect of 3 of the countries studied. Of these, two of the countries also specified a time frame of at least 10 years for the implementation of EHRs.

Very little information was available on funding in relation to proposed national EHR systems. In general the information available concerned the cost / funding of the entire health information strategy. As noted in Section 4.9, Canada Health Infoway funds 75% of all initiatives related to the health infostructure. This reimbursement is tied to achievement of specific milestones and agreement to use national standards. The table below summarizes the funding allocated in three countries towards introducing a national EHR system and the estimated cost in the USA for introducing a national EHR system.

Table 1 Currency conversion

| Country | Amount of funding | Euro conversion | Approx. Population (millions) | Cost Per Person (euros) | Cost for population of 4.22 million (Ireland) |
|---------------------|--------------------|-------------------|-------------------------------|-------------------------|---|
| Canada (a) | 1.6 billion | 1.03345 billion | 32.5 | 31.80 | 134.196 million euro |
| Canada (b) | 15% of 1.6 billion | 155.01890 million | 32.5 | 4.77 | 20.12940 million euro |
| USA (estimated) | \$200 billion | 135.94800 billion | 302.8 | 449.41 | 18.96510 billion euro |
| England (estimated) | 12.4 billion | 15.63462 billion | 50 | 312.69 | 1.31995 billion euro |
| Australia (a) | 132 million | 77.96615 million | 20 | 3.898 | 16.44956 million euro |

- Australia (a) represents the amount of money allocated in Australia for the development of individual and healthcare provider identifiers and establishing a national clinical terminology. Based on this, it can be estimated that a unique identifier service, health care provider identification service and clinical terminologies could be expected to cost in the region of €16.449 million to implement in Ireland.
- The USA's regional networks (which includes estimates for functionality, interoperability and implementation in physician offices, hospitals, nursing facilities, home health agencies, clinical laboratories, payers and pharmacies) without a central database, would cost in the region of €18.96510 billion over 10 years to implement here in Ireland.
- England's centralized model would cost in the region of €1.31995 billion over 10 years.

- Canada's Health Infostructures costs extrapolate to €134.196 million over 10 years to implement here in Ireland. However, it should be noted that Canada Health Infoway's infostructure is not yet completed and is composed of a number of other health information systems, as well as, the interoperable EHR. These are Digital Imaging Systems, Laboratory Imaging Systems, Drug Information Systems, Client Registries, Provider Registries, and Public Health Surveillance (Canada Health Infoway, 2008a).
- Canada (b) represents the cost of change management at the rate of 15% of each initiative. Based on the overall funding to date, that extrapolates to an estimated €15.8672 million in change management costs over 10 years that could be assumed for Ireland.
- Information was not available on the costs / funding for Finland and New Zealand.

Based on the information available, it is uncertain what a national EHR system development and implementation would cost in Ireland, without a conceptual architecture for the EHR model. A centralized model would appear to be more expensive than the distributed model. The implementation of a distributed EHR and ehealth services in Ireland, could be estimated to cost in the region of €150 million over 10 years. This figure is based on the cost of Canada's EHR model and infostructure, plus the costs for implementing the unique identifiers and clinical terminology. However, it should be noted that costs incurred in the introduction of a national EHR system, will be offset by reducing costs to the health sector that were incurred using paper based communication. For example, in Austria, electronic discharge letters were introduced at Innsbruck Hospital. The researcher on the project notes that that the introduction of electronic communication to replace paper based communication covered the costs of the project within one year (Schabetsberger et al, 2006).

13.7 EHR Model

Based on an evaluation of the findings of the research for this report, 3 alternative models have been proposed for introducing EHRs that can exchange information across different health care providers / hospitals. They are as follows:

- 1) A central model which replaces the existing paper record

- 2) A distributed model which replaces the existing paper record
- 3) An individual health record which does not replace the paper health record, but works along side it.

Within these 3 options, 4 types of national EHR systems have been proposed to replace existing paper records, and one alternative has been proposed to work along side existing paper records.

- 1) A central Summary Care Record with a single central national repository of data.

Data is referenced by a national unique identifier. The NHS Connecting for Health Detailed EHR will be an example of a central EHR and the NHS Summary Care Record is a central summary EHR as shown in Section 9.5. Data is pushed to the central repository known as the Spine, by the N3 which is a VPN, using HL7 messages.

- 2) The initial stages of a distributed EHR with a central national digital archive for patient documents. Data is referenced by a national unique identifier.

In this model, data will be exchanged at national level not at regional level. As shown in section 6.5 and 6.6, Finland is working towards this model currently, by joining up regional networks and has a national unique identifier in place. New Zealand also appears to be working towards this model and has a national unique identifier in place. It also has National Collections, which appear to the author to be similar to an archive (Health Information Strategy Steering Committee, 2005e).

- 3) The initial stages of a distributed EHR without a central national digital archive.

In this instance health care providers form a group and agree to share information. This EHR information is then uniquely identified within the region / group and linked electronically to provide a record of previous patient care. These EHRs are said to be virtual EHRs because patient data is integrated from many applications and repositories across health settings to provide a single view of the patient's health history. Often Master Patient Indexes (MPIs) are used to verify the many identification numbers that a patient may have in each group. These numbers are cross indexed in the MPI in order to locate and retrieve records from multiple sources / groups. Regional middleware links regional EHR systems and combines EHR location

services with ERH viewing services and security management services. Registries provide unique identification of key actors in the EHR group / region. As shown in Section 4.5 and 4.71, Canada, which has a peer to peer network of interoperable solutions with no national identifier, is working towards a distributed EHR model (Canada Health Infoway, 2006a). America also seems to be working towards this model. The NHIN will not include a national data store or centralized systems at the national level. Instead, health information exchanges will be interconnected by a shared architecture of services, adopted standards, and requirements.

- 4) An additional new channel of communication, which is not intended to replace local records, has also been proposed.

As shown in section 7.6, an example of this model is the Individual Electronic Health Record (IEHR). It is currently being proposed in Australia. The proposed IEHR will contain selected portions of an individual's health record rather than the whole record.

Findings on comparison and future vision

No research could be found relating to the EHR model that will be used in Ireland. The NHIS 2004 has stated that a unique identifier will be introduced and there will be a central database (DOHC, 2004e). This indicates to the author that a distributed model with a unique identifier could be selected as a national EHR model in Ireland. Therefore, on the basis of the information gathered during research, it is the author's opinion that the best fit would be to work towards a stepwise introduction of a distributed EHR model. The design of the distributed model should be informed by the processes and standards necessary to enable critical information flows between health providers, initially on a regional basis.

13.8 Standards Body

As shown in Chapters 4 to 9, all the countries researched have a Standards Body. Standards require ongoing work and development to meet the requirements of national EHR systems to achieve working appropriate solutions to clinical and information governance needs. As noted by Gartner, "standards development is a very exacting process with a multi-year lead time between project initiation and full realization in systems in widespread operation. To be effective, architecture both informs the selection of standards to be developed, and recognizes the opportunities of standards that are in place" (Gartner, 2007b). The standards body

provides the processes to review standards, in view of changing needs, changing business requirements and developments in technologies. Standards development involves the work of several Working Groups and Standards Committees for developing and describing which standards will deliver overall national EHR system interoperability. The standards body provides overall co-ordination of those groups and committees in bringing the standards together for use in the National EHR system, which as noted previously is large and complex. A standards body must take part in international collaboration on standards development, to learn from best practices.

Findings on comparison and future vision

HIQA has been assigned responsibility for health information standards development in Ireland.

13.9 Certification

Based on the information available, 2 out of the 6 countries researched use certification. As shown in Section 4.4 and 5.4, Canada and the United States are both undertaking certification of services in relation to the EHR systems. The USA has developed criteria for ambulatory and inpatient EHRs in relation to interoperability, security and functionality for system vendors. The eHealth Collaborative in Canada assesses products and services and provides assurances that they comply with recognised standards, if appropriate. 2 countries, Finland and New Zealand, are currently drafting certification requirements, as shown in Sections 6.4 and 8.5. 1 country, England, has a large testing facility but their solution to eHealth is based around common implementations, not common specifications, according to the Interoperability Framework of Australia (NEHTA, 2007a).

It is generally known that certification of products may increase purchaser confidence. This is because certification confirms that the product or service meets the national conformance criteria for standards and will be suitable for use in an interoperable EHR environment. However, it has been noted by Terry that certification must be rigorous to be effective (Terry, 2007). Based on the research undertaken for this report, it is uncertain if Australia has implemented certification. However, NEHTA does identify certification as being important, stating that "in isolation standards and specifications provide guidance for interoperability, but it is only through the use of some measured adherence to these standards and

specifications that benefits will be realised” (NEHTA, 2007a). Kluge suggests, specifically in relation to information security and consent regarding the EHR, that it could be appropriate to have a certification authority with the objective of ensuring that security structures and protocols are met (Kluge 2004).

Findings on comparison and future vision

In Ireland, Action 2 of the NHIS 2004 states that HIQA will assess conformity with the national health information standards framework (DOHC, 2004f). The Healthcare Informatics Society of Ireland has also called for accreditation and certification of EHRs within Ireland and across Europe to be undertaken (HISI, 2006). During research it became apparent that in relation to security and privacy, the countries researched are progressing toward embedding privacy and security in to the EHR products and services at the design stage, particularly in Canada, Australia and the USA. As shown in section 6.4, Finland is drafting certification in relation to privacy and security. Section 5.4 indicates that the USA is also undertaking certification in this respect. The certification is based on existing legislation and policies in relation to privacy and security. It is the authors opinion, based on research that in order to strengthen the confidence of users and purchasers of EHR products and services in Ireland, certification in relation to privacy and security should undertaken in the proposed national EHR.

13.10 EHR Clinical Coding Standard

SNOMED is a terminology which can be used for clinical coding. As shown in Chapters 11, Table 6, SNOMED CT is being used by all the countries researched. HISAC in New Zealand is currently working on endorsing SNOMED CT. Semantic interoperability is one goal of selecting EHR clinical coding standards. Bernstein et al report that semantic interoperability can only be achieved by continuous standardization work supported by validation and evaluation with participation from health care professionals (Bernstein et al, 2005a).

Findings on comparison and future vision

Based on the research undertaken, and in view of the fact that countries selected for research are using SNOMED CT for clinical coding, the author suggests that Ireland should adopt SNOMED CT for use in the proposed national EHR.

13.11 EHR Standards

Schloeffel confirms that the lack of interoperability between EHR systems has been a major barrier to EHR deployment and that the emergence of the open models and open architectures has provided a significant stimulus to the development of interoperability and other necessary EHR standards within the major international standards organizations such as ISO, CEN and HL7 (Schloeffel, 2004). The reason information to be shared within the EHR domain is complex, is because it arises from different clinical contexts, and is transmitted by different and often heterogeneous health information systems. HL7 is a global standard. All information systems following the HL7 standard specification are able to communicate with each other without the need for information conversion. HL7 v3 contains a Reference Information Model (RIM). This is to establish semantic interoperability. HL7 CDA allows the standardized representation of clinical documents, such as discharge summaries, medical history reports and progress reports. By using XML coded vocabularies, the CDA documents are both machine readable and human readable. HL7 version 3 is a more recent standard than HL7 version 2. CDA can be embedded in both versions. Cruz-Correia et al conducted research with regard to integration of patient data in relation to how systems are evolving in practice to meet patient needs. They found that messaging technologies such as HL7 are more used than middleware solutions and that web based technologies support most of the projects. They also found that information systems are being integrated to provide regional networks (Cruz-Correia et al, 2007).

As shown in Chapter 11, Table 6, all the countries researched are using HL7, although there are differences in which versions are being used in each of the countries. HL7 version 3 is being used in Canada and England. The United States is using HL7 version 3 CDA for NHIN prototypes and it is also using HL7 version 2. Finland is using a HL7 CDA R2 version 3 for ePrescribing and the national record archival service. It is using HL7 v2 in most hospitals and health centers. Currently HISAC in New Zealand endorses HL7, but does not endorse a particular version of it. Australia has opted to continue with HL7 version 2 for the short to medium term. Therefore, based on the information available at the time of research, the standards currently being used are as follows:

- HL7 version 2.x and / or HL7 version 3 for messaging (All countries)
- HL7 version 3 CDA for representing clinical documents (England SCR, Canada and USA)

- DICOM standards for PACS (3 countries)
- IHE XDS messaging for images and radiology (USA and Canada)
- NCPDP for ePrescribing (USA)
- CeRx HL7 v3 specifications for ePrescribing (Canada)
- HITSP 1S-01 EHR Lab to respond to query for lab results (USA)
- Rx Norm for clinical drug terminology (USA)

Findings on comparison and future vision

During research of the Finnish EHR initiative, the option of introducing EHRs in Ireland by commencing with ePrescribing and event summaries became apparent. In light of this, high level research was conducted by the author for this report, into the standards that would be required to implement such summaries and processes. This involved comparing the standards of the 2 documents below.

A review of the preliminary scope and approach document developed by HISAC, in relation to ePrescribing, shows that at a high level, the prerequisites in relation to standards, would be as follows:

- A common communication messaging standard.
- Prescription formats, a universally used electronics pharmaceutical schedule that contains definitions of medicines and how they should be used.
- An acceptable universal code for medicines especially when they are not used at packet level, as is the case in hospitals.

(HISAC, 2007).

A National Discharge Summary Data Content Specification produced by NEHTA was reviewed to find the prerequisites for an eDischarge Summary. According to NEHTA, in relation to the implementation of an eDischarge Summary, clinical information is recorded based on the nature of the health problems/ diagnosis, diagnostic tests done, assessments, medications prescribed, and interventions performed and / or planned (NEHTA, 2006a). Based on the Data Content Specification, it is assumed that the following standards would be required as follows:

- A common communication protocol or messaging standard.

- Prescription formats, a universally used electronics pharmaceutical schedule that contains definitions of medicines and how they should be used.
- An acceptable universal code for medicines especially when they are not used at packet level as is the case in hospitals, agreement about whether clinical data repositories should be held at regional or national level.
- A terminology for clinically coding / classifying diagnoses
- A terminology for clinically coding / classifying procedures.
- A terminology for clinically coding laboratory results.
- A communication protocol for representing the document such as HL7 CDA.

A subset of the standards required for eDischarge summaries seem to exist for ePrescribing. In both cases unique identification of the health care provider and the patient, are essential, while maintaining privacy and security. In both cases change management processes will be needed to provide support for new methods of delivering health care. It is the authors opinion, based on the information collated, that priority should be given to the development and consensus on the standards required for reliable exchange of ePrescription and eDischarge summaries initially. This would derive maximum benefit from the work undertaken as a similar set of standards are used within both health information flows.

13.12 Unique Identifiers

As shown in Chapter 11, Table 9, 3 countries researched had national unique identifiers in place in the health sector, Finland, New Zealand and the UK.

1 country had regional identifiers, which could be linked (Canada).

2 countries are undecided (USA and Ireland).

1 country is currently working towards national unique identifiers (Australia).

1. Canada has chosen not to use unique identifiers nationally. It has opted to use registries for patients which require master patient index software for matching.
2. The National Health Index is the cornerstone of health information in New Zealand. It is an online population based register that includes a unique random generated identifier. The NHI numbers cannot be related to

databases from other sectors of the economy or databases used for different purposes.

3. On the contrary, Finland has had a unique identifier in place since the 1970's. It is used for health, banking and employment. It is based on the birth date and a serial number in each community and a check number.
4. In England, the NHS number was designed specifically for use as a unique identifier for EHRs within the NHS, which is the largest care provider in the country. Babies will be assigned the NHS number at birth, while other patients need to join the NHS to get a NHS number.

Findings on comparison and future vision

Unique Identifiers are essential to the development of national EHR systems but may present a threat to personal privacy unless properly used. As noted by HealthOnline, "The degree to which the individual consumer's privacy is protected, and is perceived to be protected, is crucial to the success of initiatives aimed at a greater sharing of personal health information by electronic means" (Commonwealth of Australia, 2001a). Currently, multiple identifiers are in use across the health care sector in Ireland. Unique identifiers are needed because most health records are identifiable only in the location where the patient received care (DOHC, 2004b). As the model of care has changed from an inpatient model of care to the collaborative care model, there is a need to link these records together to provide a longitudinal record. The Discussion Paper on the Proposed Health Information Bill sets out the features of a unique health identifier as outlined below. Although information was not available on the features of unique identifiers in all the countries researched, these features are similar to the unique health identifier which is currently being proposed in Australia, as shown in Section 7.7.

- o A summary record: identifier, name, date of birth.
- o An identification record: summary record information, plus further identifying information, such as address.
- o A demographic record: identification record information, plus additional data fields such as mobile phone number.

As noted in Section 10.6, in Ireland the NHIS 2004 has proposed that a unique identifier will be put in place and that it may be based on the PPS number. It was suggested in the NHIS that the PPS number could be used for the purposes of unique identification. This is because each person has only one, it is a robust means for unique identification and authentication, there is provision for a high level of

protection and security, and it can provide linkages to the wider public service. The main concern regarding unique identifiers is in relation to privacy “the right to control how information is obtained, used and disclosed” (DOHC, 2008). It has to be noted that information identified by the PPS, if it were used to link health information, is also currently used as an identifier on bank account applications and mortgage applications. In Australia Tax File Numbers were misused as a means of identifying people and the Australian Parliament enacted restrictions on their use (Australian Government, 2007). New Zealand also places restrictions on the use of the NHI index. However, as noted in Section 6.7, in Finland the unique identifier is used for multiple purposes and research could not be found that indicated there were problems associated with that. It is the authors opinion, in relation to identity theft and function creep, that if Ireland were to use the PPS number, as a means of identifying people for health care purposes, it would be worth considering preventing the use of the PPS number for other purposes by legislation, as has been done in Australia and New Zealand.

13.13 Health Care Provider Identifiers

It is the author’s opinion, that all systems functioning in a national EHR will need an acceptable national method of authenticating users of the systems. Authenticating users means granting access based on permissions and identity proofing. Audit trails of those who access health information based on identifiers for health care providers will help to mitigate the risk of private data being accessed unnecessarily or misused. It was noted in Section 5.82 that this is being undertaken in the USA. Among the countries researched, information was available on the processes used in 2 countries to determine when a health worker has a valid reason to access health information. England has implemented role based access, as shown in Section 9.82. In section 5.82, it was shown that in the USA, CCHIT criteria for security include restrictive role / group based access control.

Health care provider identifiers are required by HL7 version 3 messaging for coding systems. As shown in Section 8.7 a Health Practitioners Index is currently being developed in New Zealand. As shown in Section 7.82, Australia’s NASH system will provide identity health cards for authentication of health care providers. The Australian Privacy Blueprint, also notes that authentication of health care providers is critical to the successful implementation of the EHRs (NEHTA, 2008d). A PKI system and digital certificates are used in Finland for authentication. A PKI system is a digital certificate system which allows computer users to be authenticated to

each other without prior contact. The information in their public key certificates is used to encrypt messages to each other. A PKI consists of client software, server software, hardware such as smart cards, legal contracts and assurances, and operational procedures. A PKI system uses digital certificates after agreed identification and registration processes have been completed. Digital certificates are usually stored on a smartcard. Canada Health Infoway notes that it is very likely that digital signatures will be used in prescribing in Canada because they provide a powerful data integrity mechanism. This is because digitally signed data cannot be tampered with or altered without invalidating the signature (Canada Health Infoway, 2006a). Digital signatures are based on encryption algorithms.

Findings on comparison and future vision

The NHIS 2004 mentions health provider identifiers in the context of the REACH/eBroker initiative in Action 15 (DOHC, 2004b). It has been shown that sharing health information requires an authentication system to ensure that all safety, integrity and privacy requirements are met. Based on the research collated, it is the author's opinion that Ireland should press ahead with work on health provider identifiers, in line with the countries researched for this report.

13.14 Information Governance

In 2007, public opinion was sought on EHRs in the context of privacy in Canada. It indicated that 88% of Canadians support the implementation of EHRs, but that this support is tightly linked to the need to safeguard personal information contained in those records (Canada Health Infoway, 2007a). It is well known that health information is collected in a situation of trust and confidence. The aim of information governance is to leverage strict controls and procedures to ensure the privacy and security of the information in the EHR is maintained. In view of this, information governance deals with the rules related to information collection, use, disclosure, and management in an interoperable EHR environment. Based on the information from the countries researched this includes:

- Consent by a patient to have an EHR and permit access to the information contained in it, some of which may be considered sensitive information.
- Access rights to the data.
- Authentication of the person accessing the data.
- Complaints regarding use of the data.
- Permissible secondary uses of the data.

- Legislation regarding archiving of the collected health information over the long-term and / or its disposal or anonymisation.
- Identity management of health care workers.
- Identity management of patients who may wish to access their data.
- The nature of sensitive information and how to accomplish a balance between the patient wishing to keep sensitive information private and providing access to complete medical history.
- How to define secondary use of data.
- Governance arrangements which will apply to secondary use of health information.
- Determining the consequences of breaking the rules/policies/legislation that will apply to all of the above.

It was found during the research process that all the countries are reviewing their legislation in relation to rules for collecting and disclosing information. They are focusing on consent, privacy and rules related to secondary use of data in relation to electronic health information. The purpose for the review of legislation is to achieve a balance between patient rights and trust, and facilitating the flow of health information.

In addition to legislation, as shown in Section 4.81, Canada is approaching the area of information governance with the design of a PSCA. The PSCA states the services that are critical to privacy and security and assists the designers of EHR products and services. The US is incorporating security and privacy frameworks into the architecture of the NHIN which will be based on policy and legislation. NEHTA has existing privacy legislation and is assessing the issues regarding privacy within its Interoperability Framework document and in consultation with the Australian Office of the Privacy Commissioner. Canada, NEHTA and the US have highlighted that the EHR architecture is strongly related to policy. In the US, Gartner noted that there is a bidirectional relationship between NHIN architecture and policy because each informs the other and each will be subject to change and new developments. Therefore the architecture must be flexible to accommodate changes in policy that will occur in the future (Gartner, 2007a).

Findings on comparison and future vision

A national EHR system requires a privacy and security framework based on a legal framework to enable health information to be stored, exchanged, updated and used. Such a framework is absolutely necessary for the designers of the systems which

will provide the technology to enable the EHR. It is proposed that a new Health Information Bill will be enacted in Ireland in the near future to address and state what the law requires in relation to unique identifiers and privacy in the context of the proposed EHR. It is the author's opinion, based on the research available, that it would be beneficial to develop a framework similar to a PSCA in Ireland.

13.15 Security and Privacy

This research shows that all the countries acknowledge that privacy and security are fundamental to the implementation and use of EHR systems.

Security

In terms of a national EHR, security is concerned with providing a means to protect information against improper access and interception during electronic transmission and mitigating against these risks. The objective of a security policy is to maintain the confidentiality, availability and integrity of the network, the systems, and the information. Availability means that the system is accessible and useable upon demand by authorized persons and entities. Confidentiality entails ensuring that the information is not made available or disclosed to unauthorized users, or processes. Integrity means ensuring that systems and data have not been altered or destroyed in an unauthorized manner. A security architecture is an essential requirement for a national EHR system which links records and identifications over a network. Security architectures need to be flexible because they are informed by policy and regulations, both of which are subject to evolution due to changes in society. Security in relation to the EHRs includes system security, network security, security standards and guidelines, and security training requirements.

ISO 17799 is an international standard which establishes guidelines and general principles for initiating, implementing, maintaining, and improving information security management in an organization. ISO 17799 has been renumbered ISO 27799:2006. It contains 11 security control areas which are as follows: information, asset, human resources, physical and environment, communications and operations, access control, incident handling, business continuity, compliance and information systems acquisition, development and maintenance. As shown in Chapter 11, Table 7, ISO 27799 is being implemented by Canada, Finland, and Australia. New Zealand is currently considering using ISO 27799. England is implementing the ISO 27000 series of standards.

Section 5.82 shows that in the USA, the HIPAA final security rule requires that organisations create security policies and procedures in accordance with the security requirements of the law. HIPAA Conformance testing leads to HIPAA certification. According to the most recent Strategic Plan in the US, a confidentiality, privacy and security framework is due to be published this year. As mentioned earlier in Section 13.12, Finland and Australia are developing PKI systems which issue digital certificates for authorising access to EHR information by health care workers. Audit trails are being implemented as part of the EHR systems. Audit trails of those who access health information will help to mitigate the risk of private data being accessed unnecessarily or misused.

Privacy

Privacy is concerned with how much a person feels in control of the sharing of their personal information. "Personal data is any information (including an opinion or comment) about a living individual who is capable of being identified, either from that information or from that information in conjunction with any other information currently in the possession of or likely to come into the possession of the data controller" (Data Protection Act, 1988). The motivation to protect privacy in the area of EHR systems has led to protective legislation and policy making in all the countries that were included in this research. Section 9.81 shows that England has implemented the Care Record Guarantee which sets out the standards regarding confidentiality and privacy. Further emphasis on privacy protection has led to Privacy Impact Assessments being implemented by Australia and Canada, as shown in Section 7.81 and 4.81. A PIA should state how a system functions, how it will comply with privacy legislation, and it should identify privacy risks and provide strategies to mitigate those risks. HIPAA Conformance testing in the USA leads to HIPAA certification. HIPAA's Privacy Rule provides privacy protection through informed consent to maintain privacy. As noted in section 7.81, Australia aims to embed privacy into the design process. Ensuring compliance to legislation and policy during the design stage is also being undertaken by Canada via the PSCA, as noted in section 4.81.

Findings on comparison and future vision

This is a controversial area because there is a difficulty in providing privacy while allowing records to be shared and while allowing secondary use of information for purposes such as research and health planning. The Data Protection Acts and Freedom of Information Acts, European Union and human rights legislation at present protect an individual's privacy in Ireland. The proposed Health Information

Bill will address and state what the law requires in relation to security, privacy, sensitive information and secondary use of health information in the EHR in Ireland. It is the authors opinion that Privacy Impact Assessments (PIA) should be developed, based on the forthcoming legislation. The PIAs should be used to guide system developers and designers of the proposed national EHRs.

13.16 Consent

As shown in Chapter 11, Table 8, the two main models of consent found during the research conducted for this report are "opt in" and "opt out" models of consent.

Consent must always be informed to be valid. According to the Discussion Paper on the Proposed Health Information Bill, the elements of informed consent are that "1) There must be awareness and understanding of the nature and extent of processing, especially in terms of intended and likely uses and disclosures of the information involved. 2) There must be awareness of the options to prevent such processing, either or in relation to, any particular aspect. 3) There must be an effective mechanism to enable withholding consent to be effective and 4) absence of coercion" (Discussion Paper on the Proposed Health Information Bill, 2008).

Each of the countries researched chose different consent models for patients in relation to access of their EHRs. In Finland, informed consent is required to access patient data. In Canada consent is required as defined by the jurisdiction. In New Zealand, consent will be governed by the proposed New Zealand Health Privacy Code. Australia has decided to use voluntary participation and "opt in" arrangements for individuals to use EHRs. In England, implied consent is used to access a person's Summary Care Record and patients can choose to limit their participation in 3 ways. The Care Record Guarantee sets out the conditions for accessing and sharing the Summary Care Record. In the United States consent to the use of your medical information for medical treatment or payment is not required. Ireland is working on arrangements regarding consent.

Findings on comparison and future vision

Following the research for this report, the author feels that the information retrieved was limited by lack of published reports concerning the types of consent in the selected countries. For example from the research it was not possible to determine if the consent referred to in the literature was to actually access information or consent to join in the national EHR system and then provide further

consent. It is stated in the International Medical Informatics Association (IMIA) Code of Ethics that “potential subjects of EHRs should be made aware of the existence of any systems, programs or devices for collecting and / or communicating data about them, and that they have the right of informed consent to the actual construction of such records as well as to the use, storage, communication, manipulation and other processing of these records and the data that are contained in them” (IMIA, 2002). Kluge explores consent and reports that EHRs require an appropriately designed security architecture for health information systems to protect a patients right to informed consent. Kluge also mentions that the security architecture should contain a means for reassigning consent rights, as appropriate (Kluge, 2004a). Based on Kluges article, the author feels that this will be particularly important if unique identifiers and records are assigned at birth. Ireland is currently working on consent arrangements, which is similar to the countries researched for this report. The Discussion Paper on the Proposed Health Information Bill confirms that the extent to which patient consent should determine the use and disclosure of personal health information is a critical matter, which will be addressed by the proposed Health Information Bill following public debate.

13.17 Change Management

Canada Health Infoway notes the importance of addressing change management related to the human and behavioral impacts of adopting information and communications technology in health care sector (Canada Health Infoway, 1999). The Australian Interoperability Framework also acknowledges that a commitment to change management is required, because it sees change management as an ongoing process (NEHTA, 2007). The Interoperability Framework outlines that change management is important for both ensuring that the changes in the EHR architecture are managed in response to changes in technology and business environments, and also in the dissemination of information regarding the EHR system and business environment. Knaup et al also note the changes in processes and attitudes which are needed to move to the electronic management of patient records (Knaup, 2007). Schabetsberger et al report that following the introduction of electronic discharge letters at Innsbruck Hospital, the organizational difficulties outweighed the technical difficulties. Two of the following areas are cited by them as needing organizational changes in the future: workflow in document creation, support in case of transmission failures (Schabetsberger et al, 2006a).

Findings on comparison and future vision

The NHIS 2004 highlighted that the introduction of national EHR systems is a complex process which leads to organizational, cultural, management and information governance changes (DOHC, 2004e). Information governance changes were mentioned in Sections 13.14 to 13.16. EHRs will bring changes within the health sector in relation to how information is captured and used. According to a recent report, the structure-process-outcome chain is central to the role of EHRs in quality, because an EHR is a tool that explicitly links these three. The report suggests that in order to derive value from the EHR structure, new clinical processes need to be designed to utilize the EHR functional structure (AHRQ, 2006b). Such new clinical processes will bring changes in work processes which will require guidance, education and training. The NHIS 2004 in Ireland also acknowledges the importance of a commitment to change management on the part of the stakeholders (DOHC, 2004g). It is the author's opinion, based on the research information available, that it would be beneficial to establish a work group in the future, in relation to change management. The objective of the work group would be to promote the use of EHRs so that optimal use is derived from them in existing work practices. A further objective would be to identify new opportunities for their further development. In view of this, it would be beneficial for the work group to undertake research in the area of electronic management of health information on an ongoing basis during pilots of a proposed distributed EHR system.

13.18 Health Portals

The Discussion Paper on the Proposed Health Information Bill acknowledges the need for a health information portal to promote awareness of the benefits of eHealth (DOHC, 2008c). The countries researched have expanded on this and developed communication strategies via their governance body websites specifically in relation to the EHR projects and initiatives. In Australia, NEHTA sees part of its role as informing interested parties about the EHR agenda, to promote an understanding of, and commitment to the EHR strategy and the progress being made. Canada Health Infoway, the ONC in the USA, and HISAC in New Zealand, also have similar communications strategies in place to keep interested parties informed regarding health information technology and EHRs project progress.

Findings on comparison and future vision

Action 14 of NHIS proposes that a Health Information Portal will be developed and that this will be provided for by HIQA as part of its ICT action plan. It is proposed

that this portal will contain library and data access facilities, eHealth services information, and notification of urgent information to specified stakeholders (DOHC, 2004h). It is the author's opinion, based on the research undertaken, that a communications strategy with regard to the ongoing development of the proposed national EHR system should developed and put in place. A section of the health portal could be used for that purpose.

CHAPTER 14 CONCLUSION

A review of the NHIS 2004 highlighted to the author the barriers to retrieving health information in Ireland that currently exist (DOHC 2004d). NHIS 2004 also carefully explains the plans to introduce a national EHR system. The aim of the research for this report was to make recommendations with regard to introducing a national EHR system in Ireland. The research subsequently undertaken highlighted the prerequisites for national EHR systems, which are included in chapters 2, chapters 4 to 9 and discussed in chapter 13. The main findings and recommendations are outlined below.

14.1 Findings

The research undertaken confirms that the management of introducing a national EHR system requires strategies that address the EHR model, interoperability, standards and terminologies, unique personal identifiers, unique identifiers for health care providers and locations, information governance and funding.

These strategies must also address the infrastructure in which the EHR system will operate in relation to the health care system, information governance and technology. Therefore, these strategies must include an assessment of the various levels of IT preparedness, an assessment of the current technology and standards, and an assessment of current information governance legislation and policies. Change management strategies will be needed to address the human and behavioural impacts of EHRs. Change management will be required to inform and educate the stakeholders, and to manage and promote the uptake of EHRs. National EHRs are in the early stages of development. Each country studied has taken different approaches to introducing a national EHR system, and there is potential to learn from their experiences. It is within this context that introducing a national EHR system in Ireland should be considered.

The NHIS 2004 is cognisant of these requirements. HIQA has been established to ensure that a national approach is undertaken regarding the introduction of new health information policies and initiatives. NHIS 2004 states that electronic health care records will be implemented on a phased basis (Action 15). NHIS proposes that HIQA will facilitate this in a coordinated manner throughout the primary and secondary care domains in partnership with the DOHC, the health agencies, the National Primary Care Task Force and other groups.

The authors recommendations which follow are based on possible ways in which the gaps in the action points set out in the NHIS 2004 might be addressed so that they benefit from the lessons learned from the EHR initiatives of the countries that were researched for this report.

14.2 Recommendations

These recommendations are not intended to establish a blueprint for a national EHR in Ireland. The intention is to identify possible steps which could be taken to accelerate the electronic management of health information and close information gaps.

14.2.1 Governance Model

National coordination is essential for a national EHR implementation. The NHIS indicates that HIOA has a central role in the implementation of the NHIS. However, the NHIS does not identify a work group or body related specifically to the implementation of a national EHR system. The current status regarding the development of standards to facilitate electronic exchange of health information was not available to the author. In view of this, the timing for the recommendations that follow is unknown.

Recommendation 1

- 1.1 An EHR Work Group should be established when the standards necessary for electronic health information flows of key event summaries have been developed.
- 1.2 The EHR Work Group objectives should be
 - 1.2.1 To coordinate and drive an initial national pilot implementation, followed by regional implementations,
 - 1.2.2 To facilitate stakeholder collaboration and the actions needed to bring the stakeholders together.
 - 1.2.3 To identify barriers to implementation and make recommendations on how to remove those barriers at local and national level.

- 1.2.4 To create an online communications strategy. The communications strategy will provide assistance in relation to implementation and transition support in respect of the following:
- i. In the adoption and use of EHRs.
 - ii. In terms of understanding the costs and benefits.
 - iii. In relation to avoiding implementation failures, and to respond to technical questions as appropriate.
- 1.3 The EHR Work Group should be established for a finite period of time.
- 1.4 The EHR Work Group should have a full time Group Manager who reports to the relevant governance body.
- 1.5 The EHR Work Group should be responsible for reporting on progress and impediments to progress, in the area of implementation, to the relevant governance body.

14.2.2 Strategy and goal

Research on the health information strategies of the countries reviewed shows that health information strategies need to be flexible and regularly updated. The strategy to introduce a national EHR system in Ireland was published in 2004. Action 27 of the strategy states that HIQA will review the strategy and update it (DOHC, 2004g). Recommendation 7.45 of the Report of the Commission on Patient Safety and Quality Assurance recommended that HIQA, the Department of Health and Children, the HSE and the Health Inter-Agency Group work together to review the strategy and progress with its implementation (DOHC, 2008d).

Recommendation 2

- 2.1 NHIS 2004 should be reviewed and updated.
- 2.2 The revised strategy should include the goal of introducing a national EHR system inclusive of a) a pilot implementation b) a national implementation.
- 2.3 The strategy should set out the required building blocks, steps to implementation, milestones, funding and a timeframe.

14.2.3 EHR Model

As discussed in Chapter 13, a distributed EHR model is less costly to implement than a central model. It was noted during research that eDischarge Summaries facilitate electronic management and delivery of critical health information. NEHTA has developed specifications for an eDischarge Summary Template that can be sent using EHR systems, using messaging or delivered manually.

Recommendation 3

- 3.1 A distributed regional EHR model should be chosen.
- 3.2 A conceptual architecture for the national EHR system should be developed.
- 3.3 eDischarge Summary Templates should be investigated and developed for use in Ireland.
- 3.4 A pilot of the EHR model should be commenced. It should have a regional infrastructure that would link one or more public hospitals, and GPs. It should enable the transmission of event summaries, such as eDischarge Summaries and eReferrals. This model could be then be reviewed after one year and refined as appropriate.

14.2.4 Implementation

In Ireland, the NHIS indicates that EHRs will be introduced on a phased basis throughout primary and secondary care domains. In light of the research undertaken, it can be seen that Ireland is currently working on the foundations for implementation of a national EHR system, specifically in the areas of unique identifiers, standards for clinical coding and a security, privacy and consent framework. At the moment an analysis of the current health information situation is an objective the Health Information Directorate of HIQA (HIQA, 2008).

Recommendation 4

- 4.1 An assessment of the current situation regarding health information systems and EHR use should be undertaken. This should include an assessment of the number and types of health service delivery settings and the origins of the data, the expected volumes of health service delivery events that would require EHR sharing, the technology hardware and software already in use in those settings.

- 4.2 Based on this assessment those areas which have a high use of EHRs or would be likely to implement them successfully should be identified.
- 4.3 One of the above areas should be chosen to pilot an EHR implementation.
- 4.4 Implementation guides for stakeholders should be designed and developed.
- 4.5 A stepwise approach to implementation should be taken.

14.2.5 Time Frame

Among the countries reviewed, the average time frame for introducing national EHR systems has been approximately 10 years. Ireland should set time frames, if possible, for the following milestones.

Recommendation 5

A timeframe for developing a privacy and security conceptual architecture based on the forthcoming legislation.

A timeframe for investigating and developing eDischarge Templates

A timeframe for introducing one pilot implementation of a distributed regional model based on a privacy and security conceptual architecture and implementing eDischarge Summaries and eReferrals.

14.2.6 Funding

There is uncertainty about the true cost of introducing a national electronic health record system in Ireland. The cost has been estimated during this research to be €150 million over 10 years to develop and implement the national EHR system and the national infrastructure. Funding should be allocated, initially on a yearly basis, over the next 5 years to accelerate the development of the prerequisites and a pilot implementation

Recommendation 6

Funding should be tied to conformance with national standards and the achievement of preset milestones.

Funding of €13.5 million should be allocated on a yearly basis over the next 5 years to accelerate the development of the prerequisites and a pilot implementation.

Funding of €1.5 million should be allocated on a yearly basis over the next 5 years towards change management costs.

14.2.7 Standards Body

Information sharing between heterogeneous information systems requires policies and standards for each specific information flow. As mentioned in Section 13.8, this requires bringing many Work Groups and Standards Committees together to provide overall co-ordination of their work. It also requires bringing many different standards together from many different standards organizations to establish workable solutions to provide information flows that are secure, confidential, authentic, accurate, and suitable for purpose. A national standards body is required to achieve this efficiently and effectively. Action 19 of NHIS states that a national health information standards framework will be developed. HIQA together with national stakeholders and international expert advice will be responsible for overseeing the process of standardization and conformance with the national health information standards framework (DOHC, 2004c). The author assumes that HIQA will be the standards body in respect of a national EHR system and makes no recommendation.

No recommendation

14.2.8 Certification

The Health Information Directorate within HIQA has specified the development of procedures for monitoring compliance with technical standards as one of its objectives (HIQA, 2008). As noted in section 13.9 of this report, certification is being implemented or planned in 4 countries. In Section 14.2.7, some of the required attributes of information flow were mentioned. Compliance with the standards and policies to achieve information flow with those attributes, could be strengthened by introducing national certification of products and services.

Recommendation 7

- 7.1 Introduce certification for products and services that will be used in the health information sector. This certification should specify that the product or service conforms to the proposed national standards.
- 7.2 Develop and introduce security conformance criteria informed by the forthcoming Health Information Bill.

14.2.9 Standards

Currently in Ireland, the HL7 version 2.x standard is used for messaging. Continuing with HL7 version 2.x with the option to progress to HL7 version 3 in the future would keep costs down. It could gain the support of stakeholders who already use HL7 version 2.x and it may reduce the time frame in which a pilot EHR implementation could be achieved. As noted previously, HL7 version 3 is being used by Canada and England and both of these countries have made some progress in their implementation. This means that Ireland could learn from their experiences first before choosing to use HL7 version 3. A medicines terminology will be needed to implement the eDischarge summaries. Developing national standards to support interoperability is an objective the Health Information Directorate of HIQA. It has two work programmes in relation to working on prioritising and developing standards (HIQA, 2008).

Recommendation 8

- 8.1 Ireland should continue with HL7 version 2.x for the short term.

14.2.10 Clinical coding standard

SNOMET CT has been adopted by all countries researched.

Recommendation 9

- 9.1 Ireland should adopt SNOMED CT for clinical coding

14.2.11 Unique Identifiers

Ireland is currently considering introducing a unique identifier for health information purposes. The objective is to correctly link a patient to their health information. The option of using the PPS number has been raised by both the NHIS 2004 and the Discussion Paper on the Proposed Health Information Bill. Recommendation 7.5

of the Report of the Commission on Patient Safety and Quality Assurance called for rapid progress on the development and implementation of a unique identifier for the health system in Ireland (DOHC, 2008e).

Research carried out for this report, in relation to authentication of access to personal health information contained in EHRs, showed that a system of unique identification for health care providers and those who work in the health care sector is required. A means to identify health care locations will be required and should be investigated.

Recommendation 10

- 10.1 Ireland should introduce a unique identifier for health purposes.
- 10.2 The use ISO/OID identifiers should be investigated with regard to identification of health care locations and applications.
- 10.3 Methods for identification of all health care providers should be investigated with respect to authentication and audit trails for security purposes. Following investigation as to the appropriate method, identification for all health care providers should be implemented.

14.2.12 Information Governance

A national EHR system requires a privacy and security framework based on a legal framework to enable health information to be stored, exchanged, updated and used. Such a framework is necessary for the designers of the systems which will provide the technology to enable the EHR. Action 17 of the NHIS 2004 states that the Department of Health and Children will have responsibility for publishing a Health Information Bill. Action 18 of the NHIS 2004 states that HIQA and the DOHC will put in place a framework for information governance (DOHC, 2004i). Recommendation 7.54 of the Report of the Commission on Patient Safety and Quality Assurance also calls for an effective information governance framework and legislation to underpin that framework (DOHC, 2008f). The Health Information Directorate of HIQA is developing a governance framework, which will include governance standards (HIQA, 2008).

Recommendation 11

- 11.1 An effective governance framework inclusive of governance standards should be developed.

14.2.13 Security and Privacy

Based on the information available from the research undertaken for this report, it is apparent that both technology and legislation will underpin the security standards required to implement an EHR system in Ireland. All the countries researched for this report were or have implemented the ISO 27799 standard for security. Privacy impact assessments were being used by 2 countries.

Recommendation 12

- 12.1 Ireland should investigate the option of adopting the ISO 27799 as the national standard for health information / EHR system security.
- 12.2 The introduction of a privacy and security conceptual architecture should be investigated.
- 12.3 The introduction of privacy impact assessments, based on the proposed Health Information Bill, should be investigated.

14.2.14 Consent

Consent arrangements for accessing and sharing the EHR in Ireland will be based on the outcome of the forthcoming Health Information Bill.

No recommendation

14.2.15 Change Management

NHIS 2004 acknowledges the importance of effective change management in the implementation of a national EHR system. Action 9 of NHIS indicates health agencies must prepare implementation and service plans that will include change management programmes to enhance the use and appropriate sharing of information (DOHC, 2004j).

Recommendation 13

- 13.1 A Change Management Work Group should be established to work closely with the EHR Work Group.
- 13.2 The Change Management Work Group should investigate best practice internationally in relation to change management.

14.2.16 Health Portal

Action 14 of NHIS proposes that a Health Information Portal will be developed and this will be provided for by HIQA as part of its ICT action plan. It is proposed that this portal will contain ehealth services, electronic health library services and statistical databases among other things (DOHC, 2004h). The Health Information Directorate of HIQA has established a National Working Group which involves stakeholders and is working towards developing the Health Portal (HIQA, 2008). As discussed in Chapter 13, the governance bodies of all the countries researched for this report, with the exception of Finland, have developed portals in relation to the planning and implementation of their electronic health record projects.

Recommendation 14

14.1 The Health Portal being developed should incorporate communications strategies related to promoting the strategy of introducing EHRs in Ireland.

14.2 There is an opportunity include information relating to change management within the health portal, which should be investigated.

14.3 Future Work

Based on the research undertaken for this report, the following areas related to introducing a national EHR in Ireland, could benefit from further research.

- Conduct further research in this area in the form of interviews. This may reveal those things, which did not go well in the international projects, which were not in the published documents relating to the individual projects.
- Change management.
Change management should be further investigated in relation to organizational, work process and cultural changes.
- Unique identification for health care providers.
Unique identification for health care providers should be further investigated. The use of digital signatures should be investigated for use by health care providers to authenticate the data and to mitigate the risk of it being

tampered with. Smart cards should be investigated for use in authentication of health care workers.

- A terminology for medicine.
The author notes that no public reference to work on a terminology for medicine in Ireland was found during the research process.
- Development of a privacy and security conceptual architecture.
Such an architecture would assist designers and vendors of EHR systems and services
- Development of Privacy Impact Assessments.
Such assessments are being undertaken internationally and it may be beneficial to undertake further research in this area.
- Development of a privacy and security conceptual architecture.
Such an architecture would assist designers and vendors of EHR systems and services
- Legislation and policy regarding archiving of the collected health information over the long-term and / or its disposal or anonymisation.
The author noted during research that no published reference to an archiving service was found.

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