

Elizabeth Nanouris  
Department of Political Science  
McGill University, Montreal  
Thesis Submitted: June 2011

The ethical and legal complications surrounding the implementation of a  
pan-Canadian electronic health record (EHR) system

*A thesis submitted to McGill University in partial fulfillment of the requirements of the degree of  
M.A Political Science*

©Elizabeth Nanouris, 2011

## Abstract

Canada lags behind other countries in the development of electronic health records. If Canada develops a pan-Canadian electronic health record (EHR) system, the quality of patient care can improve. A review of the literature lists potential benefits of EHRs such as improvements in medical research, a reduction in emergency room and diagnostic test wait times. Such a system will make medical records readily available to health care providers which will help them make informed critical decisions. Regardless of the benefits of such a system, there are legal and ethical implications hindering its development and implementation. The federal and provincial governments are at odds as to who is in charge of health care. Canadians need to be consulted on its implementation, and their concerns regarding privacy legislation addressed. Canada Health Infoway has undergone initiatives to create an interoperable EHR system in Canada with audit trails, smart card technology, etc. The benefits of such a system are seen in an analysis of Alberta that has created its own provincial EHR system. Case studies of both Alberta and the United Kingdom's EHR systems should be used as a foundation to begin developing Canada's national system. If Canada addresses the concerns surrounding the implementation of a national EHR system through policies with sanctions to deal with the ethical implications of such a system (informed consent, unlawful access, etc), then studies have shown that Canadians will support a pan-Canadian EHR system initiative. Before addressing ethical dilemmas, the governments must assume responsibility of who will develop and maintain this system.

Le Canada accuse un retard important par rapport à d'autres pays dans le développement de dossiers de santé électroniques. Si le Canada développe un système de dossier de santé électronique pancanadien (DSE), la qualité des soins patients peut s'améliorer. Une revue de la littérature décrit les avantages potentiels des DSEs tels que des améliorations de la recherche médicale, une réduction au niveau des temps d'attente en salle d'urgence et des tests diagnostiques. Un tel système facilitera la disponibilité des dossiers médicaux pour les fournisseurs de soins médicaux et les aideront à prendre des décisions critiques éclairées. Indépendamment des avantages d'un tel système, des implications sur le point de vue légal et éthique empêchent son développement et sa mise en œuvre. Les gouvernements fédéraux et provinciaux sont en désaccord quant à qui la responsabilité des soins médicaux incombe. Les Canadiens doivent être consultés sur la mise en œuvre de ce système et leurs préoccupations quant à la législation sur la vie privée doivent être adressées. Inforoute Santé du Canada a entrepris des démarches afin de créer un système de DSEs interopérable au Canada avec des protocoles d'audit, la technologie de carte à puce, etc. Une analyse de l'Alberta, qui a créé son propre système de DSE provincial, a permis de voir les bénéfices d'un tel système. Les études de cas portant sur les systèmes de DSEs de l'Alberta et du Royaume-Uni devraient être utilisées comme fondement afin de débiter le développement d'un système national au Canada. Les études ont démontré que les Canadiens supporteront l'initiative d'un système de DSE pancanadien si le Canada adresse les préoccupations entourant la mise en œuvre de ce système national par des mesures avec sanction afin de répondre aux implications éthiques que ce dernier pose (le consentement éclairé, l'accès illégal, etc.). Avant d'adresser les dilemmes éthiques que pose ce système, les gouvernements doivent assumer la responsabilité de décider qui développera et maintiendra ce système.

## **Acknowledgments**

My interest in Health Care Politics began by working in medical research with Professor John Sampalis of McGill University. He encouraged me to continue my education in Political Science and incorporate my interests in health care. His mentorship helped me to combine my interest in both fields and craft my thesis topic.

I would also like to thank my thesis supervisor Professor Antonia Maioni for her interest in my thesis topic. In the last year of completing my BA I took her political science seminar on Health Care in Canada. Her teachings sparked my interest in electronic health care records which inspired me to formulate my thesis topic. I am grateful that she accepted me as her MA student.

My last thank you goes to Marianna Boukas who spent long hours editing my thesis. She taught me about software validation, audit trails, data dictionaries and the FDA's 21 CFR Part 11 Requirements. Unbeknownst to us both, years later I would incorporate her teachings into my thesis. She provided me with the foundation on which I have written this thesis.

## Table of Contents

<b>I. INTRODUCTION.....</b>	<b>1</b>
<b>II. COST / BENEFIT ANALYSIS.....</b>	<b>4</b>
<i>WHY IMPLEMENT EHRs?</i> .....	4
<i>HOW WILL EHRs FUNCTION?</i> .....	11
<i>HOW MUCH WILL EHRs COST?</i> .....	18
<i>CONFIDENTIALITY ISSUES</i> .....	23
<b>III. CANADA’S EHR ADVANCEMENTS.....</b>	<b>30</b>
<i>CANADA HEALTH INFOWAY</i> .....	30
<i>FDA’S 21 CFR PART 11 REQUIREMENTS</i> .....	32
<i>ALBERTA NETCARE</i> .....	35
<b>IV. LEGAL COMPLICATIONS.....</b>	<b>41</b>
<i>FEDERALISM</i> .....	41
<i>PRIVACY LEGISLATION</i> .....	48
<i>CANADIAN PERCEPTIONS OF EHRs</i> .....	55
<b>V. UNITED KINGDOM’S NATIONAL HEALTH SERVICE (NHS).....</b>	<b>61</b>
<b>VI. CONCLUSION .....</b>	<b>66</b>
<b>VII. WORKS CITED.....</b>	<b>69</b>

## **I. Introduction**

Every Canadian has a health care tale concerning long emergency room wait times, awaiting diagnostic test appointments, lack of general practitioners in Canada, shortage of nurses, few available operating rooms, etc. Quebec citizen Jean James was told that she needed a diagnostic test to assess the blood flow to her kidneys. She called multiple Montreal hospitals, but she was only called back two years later to schedule her appointment – by that time she had already gone to a private clinic (“Tale from Health-Care Trenches” B6). “By then, as James rightly pointed out, “I could have been dead”” (“Tale from Health-Care Trenches” B6). What is a possible solution for Canada’s current health care crisis?

A pan-Canadian electronic health record (EHR) system may resolve certain issues that cause unnecessary delays. One example would be that this type of system would offer immediately available information, which would decrease redundant questions by physicians, consequently reducing emergency room wait times. A reduction in the duplication of diagnostic tests, and a decrease in serious adverse events are also advantages of such a system. Such a system will not solve all of Canada’s public health care issues, but it can improve our current system and ensure a more efficient public health care program. The question remains, how will a pan-Canadian EHR system achieve such great feats?

Electronic health records are digital medical records within a computerized system which allows medical staff to access all of a patient’s health care records throughout his/her lifetime. Whether this information is limited to doctors, or whether nurses and other medical personnel have access to it, depends on the country, province or institution that chooses to implement this system. An EHR system can potentially connect: hospitals, pharmacies, doctor offices, etc, depending on the size and complexity of the system. Some hospitals and provinces have begun

developing their own EHR systems but there should be a standardized EHR system at the national level, or at least the assurance that provincial systems are interoperable. Such a system will allow authorized users to access an individual's health care data at the point of care (*EHR Solution Blueprint V.2 8*).

This thesis supports the implementation of a pan-Canadian electronic health record system making patient information available across Canada in hospital settings, pharmacies, laboratories, physician offices, etc. Since some provinces have already developed EHR systems, the federal government cannot create a large scale national EHR system. This would mean that the federal government is entering the realm of provincial jurisdiction, and not respecting the funds that the provinces have already spent on their existing EHR systems. A more cost efficient and practical plan would be that the federal government ensures the standardization and interoperability of the existing EHR systems. In addition the federal government should ensure that equal health care is available across Canada. This would be in compliance with section 36 of the *Constitution Act* which stipulates that Canadians will be provided with equal opportunities regardless of where they reside and this will be done without hindering provincial or federal jurisdictions. Essential public services will also be provided to all Canadians.

Advances in information technology (IT) have meant that health care data on individuals could become readily available benefiting both the individual patient as well as large scale epidemiological studies that could identify serious risks to the population. In recent years the use of individual EHRs has increased in patient management and medical research. In comparison to other developed countries Canada lags in electronic advances in primary health care (Schoen, et al. w1174). This thesis will begin with a cost/benefit analysis of implementing standardized EHRs including how they will function, as well as cost and confidentiality concerns. There is a

debate surrounding the legal complications regarding the Canada-wide application of this technology, for there are many jurisdictional issues. Canada has already developed provincial and institutional EHR systems but the best example is Alberta Netcare which will also be analyzed. Canada Health Infoway's initiatives and the role of the Food & Drug Administration's (FDA) 21 CFR Part 11 requirements for electronic records will also be discussed, for both will help in the creation of a pan-Canadian EHR system.

With an upsurge in the use of electronic patient records, the likelihood of a confidentiality breach increases. The question that arises is twofold: should such a system be put into practice despite the concern that individual patient rights may be infringed? What are the legal implications surrounding a pan-Canadian EHR system? Before discussing the ethical and legal complications of such a system it is important to understand why Canada should implement a national EHR system. Canada's multi government system complicates amendments to the status quo. A successfully implemented pan-Canadian EHR system is already difficult to implement but there is also the requirement that the government passes privacy legislation and ensure the public's approval. In comparison, the United Kingdom's National Health Service (NHS) system will also be analyzed because it is an excellent case study of a nationally implemented EHR program. All in all there are ethical and legal complications to the implementation of a pan-Canadian EHR system, which must be addressed in consideration of implementing such a system in Canada.

## II. Cost / Benefit Analysis

### *Why Implement EHRs?*

In 2001 Health Canada cited the Institute of Medicine's list of advantages in implementing EHRs. The Institute of Medicine is an independent, nonprofit organization that works outside of the United States (US) government to provide unbiased and authoritative advice to decision makers and the public. The advantages of EHRs are the following:

- “Support patient care and improve its quality;
- Enhance productivity of health care professionals and reduce the administrative costs associated with health care delivery and financing;
- Support clinical and health service research;
- Accommodate future developments in health care technology, policy, management and finance; and
- Ensure patient data confidentiality at all times” (qtd. in *Toward EHRs* 19).

These health records would be lifelong records that “would make the data available to health care professionals on a need-to-know basis by connecting interoperable databases that have adopted required data and technical standards” (*Toward EHRs* 1-2). Quality of care is the most important reason why a pan-Canadian EHR system should be implemented in Canada's near future.

Canada is lagging behind other countries in relation to the development of information technology infrastructures related to primary health care (*EHR & Patient Safety* 6). In 2005 clinical studies demonstrated that both human and organizational implementation can increase patient safety and decrease mortality. Issues include: lack of doctors and nurses for patients, delays in treatment, long wait times for emergency care and diagnostic tests, etc. People and organizations must adapt to ensure the successful implementation of an EHR system to secure patient safety (*EHR & Patient Safety* 8). Electronic health records are not going to deliver better



care; it is people that are going to provide that but in facilitating the jobs of clinicians and medical staff we will provide them with more time to optimize care. Canadians must understand that the implementation of a national EHR system will increase patient safety and provide better health care (*EHR & Patient Safety* 11).

Who are the beneficiaries of EHR systems? Below is Health Canada's stakeholder's benefit table explaining who would benefit from a pan-Canadian EHR system:

**Table 1.0 Health Canada's Stakeholder Benefits Table**

STAKEHOLDER BENEFITS TABLE	
STAKEHOLDERS	POTENTIAL BENEFITS
Public	<ul style="list-style-type: none"> <li>• expanded reach of effective health care</li> <li>• more secure information</li> <li>• improved sense of well-being</li> <li>• access to information about how the health care system works</li> </ul>
Patients or their representatives (i.e. child representing elderly parent or parent representing child)	<ul style="list-style-type: none"> <li>• improved health care and decreased risks (e.g. adverse drug reactions)</li> <li>• integrated health services</li> <li>• do not have to repeat basic information, such as name, address</li> <li>• increased confidence knowing that all health care professionals have access to all relevant parts of their medical history</li> <li>• access to their own health records helps patients to make informed decisions about their health</li> <li>• avoidance of duplicate, invasive and/or expensive tests</li> <li>• reduced waiting lists</li> </ul>
Health professionals	<ul style="list-style-type: none"> <li>• integrated view of patient data</li> <li>• increased access to other related and integrated patient information</li> <li>• improved access through a portal to related health services</li> <li>• improved decisions with up-to-date patient information on an as-needed basis</li> <li>• improved seamless care through the coordination of multi-professional and multi-agency care</li> <li>• improved development of decision support systems</li> </ul>
Health administrators	<ul style="list-style-type: none"> <li>• increased patient care time</li> <li>• access to data to support clinical governance and local planning</li> <li>• reduced health care costs</li> <li>• improved health care quality</li> </ul>
Policymakers (including governments)	<ul style="list-style-type: none"> <li>• improves effective health maintenance and education</li> <li>• supports medical and administrative decision-making processes</li> <li>• provides for improved long-term planning</li> </ul>
Researchers (including governments)	<ul style="list-style-type: none"> <li>• access to timely high-quality data for research</li> <li>• access to up-to-date research findings, treatment and medication options</li> <li>• improved data quality</li> <li>• access to aggregate data</li> <li>• allows for improved trend analysis</li> </ul>
Governments	<ul style="list-style-type: none"> <li>• improved accountability</li> <li>• improved health resource allocation</li> </ul>

Source: *Toward Electronic Health Records*. Ottawa, ON: Office of Health and the Information Highway, Health Canada. 2001.

The primary function of an EHR system is to improve patient care (*Toward EHRs* 27). Provincial EHR systems should evolve so that a patient's EHRs are accessible regardless of which province one is undergoing treatment in. 21<sup>st</sup> century patients shop for the best available treatment. Patients with rare or incurable diseases often travel to other cities/countries with academic research centers for specialty treatments or to participate in clinical trials. EHRs would facilitate leaving your province, or even country, to seek medical treatment. This would ensure that patients are not geographically constrained to receive premium care. There is strong evidence that EHRs improve quality of care, studies by McGill University have demonstrated that complete electronic drug profiles have led to a decrease of 18% in incorrect prescriptions being filled (Hamilton 12). Another study demonstrated "that after implementing a computerized order entry system, medication errors decreased by 55% and there was a 17% reduction in preventable adverse drug events" (Hamilton 12).

Representatives of patients (mainly parents representing their children and children representing their elderly parents) would also benefit from such a system. Canada is a multicultural mosaic and many patients bring to hospitals and doctor appointments some sort of translator (friend, child, relative, etc). EHRs would diminish the long repetition of information because the patient's chart would be available electronically. This will bring peace of mind to representatives that are required to remember relevant medical history and translate throughout the appointment, and often to different people at one appointment (doctor, nurse, administrator, etc). This will help reduce wait times as well as avoid duplicating expensive tests, and it will ensure that doctors and patients make the most informed decisions possible (*Toward EHRs* 20). The potential for human error would also decrease as the translator may forget to provide all the

required details. A misunderstanding will also less likely occur during a conversation between a patient, health care professional and a translator.

How will the general public benefit from EHRs? The general population will also benefit; not only the outliers such as the chronically ill or the elderly. EHRs can help Canada interpret the success of different public health interventions. Is there enough awareness that childhood illnesses can be prevented by vaccinations? Due to international mobility, infectious diseases are also spreading across countries and Canada must be able to effectively detect and respond to such pandemics (Hamilton 24). An EHR system will help detect infectious diseases via technology before enough cases are detected within a hospital by overworked physicians.

EHRs would facilitate the work of health care professionals and improve patient care, for many hospitalized patients experience some kind of adverse effect while undergoing treatment. For example, patients admitted to the emergency room often forget to mention allergies to penicillin and if treated with the drug, face adverse reactions. EHRs would not require the patient to remember allergies or a list of the medication that they are taking because their EHR would list all medically relevant information. A pan-Canadian EHR system can be so much more than a replica of our paper based system, electronic prescriptions and monitoring can reduce medical errors and adverse events. Many adverse effects are caused by drug interactions, allergies, etc and could be prevented if patient information were more readily available. “Medical errors can be expensive [...] considerable research has documented the impact that errors have on lengthening hospital stays” (Hamilton 19). Every year in Canada, millions of hospitalization days are a result of medical error (Hamilton 19). EHRs can help decrease medical errors which are one of the leading causes of death in first world countries. Doctors will be provided with his/her patient’s medical history allowing him/her to make well informed decisions.

A pan-Canadian EHR system can also help circumvent duplication and error. It is often difficult for doctors to access the chart notes of other specialists, even in the same hospital (Hamilton 12). For example, quite frequently a specialist orders tests for a patient while unbeknownst to them another specialist has already ordered the same tests. There is often conflicting data when clinicians are asked to complete multiple forms (Gordon et al. 240). Though creating a pan-Canadian EHR system can be expensive, among many other reductions in current costs, administrative costs (filing, chart pulling, receiving written patient consent, faxing medical records, etc) can be reduced by implementing such a system. The combination of advancements in effective patient care, as well as an increase in staff and management efficiency, will improve Canadian health care so that the system's long term benefits outweigh its immediate costs. Issues pertaining to cost will be analyzed below.

Administrative staff may also benefit from EHRs by a reduction in the more redundant areas of their work load such as: chart pulling, filing, faxing medical records, etc. Provinces will pay less for duplicated testing which occurs when test results cannot be found or are not easily attained. Treatments costs associated with medical errors will be reduced benefiting ill patients undergoing treatment, doctors and nurses administering treatments and monitoring the patient, and an overworked administrative staff (Hamilton 17). "Paper records are increasingly becoming obsolete and inadequate. They limit the flow of information, insufficiently document patient care, impede the integration of health care delivery, create barriers to research, and limit the information available for administration and decision making" (Romanow 77-8).

EHRs can also advance medical research. Clinical trials require at least two controlled groups of individuals receiving two different types of medication, medication vs. a placebo, medication vs. surgery, etc. The results are then analyzed and such research is used to determine

how diseases should be treated and what drugs and dosages are effective and safe. Patient recruitment and the enrollment process is very costly and a lot of paperwork must be completed (Hamilton 23). “In 2002, it was estimated that the total capitalized cost to develop a new drug to market was \$802M USD (\$1,033M CAN)” (Hamilton 23).

Patient recruitment for large clinical trials is said to be a major cost in medical research. EHRs can reduce the cost of recruiting patients by creating a network of physicians who can help recruit patients for their specific condition. EHRs cannot substitute controlled Phase II and III clinical trials which assess a drug’s effectiveness. On the other hand, Phase IV studies, also known as post marketing observational studies (PMOs), will be greatly improved by the implementation of a pan-Canadian EHR system. Such studies involve the pharmacovigilance of a drug after it is approved and sold on the market. PMOs assess the long term effects of drugs on the public after widespread use. EHRs will facilitate the gathering of data across the country, on adverse reactions to a specific drug.

Medical research will also be improved because project teams will no longer face extensive chart reviews in search of patients to recruit – with patient consent key data can be easily analyzed and one can determine the impact of the drug on the patient (Hamilton 23). Cost efficient clinical trials mean greater scientific advancements. EHRs will provide the best quality data available for research; this will also improve trend analysis (*Toward EHRs* 20). EHRs can replace patient registries which are currently the trend in research. Patient/disease registries are repositories with data on patients with a specific condition. These registries are valued in medical research and are more accessible across institutions and tend to be larger when created and maintained electronically. EHRs will simplify the creation of these patient/disease registries.

Policymakers and provincial/federal governments will also benefit from a pan-Canadian EHR system. Long term planning will be improved with more information being readily available. It will be easier to evaluate trends and decree where funds should be transferred because the critical areas may be more apparent i.e. increase in traumas, decrease in pediatric illnesses, etc. This will greatly improve the allocation of health care resources (*Toward EHRs* 20).

EHRs will modernize Canada's current paper based health record system. The system will prompt the user for standardized information such as demographic information, test dates, diagnosis, etc. Information will be entered each time a patient sees a doctor, has a prescription filled, etc. EHRs will also create a standardized system so physicians do not need to interpret each other's acronyms and coding. In paper based systems "health care providers and their organizations decide what information is relevant for their purposes and what form the information should take" (Romanow 77) on paper. For the sake of clarity and continuity EHRs will make it possible for any doctor/nurse to understand a chart from their colleagues, for each EHR should be able to stand alone and not require further explanation. Access to medical charts will also be facilitated amongst medical institutions and provinces. Administrative staff will no longer have to call each other asking for a fax of a patient's chart or the mailing of x-rays.

Although there are clear benefits to EHRs, one concern is that they are too complex and not easy to use. Many people disapprove of their use because they do not understand how they function, understanding how EHRs will function may change the most rigid non-believers and the strongest supporters of Canada's current paper based system.

### *How will EHRs Function?*

21<sup>st</sup> century Canadian medical students are byproducts of the information age: “physicians are now more comfortable using a keyboard rather than a pen, and this is particularly true of the new generations of medical students and residents” (Wallace 777). Today’s patient (below the age of 60) is a more informed patient, often having accessed the internet for information regarding his/her disease, side effects of a certain prescription medication, etc. The internet does not always provide accurate information. “Statistics Canada reported in March 2001 that 53% of Canadians over 15 years of age (that is, 13 million) used the Internet over the past year” (Wallace 777) and many of them use the internet to access health care information. Technology is expanding and Canadian citizens are becoming more internet savvy, thus telemedicine should follow suit.

There are many examples of how EHRs can be maintained. The most common method is that each patient can have a Smart Card with their medical information that can be read with the appropriate technological reader and accessed with a password (*Toward EHRs* 8). Smart cards are used by MasterCard and Visa which use token based cryptographic authentication. Commercial use of these smart cards is growing thus making the product more affordable and a potentially effective product in medical settings (*For the Record* 91).

EHRs should be standardized so that when they are used across Canada by health care professionals, they can follow a common template facilitating the transfer and understanding of information across jurisdictions. An example of an EHR may be the following:

Table 2.0: Electronic Health Record Example

• Help

• Logout

<

Source: *Electronic Health Records in Canada: An Overview of Federal and Provincial Audit Reports*. Ottawa, ON: Office of the Auditor General of Canada. 2010.

Data dictionaries will become very important if Canada choose to create a pan-Canadian EHR system. Data standards are necessary in all information technology systems, without standards in EHR application the system will be substandard. Data dictionaries define the basic organization of any database. Data dictionaries list files in the database, the number of records per file, names/type of fields, etc. They also list the standardized names of tables, variables, value ranges, etc, that are contained in the database system. Data standards assist in the management of health care information by ensuring a constant flow of information that is consistent. HL7 Clinical Document Architecture and the ASTM International are developing



data standards and implementation guides for the transcription and the format of health care of documents. (Kallem, et al. 73-6).

There are issues with access in Canada's health care system whether it is access to specialists for citizens in rural areas or the management of wait times in urban areas. "Through a telemedicine link in a primary care provider's office, a patient can be interviewed and observed by a specialist from a remote location, providing backup to primary care physicians" (Hamilton 15). Doctors in British Columbia (BC) would be able to access a patient's chart in Newfoundland. A BC specialist would be able to provide a general practitioner in Newfoundland with a second opinion without ever having to move a patient who can be ill or incapacitated with limited mobility. Our aging population has created an ever pressing issue to reduce the mobility for treatment of the chronically ill or physically impaired.

EHRs can address matters of life and death. A patient enters an emergency room with chest pain. He is diagnosed with a myocardial infarction, commonly known as a heart attack, but the physician is not sure how long this has been going on. If the patient does not have a file at this hospital, the physician will not have an earlier electrocardiography (ECG) available to him to use as a baseline for comparison. Attempts will be made to quickly access the patient's chart and hopefully an old ECG will be amongst his file. If necessary, for an effective recovery the patient should be treated early with thrombolysis but this treatment may be delayed while waiting for the patient information to be retrieved which may affect the patient's outcome (Wallace 777). A pan-Canadian EHR system will ensure that the emergency room doctor who deals with life and death situations every shift has all the available information about his/her patients within minutes upon request. This includes severe allergies to medication that he/she

would have administered, important medical history, surgical details and other relevant information.

Electronic health records will not be composed of a single patient record but a collection of records including laboratory test records, diagnostic image records, drug information, immunization record, etc. EHRs allow for a repository for consent directive records and information on whether the patient would like to disclose their EHR information and at what capacity. EHRs can be developed on registries:

- “A Client Registry, containing one entry for each patient, holds name, gender, birth date and demographic data, as well as unique patient identifiers such as health card numbers
- A Provider Registry, containing one entry for each health care provider, holds the name and medical specialty of each health care provider, along with unique identifiers such as medical license number
- A User Registry may contain an entry for each registered user who can electronically access EHR information, such as a medical secretary or health records clerk [...]
- A Location Registry contains one entry for each location where health care services take place (e.g. a hospital)”

*(EHR Solution Blueprint V.2 8).*

The EHR infrastructure can also have a Public Health Surveillance Repository with information on reported infectious diseases and disease outbreaks. A data warehouse may contain data from other repositories that is allowed to be used for both statistical and medical research purposes. Data should be validated and there should be a repository of terminology to describe medical conditions *(EHR Solution Blueprint V.2 8)*. Direct access to one database would be problematic in terms of updating the databases and securing the information, which is why EHRs can be separated into registries.

Each patient can be identifiable by a unique EHR Client Identifier (ECID) and an EHR indexing service which will mean that users can quickly upload all the records of a patient from the different repositories. Information should be date / time stamped and the origin of the information should also be apparent. In the future, patients can even have access to some of their health care information through patient portals accessible through their browsers (*EHR Solution Blueprint V.2 9-10*).

There are also many matters of contention concerning EHRs. The potential users of an EHR system must be consulted in designing the system. The users should be the health care providers who will be modifying and uploading the data. If one allows the users to participate in creating a national EHR system, the designers can ensure that the system is not overly complicated and not only understood by information technology specialists. Incorporating the opinions of users is also important because they will be using the system and they are aware of what they need and what the current paper-based system may lack (Wallace 778). Health care providers who have used EHR systems in their province and hospitals can also address the issues that their existing systems may have and offer practical resolutions. Canadians who have had the experience of using such a system can help other Canadians who will be using a similar system for the first time, first time users can benefit from the experience of others.

Faculties of Medicine throughout Canada have adopted e-learning in the curriculum of some of their programs. Lectures can now be recorded digitally (Wallace 778) or there can be a time allotted where students log in via the computer and/or a conference call for a webinar training. In e-trainings a host is there to answer questions through a live feed. Methods such as

these can be useful in training existing tech-savvy physicians on how to use an EHR system when traditional methods such as group training are not available or as cost effective.

Coordination is another issue concerning the development of a pan-Canadian EHR system. Coordination may be problematic because if care is provided at different facilities, it may be difficult to update records at both locations simultaneously. This is also an issue with paper records where a physician can correct an error in a report but multiple versions of a report or copies of charts exist elsewhere. Physicians may end up using the faulty report to make medical decisions (Gordon, et al. 240). To prevent one file being accessed and edited by different sources at the same time, once an authorized user opens a EHR for editing purposes it should automatically become “read only” to others who try to edit the information at the same time. This is to coordinate changes in a clear and concise manner. When the original editor closes the patient’s record then the next person should be able to open it and edit it ensuring that he/she has the most current information. This is the same as when employees in the same office attempt to open and edit Microsoft Word or Excel documents on a network. Only one user can edit them at a time.

But how will this system work? This question is problematic because it is dependent on a variety of factors. What information should be included in an EHR? Who should have access? Can everyone access the same amount of information (*Toward EHRs* 26)? How much access a user has should be based on their job function and a justification that they require this access to complete their job. Users should only have access to the information that they will need to fulfill their job requirements. For example, it is not necessary for an administrator making a patient’s appointment to have access to an EHR beyond the patient’s phone number, address and other

contact information. Some job functions may require read-only access to provide optimal care. For example, pharmacists may require knowledge of a patient's diagnosis but he/she would not need to edit that information.

Informed consent is also an important area of EHR development, particularly pertaining to medical research. If a pan-Canadian EHR system is created, the definition of informed consent which is dependent on government regulations, has to be expanded. In Canada, different provinces have different informed consent requirements. The use of EHRs can be expanded to include access for medical research without requiring consent for every study. Canadian citizens could have three options:

1. My health care information is not available for medical research
2. My health care information is always available for medical research
3. I must be provided with informed consent every time my health care information may be used for medical research.

84% of Canadians support the use of EHRs in medical research as long as their personal information, such as their name, is omitted (*Privacy Survey 6*). EHRs and medical research can be further developed if consent is obtained ahead of time. Medical researchers can link personal health information to other records related to health care such as education and income. These possibilities should only be discussed after a national EHR system is implemented.

EHRs can also help Health Canada issue warnings concerning epidemics, medication warnings, etc (Wallace 777). We need to be able to identify outbreaks and manage drug flows to avoid challenges such as those experienced during the SARS outbreak (*EHR 2015 25*). For example, during the SARS outbreak a pop-up box could have appeared when a health care professional logged onto their account. This warning could have contained a list of symptoms,

mentioned the severity of the disease and the need for quarantine; which could have led to more informed doctors in a shorter duration of time. Regardless of the benefits of such a system, for it to be implemented its cost must be analyzed.

#### *How much will EHRs Cost?*

A pan-Canadian EHR system will be expensive to develop, upgrade, and support over the long term. However the system may prove to be cost effective in the long run because there may be considerable savings in other health care areas. Studies show that teleradiology (the transmission of radiological images such as x-rays); particularly transmitting CT images could be cost saving in its improvement of patient care. This is especially evident in rural areas where medical records outside of specific areas are not easily accessible (Wallace 777). “Technological capabilities are expanding at a great rate and their associated costs are decreasing” (*Toward EHRs 1*).

Evidence suggests that there are many advantages to paperless medical records. In Canada, health care currently costs approximately a hundred billion in annual spending. Health care Information Technology (IT) spending varies across Canada from low in parts of Atlantic Canada to high in the Calgary Health Region (*EHR 2015 14*). Depending on the type of EHR system that is developed and maintained, the cost can vary greatly.

Another concern is that implementing a pan-Canadian EHR system may not improve health care at all, thus may not be worth the cost. The United Kingdom has a nationwide EHR system and one study found that “at Chelsea and Westminster Hospital in the United Kingdom, installation of a clinical information system was found to reduce surgery cancellations by 63% by better ensuring that patients are medically cleared and adequately prepared prior to surgical procedures” (Hamilton 17). If quality care is provided at a lower cost, then Canada and the

provinces can reinvest valuable dollars elsewhere in the health care system. Medical errors are also expensive and can lead to lengthy hospital stays, expensive treatments and medication that did not need to be prescribed. “In Canada, CAES [Canadian Agricultural and Economics Society] estimates that 1.1 million days are added each year to hospitalizations as a result of medical error” (Hamilton 19) equaling an insurmountable cost. Not all medical errors are preventable but many concern prescription errors and misinformation from the patients. A paperless system on the dependency of word to mouth communication of medical information may reduce such medical errors and reduce unnecessary and costly hospitalization.

Comprehension is also important and in a cross sectional study in Great Britain it was found that paperless records were more fully comprehensible 89.2% of the time versus 69.9% of paper records (Hippisley-Cox, et al. 1439). The study concluded that although there are disadvantages to the implementation of EHRs, their use was not detrimental to health care practices (Hippisley-Cox, et al. 1442).

There are also administrative costs to our current paper system. “Partners HealthCare System in Boston, MA, estimated the average chart pull cost at \$5 USD (\$6.4 CAN) per chart and noted a 28% reduction in transcription costs by the decreased use of dictation services” (Hamilton 18). EHRs can sum up an entire patient’s chart obliterating the need to file, pull out and re-file charts. This can decrease an administrator’s workload and the likelihood of human error. Provinces and health care institutions already believe that information technology may be a solution to many of Canada’s health care issues, though provinces differ in their objectives. “Yet, despite this consensus, progress has been slow and provincial and federal initiatives are being developed in isolation, despite the fact that the costs of each government going at it alone are very high” (Romanow 77). The provincial and federal governments should create a pan-

Canadian EHR system which would be more cost effective than these individual provincial/institutional EHR projects that may one day require upgrading to ensure interoperability.

Canada Health Infoway (Infoway) created in 2001 is a nonprofit organization operating separately from the government. Infoway works closely with the Canadian Medical Association (CMA), an interest group comprised of doctors across Canada that is also in support of a more centralized approach to EHR system development. One of Infoway's objectives is to try to accelerate the development of EHRs across Canada. Their plan is that different provinces and territories will have slightly different EHR systems to suit their own needs but they will all be connected and accessible across the country. Since 2001 the federal government has provided Infoway with \$1.6 billion which they have spent across the country in EHR related initiatives (*Audit Reports 4-5*). Infoway has been audited to ensure that they have been managing the funds from the federal government to successfully implement compatible EHRs across Canada (*Audit Reports 7*). The goal of Infoway is that "by 2016, 100 percent [of Canadians] will have their electronic health record available to their authorized health care professionals" (*Audit Reports 9*). These authorized health care professionals would be in the institutional settings but Infoway estimates that 80% of patient encounters with health care professionals take place outside an institutional setting. Their mandate includes the premise that EHRs should be accessible in locations other than in hospitals, such as in clinics, pharmacies, laboratories, and physician offices (*Audit Reports 11*).

The CMA has a plan to adopt centralized Health Information Technology (HIT) solutions to current health related issues. One criticism has been that HIT developments have been costly,



but little change has occurred because of the top down approach taken by the federal and provincial jurisdictions. The CMA suggests that investments should not always be made on a large scale, especially when most healthcare appointments occur in physician offices. HIT infrastructure upgrades tend to occur in hospitals, even though “patient-physician office interactions outnumber patient-hospital interactions by a ratio of 18 to 1” (*Health Care Transformation* 22). The CMA’s main goal has been to focus HIT investments at the point of care and support smaller scale solutions, leaving Infoway to develop the larger scale solutions (*Health Care Transformation* 24). The CMA believes that the addition of an independent third party to monitor a national EHR system will limit the jurisdictional debates surrounding any changes to Canada’s health care system (*Health Care Transformation* 26). That being said, many provinces have already invested in provincial EHR systems and will not allow a third party to enter their realm and control their already costly initiatives. The federal and provincial governments must decide who will develop and maintain a pan-Canadian EHR system. Jurisdictional issues should be addressed before such a system is effectively developed in a cost efficient manner.

How much will EHRs cost Canada’s already expensive medical system? “While no complete economic benefits have been fully documented and studied in Canada [...] Canada is estimated to be on track to realize \$1 billion to \$1.9 billion in annual benefits to the system through eliminating duplicative tests and, more importantly, reducing adverse drug events” (*EHR 2015* 12). Total incremental cost in the next ten years is said to be about ten billion and twelve billion dollars in additional capital. This does not include 1.5-1.7 billion in annual operating costs (*EHR 2015* 19). On the other hand “two studies commissioned by Infoway have indicated that, once they are in place, EHRs will save an estimated \$6 billion each year” (*Audit Reports*

11). These investments represent expenditures of 2% per year out of approximately 100 billion dollars a year spent on health care and are very similar to investments made in the United Kingdom. Therefore “Canada will only be slightly below the average IT spending by other information-intensive industries (e.g., banks, [etc])” (*EHR 2015 19*). Other information-intensive industries tend to spend approximately 5% on IT (*EHR 2015 19*). The following table outlines the possible investments:

**Table 3.0: Canada’s Incremental Investment to Complete to Vision**

<b>INCREMENTAL INVESTMENT TO COMPLETE THE VISION</b>		<b>Incremental capital costs \$ Billions</b>
<b>Foundational elements</b>	Complete baseline EHR	2.2-2.6
	EMR to GPs/specialists	1.6-2.0
	Patient portal	0.1
	CIS	2.5-3.1
	<b>Total foundational elements</b>	<b>6.4-7.8</b>
<b>Additional elements</b>	Public health	~0.1
	Patient safety*	0.0
	Chronic disease	0.2-0.4
	Access/wait times	2.0-2.5
	Self-care	0.9-1.1
	Performance management	2.0-2.5
	Overlap**	-(1.6-2.4)
	<b>Total business needs</b>	<b>3.6-4.2</b>
<b>TOTAL VISION</b>		<b>10.0-12.0</b>

Note: Costs are incremental, therefore, foundational costs already incurred by Infoway and the jurisdictions are not included. Costs are inclusive of change management but do not include: annual operating costs (\$1.5 billion-\$1.7 billion); community care enablement (~\$3.7 billion), and business process redesign.

\* Costs are incurred as part of foundational elements (EMR and CIS), public health (research), and performance management (monitoring and reporting)

\*\* Costs overlap as some systems deliver multiple business needs but are only counted once in total costs

Source: *EHR 2015: Advancing Canada’s Next Generation of Healthcare*. Ottawa, ON: Canada Health Infoway, Health Canada. 2005.

In addition, the monetary risks in not investing in a pan-Canadian EHR system must be considered as well. Allowing provincial governments to make uncoordinated IT systems will lead to incompatible systems without standardization across Canada. Exposure to legal and ethical issues in relation to medical errors will also increase from a lack of timely information in an age of computers. Canada will continue to fall behind countries that can provide better healthcare to its citizens (*EHR 2015* 21). Younger physicians who are more comfortable working in computer environments will demand that improvements be made, particularly in rural areas. Perhaps physicians will be more inclined to work in rural areas if they had the same resources as the urban centers (*EHR 2015* 21). The largest ethical issues surrounding EHRs are regarding confidentiality. Do the benefits of EHR systems outweigh the possible confidentiality breaches, amongst other issues?

### *Confidentiality Issues*

Privacy is the largest ethical issue in relation to EHRs. While technological advances concerning EHRs are progressing, policy development in relation to EHRs has been stagnant. If confidentiality breaches are not addressed through policy, then the public will not feel secure about their patient records being computerized and available across Canada. Public support is needed for the successful implementation of EHRs. "Privacy involves the right of individuals to determine when, how and to what extent they share information about themselves and others. Survey after survey has found that Canadians are concerned about the loss of privacy in an electronic world" (*Toward EHRs* 26). If a pan-Canadian EHR system is implemented, EHR specific legislation must follow to secure the privacy rights of Canadians. Such a system cannot be created without the constant need for upgrading to the latest technological standards and an

adaptable system to guard against new viruses and illegal attempts at access. It is important that a pan-Canadian EHR system is upgraded as developments in health care technology occur and that policy closely follows. Patient confidentiality can be protected in an EHR system in compliance with strong policies.

Another point to consider is that there is a fragile balance between what is best for the individual patient, the population and society, and the protection of patient information. At what point in time does protection of privacy becomes harmful to the patient and to society? There is a demand for interventions that not only save lives but maintain wellness and safeguard a youthful quality of life. Though confidentiality must be protected in a pan-Canadian EHR system, protecting confidentiality should not mean that primary care suffers and that the populace is not given the best health care possible.

The largest point of controversy is that if these electronic health records are easily accessible by health care professionals, confidentiality can be breached and sensitive information can be exposed including: abortion information, emotional psychiatric problems, sexual behaviors and transmitted diseases, substance abuse, genetic predispositions, to name a few. Scholars have noted that such breaches occur just as frequently in paper based systems (Rindfleisch 94). Most North Americans are unaware as to who has access to their health care information in our current paper based system. Health care data is sent to insurers, used in quality reviews, incorporated in research, public health management, etc. Although consent is necessary, most patients are not clear what they are consenting to. The greatest threats to patient confidentiality usually occur within the hospital via accidental disclosure, subordination, curiosity, etc. Breaches due to curiosity usually occur when medical personnel access the records of family members, friends and even acquaintances. Subordination is when health care records

are accessed for profit, revenge, etc – this is often done to people with celebrity and political status (Rindfleisch 95). None of this is to say that electronic breaches of confidentiality are not a concern. There are difficult tradeoffs to be made, but it goes without saying that with either electronic or paper records confidentiality will never be ensured 100% of the time.

Audit trails are an effective tool to ensure confidentiality in any database. If the users are aware that a technological system is recording what they are accessing and at what time, then users lacking ethical boundaries may choose not to abuse the system (Rindfleisch 98). Audit trails would deter abuse because all authorized users would be aware that every time they access medical records the name of the user and date/time of access is logged. Deterrents are effective especially the fear of legal action and job loss. Audit trails should be reviewed at random to detect unauthorized access (*For the Record* 97-8). “Firewalls [also] enforce manageable perimeters around distributed information systems, and limit modes/protocols for access” (Rindfleisch 98). Currently paper record systems only leave a trail if a notation was made on a record i.e. nurse adds a penned entry. EHRs can have audit trails which can note something as basic as someone simply viewing patient’s record without making any changes (*NHS Guarantee* 8).

If Canada created a pan-Canadian EHR system they would require rights management software ensuring a secure delivery of information. In this system content would be both segmented and encrypted, users would be granted access keys and access to different levels based on their identity and job function. Access keys can connect provinces and institutions. EHRs can also be watermarked and even fingerprinted. Watermarking adds visible translucent images on all pages. Fingerprinting adds hidden data about who bought and has rights to use the

software. Decryption keys will also authenticate who can access the software. An audit trail would list who has obtained access, if copies were made of the record and when the access took place. In some provinces such a system also exists with paper records (Rozovsky & Rozovsky 77) but human error would not be an issue because the audit trail would automatically log all of a user's actions when he/she accesses an EHR.

The possibility of using smart cards as a security measure was briefly discussed above. A smart card token can go further than what is available on credit cards. It can have a dynamic display where "each user card generates a unique sequence of numbers over time, and, through a shared secret algorithm, servers for which the user has been assigned access privileges can generate the corresponding sequence of numbers" (*For the Record* 91). This would mean that the random number acts as a password so an unauthorized user would only have a short window of time to access information before a new number is randomly generated (*For the Record* 91). This would help ensure the security of one's information.

Biometric authentication technologies are also an option. This would mean that a features such as retina scans, fingerprint scans, etc would be part of the EHR identification system (*For the Record* 92). Inexpensive laptops now come with fingerprint scanners to enter a user's account. On the other hand biometric systems are not always reliable and at times take many attempts at scanning before the physical scan is accepted by the system. This can lead to user frustration and precious time can be wasted. In the US, biometric identification is already being used to avoid forgeries in immigration control, driver's license verification, etc (*For the Record* 92).

The Computer Emergency Response Team (CERT) says that viruses and other forms of network attacks are often due to a lack in the configurations of existing systems to current technological standards and to new software (Rindfleisch 98). In sum, a confidential pan-Canadian EHR system should be constantly updated to the highest standards to protect the data. Confidentiality is an issue with both people and ethics, a strong technological system can ensure that EHRs are accessed on a need-to-know basis, but once they are accessed it is up to the individuals accessing them not to abuse confidentiality standards. “That depends on ethics and an effective supervisory and legal structures that provides sanctions against detected misuse” (Rindfleisch 99). We must not forget that human beings without audit trails to fear can also access paper based patient data for unethical reasons. A balance must be made between the protection of privacy and ensuring that patients are receiving the best possible care. Informed consent is an important part of a pan-Canadian EHR system reassuring patients that access to their information is not being abused.

Physical protection ensuring the safety of computer systems that can access EHRs is also important. These computers should be in buildings with alarms for off hours, computer screens should not be visible to anyone walking by, etc. Computers should have automatic screen lock outs after a pre-determined time of inactivity has occurred. Screen lock outs are important if an employee has left his/her post and his/her computer is on and easily accessible. Printers and recycling bins should also be in monitored locations and freshly printed papers should be picked up regularly so that they are not read or taken before the person who printed them has a chance to retrieve them. Outdated computer programs and other media must also be destroyed appropriately so that information is not extracted from them (*For the Record* 100-1). To ensure

that data cannot be physically taken from computers with EHR access, CD-Rom burners and online software downloads should be disabled from those computers (*For the Record* 109). Many of these physical security concerns also exist with paper based systems.

Perhaps we should aim for the confidentiality standards of banks and other financial institutions. Banks are privately run institutions which have more funds available at their disposal, thus they can afford to offer the best protection. “However, whereas financial enterprises such as banks and credit card systems can absorb the costs of abuse over the user community, without undue hardship on individuals, medical enterprises can not” (Rindfleisch 100). When a person’s debit or credit card is compromised the account can be frozen and the individual issued a new card and number. The inconvenience is as slight as not having access to his/her funds for a few days and having to go to the bank to activate his/her new card. When electronic medical information is compromised and accessed without cause, the damage is done. One can remove the intruder from the system and legal sanctions may occur but he/she will still have that person’s medical information. This is why it is imperative that we minimize all possibility of illegal breaches. “Canada’s healthcare system would rank No. 10 in the *Fortune* 500, is 3 times the size of the Royal Bank, and yet has limited ability to manage its information” (*EHR 2015* 14). In a survey in 2007, one Canadian responded: “We trust banking electronically, so we can trust electronic health records using proper encryption and proper storage.” (*Privacy Survey* 51).

Interac<sup>®</sup> has both created and manages Canada’s national network of both Shared Cash Dispensing at automated bank machines and Interac<sup>®</sup> Direct Payment. The network is decentralized meaning there is no single point of failure that can compromise the 35, 000 ATMs.



Interac<sup>®</sup> does not transfer the funds, it only “exists to facilitate the exchange of settlement obligations between a cardholder’s financial institution and the operator of the terminal” (*White Paper EHR* 60). A 14 person Board oversees the rules governing transactions and the services. What does this mean for EHRs? “The Interac<sup>[®]</sup> experience shows that a large-scale, Canada-wide IT network can be efficiently deployed and governed to enable highly reliable, high-volume exchanges of confidential personal information among a diverse set of stakeholders” (*White Paper EHR* 60). Canada should look at the security measures taken by other institutions like Interac<sup>®</sup> to protect EHRs. Canadians will feel more secure if Canada adopts measures used by other institutions that Canadians already trust and use.

Validation is also an important tool to consider. Validation is documented proof of testing a system that involves user specifications and requirements, a pre-approved testing plan, execution of the test plan and discrepancy reporting and resolution. A help desk process should also be implemented to ensure that discrepancies during regular use are reported, resolved and documented. Trends in discrepancies can be detected if a help desk system is implemented and similar bugs can be prevented when upgrading the system. If computer systems are validated to ensure that they are functioning as expected, then the risk of malfunction decreases. Regular audits by Health Canada or objective third parties can also ensure that users of a system have documented training, that the EHR system is running as expected and that malfunctioning is reported and resolved in a timely manner (*For the Record* 106-7). If EHRs are implemented across Canada we cannot preempt every potential technological disaster, but neither can banks or other institutions that hold our personal data electronically. With strong disaster planning and recovery procedures, and with a validated system that is audited yearly, we can protect our electronic health care information.

### III. Canada's EHR Advancements

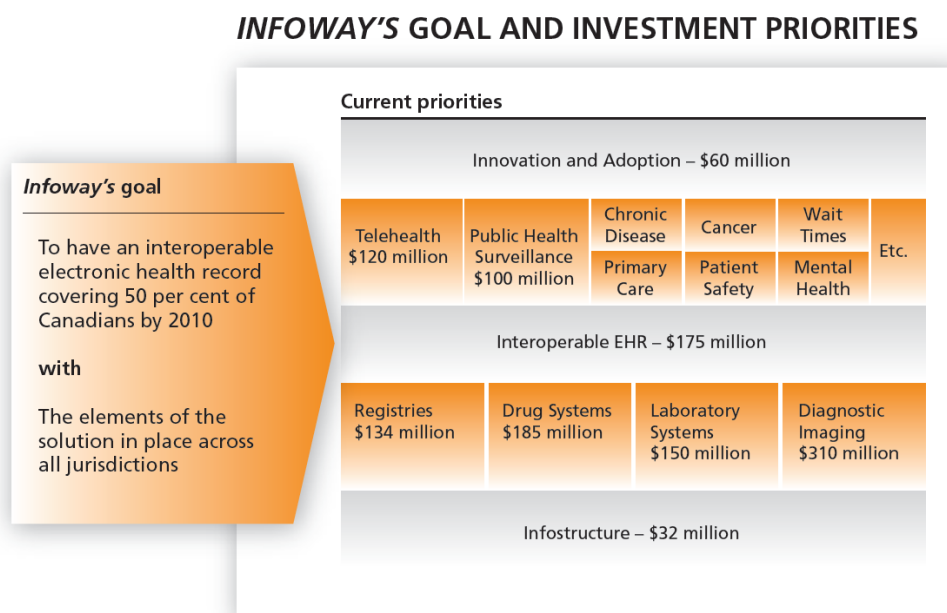
#### *Canada Health Infoway*

After the First Ministers' Agreement in 2000 the federal government chose Canada Health Infoway to invest 500 million dollars and stated that the top health care priority included an interoperable EHR system to be used across and within jurisdictions. Political leaders discussed such a system again in the 2003 Accord on Healthcare Renewal and again in 2004 in the 10-Year Plan to Strengthen Healthcare (*EHR 2015 5*). "Infoway is an independent, non-profit corporation with responsibility for accelerating the development and adoption of modern systems of information technology with the aim of providing better health care" (Romanow 79-80). As of 2005, the Government of Canada has invested \$1.2 billion dollars in Infoway (*EHR 2015 5*).

Infoway is forging a relationship with the provinces and with the Advisory Committee on Health Infostructure. Presently Canada Health Infoway is assisting the provinces in building separate EHR systems, "system by system, community by community, provinces and territories are making EHRs happen for Canadians, fuelled by local initiatives such as patient registries, diagnostic imaging repositories and telehealth solutions" (*Canada Health Infoway Web*). Infoway is making these EHR systems interoperable to ensure compatibility. They have created the *EHR Solution Blueprint* to ensure that EHR systems are fast and secure, as well as explain how they manage health care data. We should not only ensure that EHR systems across the country are developed to be interoperable, but also standardized using a similar template. Changes in the template should only be made for important differences amongst the provinces that may require changes to individual EHRs.

Infoway is taking into account all questions concerning the safety and durability of EHRs. They have integrated privacy and security architecture and demonstrated how information can be securely shared in Canada. The argument is that privacy can be bolstered if the EHR infrastructure continues being developed according to Infoway's plan of action (*EHR Solution Blueprint V.2 4*). Canada Health Infoway suggests that the implementation of EHRs can lead to a reduction in wait times and a decrease in repeated diagnostic tests, new methods for patients and health care providers to manage chronic diseases, an improvement in overall care leaving more time to devote to patients, and better control over infectious disease outbreaks through access to trends and valuable information (*Canada Health Infoway Web*). Canada Health Infoway has set a certain standard for building electronic records and has prioritized their investments up to 2015-2016:

**Table 4.0 Canada Health Infoway's Goal and Investment Priorities until 2015**



Source: *EHR 2015: Advancing Canada's Next Generation of Healthcare*. Ottawa, ON: Canada Health Infoway, Health Canada. 2005.

In the 21<sup>st</sup> century Canada has been trying to make the development of EHRs a political priority because Canada has had a history of under investing in health care information technology. When investments did occur they were often fragmented and duplication occurred due to a lack of organization, but Canada Health Infoway is trying to change that (*EHR 2015 14*).

Canada Health Infoway recognizes that the EHR infrastructure will differ depending on regional jurisdictions but will eventually expand beyond hospitals to physician offices, community care centers, etc (*EHR 2015 16*). Many medical encounters occur in physician and specialist offices, thus EHRs must also be accessible at these locations. This will cause a whole slew of challenges which will not be solved by 2015-2016, which is when Infoway would like to connect all Canadian hospitals through respective compatible EHR systems (*EHR 2015 25*).

#### *FDA's 21 CFR Part 11 Requirements*

In the United States the Food and Drug Administration (FDA) developed 21 CFR Part 11 Guidelines on reliable electronic records and electronic signatures that are also equivalent to paper record guidelines. 21 CFR Part 11 requirements are mostly used in relation to FDA regulated industries such as pharmaceutical companies, but can be applied to any field that uses electronic records and signatures, especially in conjunction with human data. What is important is that if an industry keeps paper records, then this be considered the source document and the electronic records need not meet FDA requirements (*21 CFR Part 11 13430*). In a pan-Canadian EHR system the source document would be the electronic record. Canada does not have any electronic record guidelines as extensive as those by the FDA. Clinical research organizations, pharmaceutical companies and other medically orientated industries, as well as Health Canada,

tend to follow the FDA's 21 CFR Part 11 Requirements for Electronic Record Handling and Electronic Signatures (21 CFR Part 11 13448).

21 CFR Part 11 Guidelines discuss the following requirements: security, audit trails, backup, archiving, record retention, validation, etc. In Canada according to the *Guidance for Records Related to Clinical Trials*, clinical data must be saved by the sponsor for 25 years after the record was created (*Records Related to Clinical Trials* 8-10). "This retention period will allow for patient follow-up [...] as well as provide the ability to assess the impact on second generation" (*Records Related to Clinical Trials* 10). Canada's *Guidance for Records Related to Clinical Trials* is in relation to clinical trial data but the guidelines are applicable to electronic health data. Data can be transferred to a medium (i.e. tapes, DVDs, etc) and archived but the data must be validated after the transfer process is completed. This ensures that the mediums retain an identical copy of the source documents (*Records Related to Clinical Trials* 10).

Besides government policies, standard operating procedures must be developed on how to edit, handle, access, backup and archive electronic health records. Users should be made aware of audit trails and there should be other protections against unauthorized editing and browsing of the data (*Systems in Clinical Investigations* 3-5). How will electronic health records be stored over the long term and where will they be archived? How long should they be kept?

The future accessibility and compatibility of archived data and once again the security of these archives is important. Data should be retrievable throughout its retention period but this can be complicated because information technology systems will be upgraded yet they must be capable of reading data that was recorded on the older systems. "When electronic formats are the only ones used to create and preserve electronic records, sufficient backup and recovery

procedures should be designed to protect against data loss” (*Systems in Clinical Investigations* 6). Backup records should be stored offsite at secure locations such as Docu-Dépôt in Quebec which provides storage facilities for archived documents and media. Locations such as Docu-Dépôt can host data tapes and have taken precautionary measures against fire, flooding, etc. If archiving data at an offsite location is too expensive, large hospitals may choose to build fireproof archive rooms separate from the main records with an elevated floor to preempt the possibility of floods. Besides archiving electronic records, the system should be backed up daily to minimize the loss of data due to a system failure (*Systems in Clinical Investigations* 6-7).

The FDA has suggested two methods for archiving medical data with the assurance that it will be accessible in the future. One is the time capsule method which “involves the preservation of the exact computing environment in which the data were acquired and processed” (Fergus & Kuehl 32). The time capsule option is because there is a fear that electronic data is reliant on the original information technology but this is not a long term solution. This solution can get expensive and if the advancements are numerous, storage may become an issue (Fergus & Kuehl 32). Another solution is data migration which “involves the translation and migration of records through, if necessary, several successive computerized systems during a record’s retention period” (Fergus & Kuehl 32). Therefore data will always be upgraded and transferred to the latest mediums of data to ensure its compatibility throughout its retention period. One should be able to access the records that were transferred to the new system in the same capacity that they were accessible in the old system. Periodic testing and auditing would be a necessity to ensure that the records are accessible (Fergus & Kuehl 34).

Ensuring that data is retrieved when needed is important in convincing the government that a pan-Canadian electronic health record system can improve Canada's healthcare system. Retention and retrieval is important so that the system is not overloaded with old health care records (i.e. deceased patient records). These records must be saved in case of FDA or Health Canada audits, to trace hereditary diseases in relatives, for medical research, etc. Unfortunately "science-based industry has puzzled over ways to guarantee long-term access to its archives of historical analytical data" (Fergus & Kuehl 36) and it seems that there is still no proven method, only suggestions on how to archive data. In Canada, healthcare data may migrate across different provincial computing platforms thus operating systems, storage media and the information technology itself should be similar and compatible across the provinces (Fergus & Kuehl 34).

#### *Alberta Netcare*

There have been success stories across Canada concerning EHR implementation. "At the federal level, Health Canada has undertaken an initiative to implement the First Nations Health Information System" (*Toward EHRs* 22). Aboriginals have many genetic health problems and an advanced information system was necessary to provide the aboriginals across Canada with proper care. The system holds information on chronic diseases and other health facts such as immunizations. Aboriginals have specific disease trends and this EHR system has helped identify them. This is an example of how a Canadian EHR system has benefitted a specific group of Canadians.

In remote areas such as northern Canada having an EHR system is an undisputed necessity. Dr. Ewan Affleck lobbied the local health authority in Yellowknife to fund such a system. Prior to having an EHR system patients would go to different clinics very far apart

depending on where their nomadic lifestyle brought them. Doctors and medical staff would be unaware of their patient's file in another clinic. Medical staff would also have to travel long distances in diverse weather conditions to receive patient information or view an important x-ray and often things would be missed, but this is no longer the case (*Canada Health Infoway Web*). "Really, this is the standard of care now. We're well past the stage where people debate if this is a tool that is required. It is absolutely required to provide effective care" (*Canada Health Infoway Web*).

The most successful implementation of a provincial EHR system in Canada is the development of the Alberta Netcare EHR system. It has "more than 6,000 users, provides physicians with the ability to track their patients' test results and medication histories within the health region, regardless of location/facility where a given treatment has taken place" (*EHR 2015 12*). Chronic disease treatment has improved as well as support for decision making and dosage alerts. Benefits of this system include a 50% reduction in lab requests within a year and a half of its implementation (*EHR 2015 12*).

To date, Alberta Netcare does not cover all of Alberta but most authorized health service providers. The EHR is a lifetime record but it is not a full medical record because the entire province is not yet connected. Alberta EHRs include demographic information, list of prescriptions, allergies, immunizations, medical reports, etc. Alberta Netcare is more than a replica of paper based records it also advises health service providers on drug to drug and drug to allergy interactions when prescriptions conflict. The system holds a database of all available drugs and their common dosages and other links to information (*Alberta Netcare Web*).



The EHRs are accessed through the existing information technology systems in pharmacies, labs, etc. Data has not been re-entered into the new system, thus limiting chances of errors. Of course some data can be directly entered into the system by authorized users. Alberta Netcare has benefitted patients by allowing clinicians to have current information on their patients, access reference tools to make sound decisions, and access more information at the point of care which can reduce delays in treatment and help make decisions in critical situations. Patient records are now more easily read and understood leading to a decrease in unnecessary treatments which in turn has reduced adverse events. Netcare has also benefitted patients because diagnostic test results are easily accessible with EHRs thus the duplication of tests has also been reduced (*Alberta Netcare Web*).

Alberta Netcare boasts a deployment team in charge of placing the Alberta Netcare Portal in practices and facilities, and training those who use Alberta Netcare Portal within their office (*Alberta Netcare Web*). If Canada chooses to use existing EHR systems in the creation of a pan-Canadian EHR system, it has to take into account that some systems, like Alberta Netcare, will be more advanced and informative than others. Without a pan-Canadian EHR system, there will not be standard of care across the country because some provinces remain more advanced than others.

Alberta Netcare uses a data model based on eXtensible Markup Language (XML) which is a format for the translation of completely secure computer records. PDF records used to be used by the FDA but this did not permit the processing of record information because it was a static form of data that did not allow the manipulation of data to generate analyses, amongst other functions (Fergus & Kuehl 34). PDF documents are difficult to alter but XML is now more

common for it is more dynamic and static documents are no longer compliant with 21 CFR Part 11 requirements. XML is now being used as both a data interchange and a storage format. “It is a public-domain, platform-neutral data-formatting standard that offers an application-independent way of representing data” (Fergus & Kuehl 34). Since XML can be used in different industries it is important that its use and structure is documented to enable controlled usage. Numerical accuracy must be enforced using standard ASCII characters.

The United Kingdom has a national EHR program and in 2000 the UK said that they have “focused on pharmaceutical R&D, [and] over 75% of the executives who responded indicated that they were planning to deploy XML as part of their R&D strategy or commercial product” (Fergus & Kuehl 34). The FDA has been recommending the use of XML for years and if Canada decides on this format for their national EHR system, then this can ensure a common format across the country. This format will allow the migration of electronic health records while complying with FDA and Health Canada guides on the retention period of electronic health records (Fergus & Kuehl 36).

Alberta also has a prescription information technology system known as PIN. “PIN is a separate drug information management system that has been seamlessly integrated into Alberta Netcare EHR Portal to support access to prescribed drug and Over the Counter (OTCs) drug information” (*Alberta Netcare Web*). PIN provides health care professionals with prescription information creating a network of doctors who can seek advice from each other. Patients can now view their drug information at the same time as their lab results, and diagnostic imaging results. “Currently approximately 90% of DI [Diagnostic Imaging] reports on DI tests are available through Alberta Netcare EHR Portal” (*Alberta Netcare Web*). Alberta Netcare EHR

Portal holds 90% of prescribed drug dispense activity in Alberta. Alberta Netcare is also ensuring that each drug dispense event is associated with a specific Provincial Health Number (PHN) or Unique Lifetime Identifier (ULI) to identify patients receiving drugs (*Alberta Netcare Web*).

Alberta has developed registries to increase the security of their system and support the secure authorization of the health care service providers using Alberta Netcare EHR. Registry projects include a client registry identifying each patient uniquely and securely adding their medical information to their record. A provider registry for physicians, pharmacists, and other health care providers to attribute care decisions and directions, which also identifies who is accessing Alberta Netcare. A service location registry has also been created explaining where medical services were performed and other administrative information. Finally Alberta has a client event repository which captures key clinical events at the point of care to help physicians assess their patient's encounters with the health care system (*Alberta Netcare Web*).

*Alberta's Health Information Act* (HIA) has established rules to protect individual health information and to regulate the use and disclosure of this information. The legislation specifies a limited manner that health information can be collected and disclosed with a high degree of anonymity. In Alberta the Office of the Information and Privacy Commissioner oversees what is outlined in the HIA and ensures that this legislation is being followed (*Alberta Netcare Web*).

Before a user is authorized to use Alberta Netcare they must pass privacy and security assessments and sign an information manager agreement with Alberta Health and Wellness limiting what health information can be accessed. Users are restricted based on their job description and they are given a login ID. If users need to access Alberta Netcare outside a

government or Alberta Health Services network they are issued SecurID® remote access fobs. All access to Alberta Netcare is logged via audit trails, electronic messages are encrypted and data is protected by firewalls. Even an intrusion detection system detects unusual activity (*Alberta Netcare Web*).

Alberta also offers individuals a form for opting out. Patients can request that their information be masked meaning that not all information will be automatically visible when a record is opened, except for demographic information. Alberta calls this Global Person-Level Masking (GPLM). Health service providers can choose to unmask a record under limited circumstances and unmasking can be audited (*Alberta Netcare Web*). It is important that in a pan-Canadian EHR system Canadians have similar options if they do not wish their medical information unmasked. Currently consent and opt out options vary per province.

If a person discloses health information without a subpoena, warrant or other court request, that person can be penalized. According to section 108 (7) of the *Health Information Act* a person who “is guilty of an offence and liable in the case of an individual, to a fine of not less than \$2000 and not more than \$10 000, and in the case of any other person, to a fine of not less than \$200 000 and not more than \$500 000” (*HIA* 76). It is important that legislation follows the implementation of a pan-Canadian EHR system protecting Canadians and providing sanctions to demonstrate that Canada does not take breaches of confidentiality lightly.

#### IV. Legal Complications

##### *Federalism*

In 2002 the infamous Roy Romanow report was published on the future of health care in Canada. Recommendation #8 was “a personal electronic health record for each Canadian that builds upon the work currently underway in provinces and territories” (Romanow 76). Recommendations 9 to 11 suggested that Canada Health Infoway leads the development of a pan-Canadian EHR system built on the foundations set by differing provincial and institutional electronic health care systems. The report discussed the importance of Canadians accessing and controlling their personal health care data and the importance in maintaining the confidentiality of such records. The report also recommended amendments to the *Criminal Code of Canada* to protect rights to privacy and sanction the abuse of personal information (Romanow 76).

The mix of provincial/territorial governments, the federal government and the differing existing EHR systems can make implementing a pan-Canadian EHR system difficult. “The Canadian constitution does not address health and health care as a single subject nor does it explicitly allocate responsibility to one order of government or another. Both provincial and federal governments have varying degrees of jurisdiction over different aspects of the health care system” (Romanow 3). Many court cases as well as legal interpretations have led to the conclusion that the provinces have jurisdiction over health care services in Canada; it is a little more complicated with the territories. According to section 92(7) of the 1867 *British North American Act* “In each Province the Legislature may exclusively make Laws in relation to Matters coming within the Classes of Subjects next hereinafter enumerated; that is to say, the Establishment, Maintenance, and Management of Hospitals, Asylums, Charities, and Eleemosynary Institutions in and for the Province, other than Marine Hospitals,” this is the main

section that has been interpreted to mean that the provinces have jurisdiction over the majority of health care areas. Other sections have also been interpreted in the provinces favour such as section 93 where “in and for each province the Legislature may exclusively make laws in relation to education” thus the provinces control the education and training of doctors, nurses, etc.

When the provinces were given jurisdiction over general health care services in 1867, health care mainly concerned diseases and hospitals. In the 1800s health care was mainly controlled by the Church and was not a government provided social service, it has since been expanded to encompass so much more (Leeson 3). When constitutional sections are unclear in Canada, the court, more often the Supreme Court interprets the section in question. This is a difficult responsibility of the courts, for they do not want to strip too much power from the provinces or the federal government. Today health care is high tech and research is at time more miraculous than pharmaceutical medications, for research has taught us that changes in lifestyles, diet, exercise and preventive care in general has helped more people at a lower cost than medicine after they are sick (Leeson 20). In *Schneider v. the Queen* (1982) the Supreme Court said that “in sum ‘health’ is not a matter which is subject to specific constitutional assignment but instead is an amorphous topic which can be addressed by valid federal or provincial legislation, depending on the circumstances of each case on the nature or scope of the health problem in question” (qtd. in Braën 3). In *Schneider v. the Queen* the Supreme Court upheld the constitutionality of British Columbia imposing drug treatment because drug dependency is a local concern, though this could have fallen under the federal government’s jurisdiction since it is also a criminal law concern (Braën 8).

A contention is that because provinces manage health care there are different health care services and structures across the country. In some provinces health care is controlled by a regional board, some services can be controlled by local governments and larger services at the provincial level. It would be the most efficient if provinces ran their respective EHR systems but existing EHR systems are often run at the hospital level or by private service providers. Some have suggested that a third party company should manage EHRs in Canada but this is a complicated and problematic solution to federal / provincial jurisdictional issues (*Toward EHRs* 24). Currently Canada has different EHR systems in some of its provinces; some provinces even have multiple EHR systems in different provincial health care institutions. “The issue of linking these separate systems could be very problematic, thereby supporting the need for a coordinated national approach to EHRs” (*Toward EHRs* 24).

Governments have increased their involvement in societal matters since the implementation of the *British North America Act (BNA)*. The provinces have jurisdiction over the delivery of health care but health care services are expanding and the federal government has become a major contributor. Constitutional amendments are infrequent and are part of a complex process thus the government cannot wait for an amendment to decide who is in charge of health care. The courts may reinterpret existing sections of the Constitution but analyzing common practice should be the method chosen to decide who is in charge of what area of health care (*Leeson v*).

According to the *BNA* and case precedent, the federal government has responsibilities under more specialized areas of health care such as approving and regulating prescription drugs, providing health care to First Nations and Inuit people, etc. The *Federal Privacy Act* came into effect in 1983 to ensure that health records were protected in federal government institutions.

*Freedom of Information and Protection of Privacy Acts* exist in different provinces, they control how personal information is collected and disclosed in sectors such as hospitals, health ministries and other public entities. (*EHR Solution Blueprint V.2* 42).

The most important role that the federal government plays in supporting health care in Canada is by transferring funds to the provinces. This “federal spending power” is not explicitly stated in the Constitution but has been granted by the courts. These transfers may come with conditions on how the funds should be allocated (Romanow 3-4). The federal government uses its federal spending power to give bursaries to students, share the cost of Medicare, etc. There have been few court cases concerning federal spending power, one reason being that the citizens would not be pleased with the provinces for the federal government provides funds to many important provincial programs (Gibson 30). One complaint is that because the federal government can choose which provincial programs to fund, the priorities of the provinces are skewed to pleasing the federal government so that they receive funding. The federal government first proposed the Medicare system to the provinces but they rejected it, though later provinces began accepting it when large amounts of funding were promised. Today, the provinces would not argue that Medicare was an unnecessary expenditure but this is an example of how they were swayed towards receiving federal funding as opposed to what they believe was in the best interest of Canadians (Leeson 12).

The *BNAA* provides the provinces with jurisdiction over the social services that in 1867 were controlled mainly by the Church. After the Depression in the 1930s, the provinces did not have the funds to cope with the public demand that the government provide its citizens with basic social services. The federal government stepped in and federal transfers began (Leeson 4). In 1984 the federal government placed conditions on the funds it transferred to the provinces, the



provinces also had to annually update the federal government as to how they met said conditions. The federal government did this through “the *Canada Health Act (CHA)* which enumerated the five principles that have, in recent years, come to define the Canadian health care system: public administration, universality, accessibility, portability, and comprehensiveness” (Romanow 4).

Hogg, a well known political scientist has pointed out that cutting back funding does not translate to the regulation of health care. The federal government has been using its spending power to enforce the goals outlined in *CHA*. The provinces can always choose not to accept the funds and therefore not meet the conditions attached to the funds (Leeson 13). On the other hand “if a province refuses to participate in a federal initiative aimed at, say, implementing a new program, the taxpayers of that province would pay (through their federal taxes) for the program to be implemented in participating provinces without being able to reap the benefits themselves” (Braën 12). This is further complicated because who should be held accountable to maintain a federally funded provincial health care program is unclear and what if the federal governments cuts back on the federal transfers towards a specific program? Will the province be forced to support the program on its own (Braën 12)?

Besides federal spending power the federal government has taken control of areas of health care for varied reasons. One of the reasons concerns security and national defence which was demonstrated during the mailing of anthrax bacterial spores across the country. Among other areas of health care, the federal government also has exclusive jurisdiction over marine hospitals and quarantine, as well as Amerindians and Inuit as per the *BNAA*’s sections 91(11) and 91(24). A powerful area that the federal government also controls is section 91(22) which concerns patents of invention and discovery. Patents award the exclusive right to manufacture and profit from inventions. Patents are as long as 21 years in Canada and drug patents are very important in

both health care and medical research (Leeson 6-7). The federal government's control over criminal law in section 91(27) also complicates the province's jurisdictional authority over health care. The federal government can declare a health issue a crime and make it illegal, for example, certain drugs and abortion (Leeson 8). The federal government's jurisdictional rights over patent and criminal law elevate its role in the health care system due to the importance of these issues and that they may affect the country in its entirety.

Though there have been unfounded concerns, the *Canadian Charter of Rights and Freedoms* has not led to a change in health care jurisdictions nor have the courts used the *Charter* to re allocate powers. The *Charter* exists to limit federal and provincial sovereignty; therefore the *Charter* cannot be evoked to contest the distribution of powers. On the other hand if the provincial or federal governments enact legislation and exercise their jurisdictional rights, then this can be challenged using the *Charter* (Braën 5). Interestingly the *Charter* did not provide individuals with rights to health. In *Eldridge v. British Columbia* (1977) the Supreme Court stated that hospitals, even if they are private, must comply with the *Charter* (Braën 5-6). Therefore the *Charter* does have an effect on health care but may not necessarily be a direct effect.

The *Charter*'s section 15 equality rights can also lead to the federal government playing a more active role in health care because any health policy must adhere to the equality right standards (Leeson 17). Section 6 mobility rights also empower the federal government because equality of access between the provinces is important. Mobility rights draw on an interesting issue concerning electronic health records which are currently only available in some provinces and not necessarily throughout a province. Would mobility rights ensure the implementation of a pan-Canadian EHR system? Can the federal government create such a system under the premise

that Canadians have the *Charter* right to move across the country and receive the same level of care? Therefore provincial residents should be able to live in different provinces and be allocated the same health care services. The federal government can craft laws using *Charter* sections 6 and 15 under Peace Order and Good Government (POGG) (Leeson 18). POGG is the principle on which the country was built and is the main principle in which parliament should craft legislation. The federal government concerns itself with health care when it concerns criminal law, spending power and when the federal government ensures POGG (Braën 10).

The federal government also has jurisdiction over issues of national concern. In *R v. Crown Zellerbach Ltd.* (1988) the Supreme Court explained that many issues are important to Canada as a whole but that does not mean that they are of national concern. Therefore they are not always within the jurisdiction of the federal government. National concerns are separate from national emergencies and for an issue to be of national concern it must be distinguishable from areas of provincial concern and it must be on a grand scale. If an issue is not of national concern then the impact on Canada if the provinces fail in dealing with an issue should be minute, if not then the issue is of national concern. This distinction made in *R v. Crown Zellerbach Ltd.* is to ensure that the federal government does not claim that certain issues are of national concern simply to gain control of areas of provincial jurisdiction (Braën 13). The courts have played an active role in separating the jurisdictions concerning health care. If the courts are ever asked if the *Canada Health Act* should have conditions accompanying the federal funds to the provinces, they will likely uphold the Act (Gibson 32) because the federal government has a right to place conditions on funds that they provide.

In the 21<sup>st</sup> century it seems that the government is involved in many issues concerning security and the economy thus health care remains mainly under the provinces' jurisdiction.

There may be even a further decentralization in health care. On the other hand with the onset of globalization the federal government may decide that they must play a more active role in health care because it is in the best position to do so (Leeson 22-3). The federal government is currently acting on its promise in the *Constitution Act* section 36 that Canadians will be provided with equal and reasonable public services and taxation across the country. The provincial governments want the right to exercise their jurisdictional power in the area of health care with funding from the federal government but without conditions attached (Braën 12). As these issues become prevalent and enter the court's arena, it will be up to the Supreme Court to decide. Canada's jurisdictional issues are mainly discussed at the political / legal level whereas Canadians are more concerned with EHR privacy legislation, or lack thereof.

#### *Privacy Legislation*

The Romanow Report on the future of health care in Canada also provided suggestions for the implementation of EHRs. It encouraged a pan-Canadian EHR system that protected the security and confidentiality of the health information of Canadians through amendments to the *Criminal Code of Canada*. "The electronic health record system would enhance the ability of health care managers and researchers to identify and respond to medical errors or problems that occur in the health care system, and improve patient safety and quality of care" (Romanow 79). In other words, EHRs can identify serious risks to the population and allow scientists to assess the effectiveness of treatments across Canada and to detect rare but potentially serious adverse consequences. But at what cost will this affect the privacy rights of Canadians?

Canada needs to develop national policy initiatives concerning information technology and privacy. Infoway has privacy and security requirements, but there is also the *Pan-Canadian*

*Health Information Privacy and Confidentiality Framework* which was developed by the Advisory Committee on Information and Emerging Technologies (ACIET). This framework was endorsed by the federal government and the provincial governments of all provinces, except Saskatchewan and Quebec. This framework by ACIET provides guidelines in crafting statutes concerning the informed consent of personal health information. Health privacy statutes are revised according to these guidelines (*EHR Solution Blueprint V.2 12*). The provisions in this framework are consistent with requirements from both the *Personal Information Protection and Electronic Documents Act (PIPEDA)* and the *Charter of Rights and Freedoms*. The main principle of these guidelines is that health care information must be used and disclosed in a limited manner and in an anonymous fashion. *PIPEDA* also stipulates that privacy is a protected right and that individual consent is required for anything concerning personal health records. It is important to note that this is only a guide, thus legislatures must implement laws legitimizing this federal guide (*Health Privacy & Confidentiality Framework Web*).

Provincial data protection laws and *PIPEDA* have general clauses for protecting information but in the end academics must work out their own processes in conducting medical research (Willison 13). “Privacy protection of research participants is also a component of human research protection. In Canada there is no specific legislation. Instead, human research protections are informed by the Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans” (Willison 13). In Canada our multiple jurisdictions make it unclear as to who should take the lead. If EHRs are implemented, informed consent will have to be collected in a standard way across the country. It is important that the public understands what consenting to

the transfer of your medical records from paper to an electronic format means, and what those records can be used for (Willison 15).

The *Pan-Canadian Health Information Privacy and Confidentiality Framework* includes guidelines that request that technical and physical up-to-date safeguards exist to protect health care records from viruses, unauthorized access, etc. Laws with strict sanctions must be drafted to ensure that health records, whether in paper or electronic format, are respected. Informed consent is also discussed because individuals need to be aware as to why their health care information is required and who is accessing it (*Health Privacy & Confidentiality Framework Web*).

The Canadian Standards Association created its *Model Code for the Protection of Personal Information* which contains ten privacy principles based on internationally recognized practices. “All privacy statutes enacted in Canada since 1996 incorporate these principles in some form” (*EHR Solution Blueprint V.2 12*). These principles do require interpretation which has meant that there have been jurisdictional variables to the interpretation of these principles. The premise behind these standards is that advances in information technology have led to concerns surrounding the confidentiality of information and the right promising individuals that they can control their own information. Though EHRs will improve Canada’s health care system, this does not entail that a certain measure of anonymity should be forsaken to pursue this goal (*Protection of Personal Info viii*).

The principles are the following:

1. “Accountability - An organization is responsible for personal information under its control and shall designate an individual or individuals who are accountable for the organization's compliance with the following principles.
2. Identifying Purposes - The purposes for which personal information is collected shall be identified by the organization at or before the time the information is collected.
3. Consent - The knowledge and consent of the individual are required for the collection, use, or disclosure of personal information, except where inappropriate.
4. Limiting Collection - The collection of personal information shall be limited to that which is necessary for the purposes identified by the organization. Information shall be collected by fair and lawful means.
5. Limiting Use, Disclosure, and Retention - Personal information shall not be used or disclosed for purposes other than those for which it was collected, except with the consent of the individual or as required by law. Personal information shall be retained only as long as necessary for the fulfillment of those purposes.
6. Accuracy - Personal information shall be as accurate, complete, and up-to-date as is necessary for the purposes for which it is to be used.
7. Safeguards - Personal information shall be protected by security safeguards appropriate to the sensitivity of the information.
8. Openness - An organization shall make readily available to individuals specific information about its policies and practices relating to the management of personal information.
9. Individual Access - Upon request, an individual shall be informed of the existence, use, and disclosure of his or her personal information and shall be given access to that information. An individual shall be able to challenge the accuracy and completeness of the information and have it amended as appropriate.
10. Challenging Compliance - An individual shall be able to address a challenge concerning compliance with the above principles to the designated individual or individuals accountable for the organization's compliance.”

*(Protection of Personal Info ix).*

This international model encompasses the minimum requirements needed to protect personal information and legislation must follow suit. It was created prior to the EHR infrastructure developed by Canada Health Infoway. With EHR systems across the country, jurisdictions are being brought together under the health care domain. Privacy legislation concerning electronic records is necessary (*EHR Solution Blueprint V.2 45*).

The *Personal Information Protection and Electronic Documents Act (PIPEDA)* has enacted into law the ten principles outlined in the *Model Code for the Protection of Personal Information (EHR Solution Blueprint V.2 43)*. *PIPEDA* established national privacy standards that applied to health care providers, amongst others, in the collection, usage and disclosure of personal information. Provinces across Canada are drafting and passing legislation protecting health information. If provinces have similar legislation to *PIPEDA*, then the federal government's *PIPEDA* does not apply, such is the case in Ontario, Alberta, Quebec, etc. Some provincial statutes have security requirements that are stricter and more detailed than those outlined in *PIPEDA (EHR Solution Blueprint V.2 43-4)*. *PIPEDA* expired November 14<sup>th</sup>, 2010 and before it is renewed the Office of the Privacy Commissioner of Canada (*Privacy Commissioner Web*) has accepted submissions related to *PIPEDA*'s review. There have been many cases where courts have clarified sections of *PIPEDA* and the Privacy Commissioner has detailed summaries of court cases and how *PIPEDA* was read into. This is helpful in understanding *PIPEDA* more fully (*Privacy Commissioner Web*). It is up to Canadians who are unhappy with Canada's current protection of their electronic information to lobby the Privacy Commissioner concerning changes that they would like to see in *PIPEDA*, especially in preparation of a future with EHRs. The fear of breaches of confidentiality should not be a reason to stunt the development of EHRs in a technologically based society; instead acts like *PIPEDA* should be revised to protect personal electronic information where technological security fails. Such protections would include strict sanctions to those who break *PIPEDA*'s laws and other deterrents.



Jurisdictions developing EHR systems must adopt policies and enact statutes to protect the health information within their system. The issue concerning the different jurisdictions and their unique health care models is that consent is often different across the country. For example in Ontario, the *Personal Health Information Protection Act (PHIPA)*, states that consent is implied if the patient is aware of the purpose for needing his/her health care information for health care purposes. In Manitoba, the *Personal Health Information Act (PHIA)* is less rigid and consent is not necessary if the health care record is used for treatment reasons. Both provinces include opt-out rights but are not clear on the standard for consent. In Alberta the *Personal Information Protection Act* stipulates that individuals must give consent for the use of their health information. Consent in this context must be given explicitly and voluntarily or obvious to a reasonable person (*EHR Solution Blueprint V.2 113-4*).

Differing laws such as the differing EHR systems across Canada complicates both the transfers of information and the accessing of information in other provincial jurisdictions. If a pan-Canadian EHR system is implemented, then provincial informed consent legislation becomes an issue when health care information is accessed across jurisdictions. The solution is that “consent rules in jurisdiction X must be satisfied before personal health information in jurisdiction X may be disclosed to jurisdiction Y” (*EHR Solution Blueprint V.2 114*). Infoway is the coordinator of interoperable EHR systems and they follow the CSA Model Code which states that patients need to be informed on who is collecting their information, for what, and that safeguards exist to protect them (*White Paper EHR 9*). Other complications concern ownership of the data. Historically, the courts have allocated physicians or their institutions with rights over their paper medical records. If an electronic system is implemented, this outlook on health

records will change because the records will not be attributable to one doctor / institution because as the patient seeks care elsewhere, his/her records will be updated in those locations.

With the exception of a few provinces, Canada's EHR related laws are being crafted slower than EHRs are developing. "While technological developments related to EHRs are moving rapidly, the development of key policies central to adopting EHRs has not kept pace" (*Toward EHRs* 26). Often privacy laws are simply applied to EHRs but do not explicitly discuss them. The *Charter* does not give a right to privacy but the Supreme Court recognized this right in *R v. O'Connor* (1995) where therapeutic records such as counselling records were said to have a reasonable expectation of privacy. Since then the federal government has passed legislation to protect the privacy of Canadians (*White Paper EHR* 25-6). "Alberta, British Columbia and Quebec have private sector privacy legislation that protect personal information, including health information held by private health sector entities [and][...] Alberta is the only province with both a general private sector law and a health specific law" (*White Paper EHR* 27). Privacy and informed consent laws differ across the country, when information crosses jurisdictions it is unclear which laws/requirements should be followed. Laws are now being revised to add sanctions to breaches of privacy. Regulatory tribunals can deliver sanctions, these rulings are setting a precedent which should be converted to law (*White Paper EHR* 37).

Due to their advanced systems, health privacy laws in Ontario, Manitoba, Saskatchewan and Alberta are applicable across the country to all health care providers. British Columbia's *Personal Health Information Access and Protection of Privacy Act* is the most specific legislation concerning EHRs. Most of Canada's privacy laws are applied to EHRs but they do not explicitly mention EHRs. Canada should develop specific laws concerning EHRs (Young).

British Columbia's laws have strict sanctions and may set a good example for the rest of Canada. For example, in BC an offence can be fined up to \$200 000 for a variety of breaches and the bill even outlines the steps that occur when there are complaints concerning requests of information (*BC E-Health Act* Web). Stricter legislation with clearly outlined sanctions may ensure that the Canadian public accepts the implementation of a pan-Canadian EHR system.

### *Canadian Perceptions of EHRs*

What is going on with health care? Long emergency room wait times, lack of physicians and nurses, etc. These are some of the health care issues plaguing Canadians which are constantly addressed by the media. Solutions have been proposed but there is no definitive impact on the average Canadian. There does not seem to be any set plans to improve our current health care system. In an age where information on disease diagnoses and treatments is available online, the average Canadian turns to the internet for help and comes to medical appointments knowledgeable and filled with medical questions. 21<sup>st</sup> century "Canadians are demanding a greater voice and want to play a larger role in their health care" (*Toward EHRs* 1). The Romanow report suggests that Canadians are unhappy with the current health care system and are uninformed about EHRs and why they can help solve health care dilemmas (*EHR & Patient Safety* 9). One should adopt a patient-centric perspective to ensure that patients participate in the creation of EHR systems. Governments should determine a list of necessities from the patients' perspectives (*EHR & Patient Safety* 10). "Canadians' confidence in the health care system must be restored. They need to know what they can expect from the system and what the system expects from them. A critical step in restoring their confidence lies in making a clear statement of values and expectations that underlie the system and guide its future" (Romanow 48).

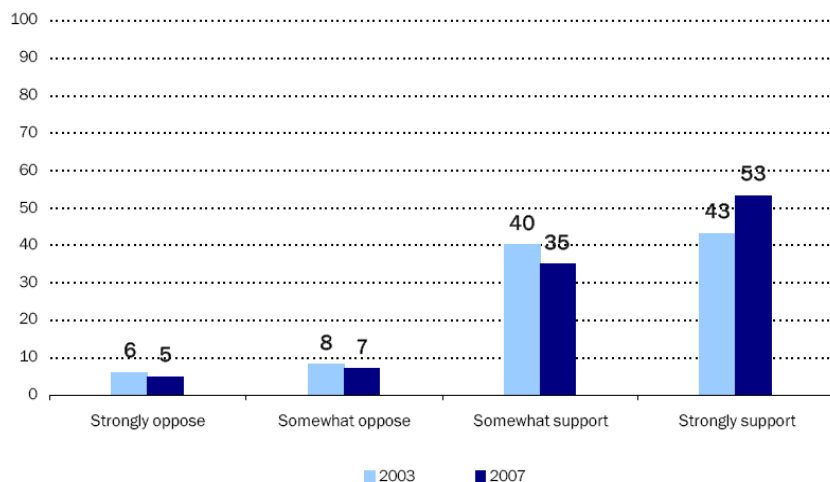
In 2007 an Electronic Health and Information Privacy Survey was conducted to evaluate the thoughts of Canadians on electronic health records. 87% found that access to personal health records will improve the quality of health care that they received. One in two Canadians worries about the medical errors in diagnoses or treatment decisions due to incomplete medical records (*Privacy Survey 2*). Canadians who have interacted with provincial or institutional electronic health record systems tended to be more aware of legislation and policies that protect their medical records, than those who had never used EHR systems. The Canadians who have interacted with EHRs also tended to approve of a national EHR system more so than others. 31% see the benefits of an EHR system more clearly after using or being part of it. According to this survey, Canadians deem privacy laws important but are not aware of what laws exist to protect their health records (*Privacy Survey 3-4*).

EHRs in general seem to be gaining support from Canadians. “Close to nine in ten Canadians (88 per cent) support the development of EHRs (up five percentage points since 2003)” (*Privacy Survey 4*):

**Table 5.0: Canadians Perceptions of EHR Systems in 2003 and 2007****Q:**

Overall, do you strongly support, somewhat support, somewhat oppose or strongly oppose the development of a system of electronic health records that would allow health care professionals to be able to access your records no matter where in Canada you are receiving care?

(Base: All Canadians; June/July 2007, n=2469)

**Support for EHRs:**

Source: *Electronic Health Information and Privacy Survey: What Canadians Think — 2007*. Canada: Canada Health Infoway, Health Canada. 2007.

A sample of approximately two thousand Canadians wrote in an open ended question that they supported EHRs due to the following reasons (the reasons are ordered from most popular to least popular reason): accessibility, efficiency, records available when travelling, improving health care services, up to date information, faster diagnosis, records available in emergency situations etc (*Privacy Survey 46*).

In 2007 more Canadians saw paper based systems as less secure than EHR systems. Since 2003 Canadians have become more supportive of EHR systems especially after hearing and understanding the arguments in favour of such a system. In general the public seems to be accepting EHRs and the largest contention against them is the fear that confidentiality will be

breached. If Canada satisfactorily addresses the confidentiality concerns of Canadians, then a pan-Canadian EHR system will be generally accepted across Canada. Right now, 77% of Canadians claimed that they would feel more comfortable if audit trails existed to see who is accessing their health records, and 74% support the enactment of new legislation making the illegal access of EHRs a criminal offence (*Privacy Survey* 4-5). The *Criminal Code of Canada* must be updated to squelch the concerns over the lack of sanctions for unauthorized access to EHRs. Both academics and Canadian citizens agree that it is of utmost importance that Canada's *Criminal Code* is updated as EHR systems evolve across the country.

Patients also want to be informed of security breaches, 70% said that they would feel better knowing that they will be informed if a breach or the risk of a breach occurs (*Privacy Survey* 5). In June 2009, Alberta's Netcare in Edmonton was attacked by a virus and impacted the Alberta Health Services Network before it was removed. The virus was a variant of the Trojan horse program and was controlled by a hacker to steal data. The patients at risk were ones whose information was accessed in Netcare using a computer with the virus, as well as employees who used the system for banking and other password protected mediums ("Virus AB Health Services" 30). Alberta Health Services sent over ten thousand letters to patients whose information was potentially exposed. Antivirus software has since been run and all systems are back to normal. Alberta Health Services investigated how this occurred and how to avoid such a breach in the future. What is important is that high risk patients were contacted, many whose information was in all likelihood never accessed ("Virus AB Health Services" 30). Canadians will feel more secure if they trust that their government will keep them informed of any EHR breaches.

Another issue explaining the public's hesitancy towards EHRs is the concern that many law suits may arise if a patient feels that his/her health records were used without his/her consent. Section 1.11 of the *Pan-Canadian Health Information Privacy and Confidentiality Framework* states: "No criminal or civil proceedings lie against the Commissioner/Review Officer, or against any person acting on behalf or under the direction of the Commissioner/Review Officer, for anything done, reported or said in good faith as a result of the performance or exercise or purported performance or exercise of any duty or power of the Commissioner as included in the respective legislation" (*Health Privacy & Confidentiality Framework* Web). That being said there are exceptions where the government can be held responsible if electronic information is breached. One instance is if the government did not take proper precautions or use up to date software and other available tools for protection. Law suits can arise for a multitude of reasons. A fear of law suits should lead to governments doing everything in their power to secure their EHR systems. Governments should not refuse to implement EHR systems over potential issues.

*PIPEDA* requirements do not include the right to sue if one's electronic information is violated. Complaints are taken to the Office of the Privacy Commissioner of Canada. The Commissioner must investigate any complaints and produce a recommendation report, but the defendant institution does not need to follow the recommendations. According to section 14 of *PIPEDA*, the complainant can take the report to the Federal Court of Canada and request a hearing (*PIPEDA* 16). According to section 16 of *PIPEDA*, the court may choose to award remedies. Other protections include the section 18 stipulation that if many complaints have occurred against an institution, the Commissioner can perform audits on personal information

management practices; if there are grounds to believe that an institution has not been following recommendations (*PIPEDA* 17). Mechanisms of investigation and auditing exist to ensure that complaints are dealt with and that EHR systems remain secure. All in all studies demonstrate that the Canadian public supports the implementation of a pan-Canadian EHR system but that certain confidentiality concerns should be met, and statutes developed before such a pan-Canadian EHR system is implemented.



## **V. United Kingdom's National Health Service (NHS)**

The United Kingdom (UK) has the National Health Service (NHS) making electronic health records accessible across the country. Citizens were contacted by their local NHS before summary records were implemented in their area. A letter and information package was sent to homes informing patients of the new system. In the UK citizens have summary care records listing a patient's allergies, medications that they have taken, etc. If a patient arrives in an Emergency Room (ER) unconscious, the physician treating him/her can access the patient's information and retrieve medical records to make critical decisions. In emergency situations it is not easy for ER physicians to contact local GPs or other hospitals for patient information. England has recognized that though their national EHR system is revolutionary, not all patients may want to participate in it. The UK has created an opt out system for those who do not wish to have summary care records and those patients will have paper records based on the previous paper based system (*NHS Web*).

The goal of the UK's NHS is that every English citizen has an electronic medical record across their lifetime, available at any time, in every NHS organization, including 90% of GP offices (*International EHRs* 13). In the UK, electronic health records have been taken one step further because citizens can access their summary records using HealthSpace, an online system in based in England. As in Canada, confidentiality is an issue, so health care providers who can access NHS records must have a smartcard with a chip and password, and their access will leave an audit trail to deter unauthorized access (*NHS Web*). Canada, like the United Kingdom, has chosen to create hub-and-spoke repository systems meaning that "they collect and store copies of critical health information in jurisdictionally coordinated repositories" (*EHR 2015* 7). The NHS also has a numbering system of ten digits, with the last digit being a validation digit designed to

prevent errors when entering information electronically. The NHS has advanced identification, has increased patient confidentiality and has improved the quality of health care data. The NHS is comprised of child health, breast screenings, patient registers, etc (*Int. Activities Toward EHRs* 7-8).

According to a 2009 survey “Health Information Practice Capacity Among Primary Care Physicians in Eleven Countries,” 96% of physicians in the UK said that they used EHRs, comparable to only 37% of Canadian physicians who have used them (Schoen, et al. w1175). In Canada a majority of specialists said that their patients were faced with long wait times, whereas less than 30% of UK doctors reported long waits, the lowest rate out of eleven countries (Schoen, et al. w1176). The creation of a national EHR system in the UK has improved both ER wait times and the wait for diagnostic tests. These two types of wait times are large scale issues in Canada which has lead to many patients seeking private care due to the problems with Canada’s current public system.

Electronic health records can help reduce adverse events particularly in emergency rooms where physicians are making critical decisions, often with limited medical information on their patient. Some adverse events occurred outside the hospital and the majority of doctors in Canada claimed that they lacked guidelines for identifying adverse events as well as a sound action plan. UK doctors claimed that they had processes that worked well to prevent the occurrences of adverse events (Schoen, et al. w1180). This is partially due to the existence of the UK’s national EHR system and other forms of electronic connections that physicians use to consult one another.

The NHS also has a constitution; the latest edition is from 2010 and sets out guidelines on patient rights in the national EHR system and the responsibilities of those accessing the system.

NHS services are free of charge and exist to reflect the needs of patients (*NHS Constitution* 2-3). Legal rights are an important aspect of this constitution, for example, you have the right to receive and access the NHS free of charge, you can travel to other European countries which are connected to the UK's NHS, etc. What is important is that “you have the right to access services within maximum waiting times, or for the NHS to take all reasonable steps to offer you a range of alternative providers if this is not possible” (*NHS Constitution* 5). The NHS has a list of maximum waiting times described in the Handbook to the NHS Constitution. The NHS also promises to secure a patient's EHR information and protect the confidentiality of medical records (*NHS Constitution* 5).

The United Kingdom has taken their national EHR system one step further with the creation of a national health line providing medical advice through the telephone and their website. This helpline assists both patients and doctors who have questions outside the day's working hours because the national health line is active 24 hours a day all year long. It helps patients deal with medical concerns, it is there to answer post operative questions and it provides support for patients with chronic conditions. The helpline answers 5 million calls per year, and another 5 million patients use the online services such as the symptom checker (*NHS Direct Web*).

In addition, England provides the Care Record Guarantee meaning that patients have the right to know who has access to their patient records and for what purpose. For example EHRs are accessed to provide patients with safe and effective care, protect the health of the public, audit NHS, etc. England has frameworks to ensure the confidentiality of EHRs. Alberta has developed frameworks which were said to be overly complex, but Canada has the *CIHR Best*

*Practices for Protecting Privacy in Health Research* (Willison 15-6) which can be made more specific if a pan-Canadian EHR system is implemented.

The government of England insists that patients control their own EHRs and are allowed to see them at any time. UK laws provide confidentiality under common law. The laws also provide guidelines on how your personal information is handled under the *Data Protection Act* 1998 and guidelines on privacy under the *Human Rights Act* 1998 (*NHS Guarantee* 2). In the United Kingdom, the Secretary of State for Health and the National Information Governance Board for Health and Social Care can decide if health care information can be provided for medical research without explicit consent. The UK's system ensures that patients are explicitly aware of what they are consenting to. UK citizens can add to their health care record the specific purpose(s) that they consent access for (*NHS Guarantee* 6), for example some may consent to the use of their EHRs for medical research and others may not. A patient is also informed when their EHR information is distributed to organizations outside of the NHS.

The UK has a Patient Advice and Liaison Service (PALS) for people who need advice and have questions concerning this national system. The NHS puts patients in charge of their EHRs (*NHS Guarantee* 7). Canada may choose to not make EHRs so easily accessible by patients; perhaps patients can have their doctor or administrator show them their record, but Canada can choose not to implement an EHR system where patients have read only access to their medical records. Patients having access to their medical records is complicated with mentally ill or handicapped patients where reading a doctor's comments can affect their mental well being. As Canada works through the ethical and legal issues with the potentiality of a national EHR system, they can later choose to have patients access their information through an online service like the UK's HealthSpace.

How does the UK protect patient confidentiality? Similar to the methods outlined above, the UK's national system uses smart card technology accompanied by a user name and password. Staff must have permission to access a patient's information and each smart card contains information on the user's job so that different people have access to different types of information; i.e. administrator, doctor, etc may not require the same access privileges. The NHS also uses audit trails which list who viewed/changed a record and date/time stamps the record every time a record is accessed. The latest EHR systems can also seal parts of a record that a patient may want to remain confidential. For example, infectious disease information can be made private from anyone accessing the information other than your doctor. Some systems have clauses where doctors can access your information in an emergency situation whereas other systems do not even allow for that if have chosen to seal parts of your health care information (*NHS Guarantee* 13-4).

As in England, Canadian citizens should be informed of their confidentiality rights and what sanctions will accompany breaches in confidentiality. National EHRs will be more accepted when they are understood and when laws with strong sanctions follow the development of such a system. In Canada, only 39% of Canadians in 2007 were aware of the laws in place to protect them from confidentiality infringement. Canadian citizens that understand EHRs and are aware of existing confidentiality legislation tend to embrace the creation of a national EHR system, as opposed to those who are unaware of the pros and cons associated such a system (*Privacy Survey* 3).

## **VI. Conclusion**

Is Canada ready for a pan-Canadian EHR system? Will the ethical and legal implications outweigh the benefits of such a system? Based on the evidence, it is clear that if Canada chooses to implement a pan-Canadian EHR system there are ethical and legal issues concerning both confidentiality, as well as jurisdictional debates that must be addressed through laws and at the Supreme Court level. All large scale electronic systems such as Interac® and the internet come with confidentiality risks that are associated with all IT systems. It is important to pre-empt potential issues and create a protected electronic system with firewalls and audit trails to protect the system. Such a system should also have legislative sanctions as a warning to perpetrators that were going to misuse electronic health records. In the end the benefits associated with a national EHR seem to outweigh the costs. Canada should look at success stories like the United Kingdom's and develop a unique system suited to the needs of Canadians.

A separate thesis could be written on the medical research benefits surrounding the implementation of a pan-Canadian EHR system. Though the benefits of a national EHR system on medical research were discussed above, they were not discussed in detail because this thesis focused on improving the quality of patient care through the use of EHRs.

In summary, at the present time Canada seems to be ready for an EHR system. The growing inadequacy of the health care system as it is to date, to provide quality care, the growing diverse population across large geographical locations, and the successful use of EHR systems in other countries are indicators of the current need for a pan-Canadian EHR system. The evidence demonstrates that Canadians seem to be ready to adapt to the use of such a system as long as the main concerns regarding confidentiality issues are addressed through written specific policies. Canadians stand to benefit from such a system in the reduction of waiting times for diagnostic

tests, procedures and medical care. In addition, health care providers could have direct access to personal medical information in a prompt manner which is imperative in the ER or when a patient is unconscious.

However, the implementation of a pan-Canadian EHR system seems to be a large undertaking that would involve many factors. Concerns regarding health care, human rights and safety requirements, research, ethical and legal issues, and government jurisdictions must be addressed prior to the implementation of such a system. It seems that the best of course of action would be to develop a committee to primarily address the legal and ethical issues. Such a committee can review laws and requirements such as the newly expired *PIPEDA*, as well as provincial laws, to develop general requirements that would satisfy the stakeholders across the country.

Input from the users should also be required through surveys and conferences. Not only health care providers but patients, lawyers and political representatives should also be consulted. User requirements should be outlined clearly in writing. Finally, IT specialists that have previous experience with such systems and with medical information should be consulted for their recommendations in developing such a system. Requirements regarding electronic records should be addressed. Security and access rights should be provided in detail, who will be allowed to edit medical records and for what reasons should be clearly defined. Users with read only access should also defined, as well as other areas of contention such as archiving and accessing stored data in the future, physical security of information, etc. There are many concerns and benefits to the creation of a pan-Canadian EHR system, what is important is that the concerns can be resolved. The table below outlines a brief summary of the pros and cons of EHRs that were discussed in this thesis:

Canada can use the United Kingdom's national EHR system as a foundation to its own initiatives. As an international player Canada should catch up to other countries whose use of IT methods is more advanced in the health care industry. Canadians are demonstrating support for Electronic Health Records and "a survey respondent perhaps encapsulated the essence of the majority view on these issues: "If you can protect my privacy, I am okay with [electronic health records.]"" (*Privacy Survey* 6). If we have allowed our tax information, bank accounts, pharmacy prescriptions, etc to be processed electronically, why are we hesitant concerning our medical records? Canada Health Infoway has outlined how we can make our health records electronic. We should not simply do so to facilitate clinicians and hospital staff, but to improve quality of care, reduce wait times and try to put to an end those ghastly tales from Canada's health care trenches.



## VII. Works Cited

*A 'Conceptual' Privacy Impact Assessment (PIA) on Canada's Electronic Health Record Solution (EHRS) Blueprint Version 2.* Canada: Canada Health Infoway. 2008.

*Alberta Netcare: Electronic Health Records.* Government of Alberta: Health and Wellness. 2010. <<http://www.albertanetcare.ca/default.htm>>.

"Another Scary Tale from the Health-Care Trenches." *The Gazette* 26 Feb. 2011: B6.

Braën, André. *Health and the Distribution of Powers in Canada: Discussion Paper No. 2.* Canada: Commission on the Future of Health Care in Canada, 2002.

*Canada Health Infoway.* Canada Health Infoway. 2010. <<https://www.infoway-inforoute.ca/lang-en>>.

*Canadian Charter of Rights and Freedoms, Constitution Act 1982.* Ottawa, ON: Department of Justice. 1982.

"Commissioner Urges Vigilance in Wake of Computer Virus Outbreak at Alberta Health Services." *EMR Daily News* 13 Jul. 2009. 10 Feb. 2011  
<<http://emrdailynews.com/2009/07/13/commission-urges-vigilance-in-wake-of-computer-virus-outbreak-at-alberta-health-services/>>.

Committee on Maintaining Privacy and Security in Health Care Applications of the National Information Infrastructure. *For the Record: Protecting Electronic Health Information.* Washington, D.C.: National Academy Press, 1997.

Computer Science and Telecommunications Board National Research Council. *For the Record: Protecting Electronic Health Information.* Washington, D.C.: National Academy Press. 1997.

Department of Health and Human Services, Food & Drug Administration (FDA). "21 CFR Part 11 for Electronic Record Handling." *Federal Register* 62.54 (1997): 13429-66.

Dick, Richard S., Elaine B Steen, and the Institute of Medicine (U.S.) Committee on Improving the Patient Record. *The Computer-Based Patient Record: An Essential Technology for Health Care.* Washington, D.C.: National Academy Press, 1991.

Donaldson, Molla S., Kathleen N. Lohr, and the Institute of Medicine (U.S.) Committee on Regional Health Data Works. *Health Data in the Information Age: Use, Disclosure, and Privacy.* Washington, D.C.: National Academy Press, 1994.

*E-Health (Personal Health Information Access and Protection of Privacy) Act: Bill 24.* Victoria, BC: Ministry of Health. 2008.

*EHR 2015: Advancing Canada's Next Generation of Healthcare.* Ottawa, ON: Canada Health Infoway. 2005.

*Eldridge v. British Columbia (A.G.),* [1997] 151 D.L.R. (4) 577.

*Electronic Health Information and Privacy Survey: What Canadians Think — 2007.* Canada: Canada Health Infoway. 2007.

*Electronic Health Records in Canada: An Overview of Federal and Provincial Audit Reports.* Ottawa, ON: Office of the Auditor General of Canada. 2010.

Fergus, Adrian, and Don Kuehl. "Implications of 21 CFR Part 11 Guidelines on the Archival of Analytical Data." *American Laboratory* 35.5 (2003): 32-6.

Fritz, James. *Experiences from the forefront of EMR use: 20 Canadian Physician Case Studies.* Canada: Canada Health Infoway & Canadian Medical Association. 2009.

Gibson, Dale. "The *Canada Health Act* and the Constitution." *Health Law Journal* 4 (1996): 1-33.

Gordon, Daniel, Gleis Geiger, Nina Lowe, and Joan Jickling. "What is an Electronic Patient Record?" *AMIA* (1998): 240-44.

*Guidance for Records Related to Clinical Trials Guide 0068: Interpretation of section C.05.012 of the Food and Drug Regulations - Division 5 "Drugs for Clinical Trials Involving Human Subjects."* Ottawa, ON: Health Products and Food Branch Inspectorate, Health Canada. 2006.

Hamilton, Booz Allen. *Pan-Canadian Electronic Health Record: Quantitative and Qualitative Benefits.* Canada: Canada Health Infoway. 2005.

*Health Care Transformation in Canada.* Ottawa, ON: Canadian Medical Association. 2010.

Hippisley-Cox, Julia, Mike Pringle, Rutherford Carter, Alison Wynn, et al. "The Electronic Patient Record in Primary Care – Regression or Progression? A Cross Sectional Study." *BMJ* 326 (2003): 1439-43.

*International Activities Toward Electronic Health Records: Unique Identification and PKI.* Ottawa, ON: Office of Health and the Information Highway, Health Canada. 1998.

Kallem, Crystal, Jill Burrington-Brown, Jill, and Angela K. Dinh. "Data Content for EHR Documentation." *Journal of AHIMA* 78.7 (2007): 73-6.

Kosseim, Patricia, and Megan Brady. "Policy by Procrastination: Secondary use of Electronic Health Records for Health Research Purposes." *McGill Journal of Law and Health* 2.1 (2008): 5-45.

Leeson, Howard. *Constitutional Jurisdiction over Health and Health Care Services in Canada: Discussion Paper No. 12*. Canada: Commission on the Future of Health Care in Canada, 2002.

*Model Code for the Protection of Personal Information*. Canada: Canadian Standards Association. 1996.

Moehr, Jochen R, and Andrew Grant. "Medical Informatics and Medical Education in Canada in the 21<sup>st</sup> Century." *Clinical and Investigative Medicine* 23.4 (2000): 275-80.

*National Health Service (NHS)*. Department of Health, United Kingdom: Crown Copyright. 2010. <<http://www.nhscarerecords.nhs.uk/index.html>>.

*National Health Service (NHS) Direct*. Department of Health, United Kingdom: Crown Copyright. 2011. <<http://www.nhsdirect.nhs.uk/Default.aspx>>.

National Research Council (U.S.) Committee on Maintaining Privacy and Security in Health Care Applications of the National Information Infrastructure. *For the Record: Protecting Electronic Health Information*. Washington D.C.: National Academy Press, 1997.

*Office of the Privacy Commissioner of Canada*. Ottawa, ON: Office of the Privacy Commissioner of Canada. 6 Apr. 2011. <<http://www.priv.gc.ca/>>.

*Pan-Canadian Health Information Privacy and Confidentiality Framework*. Ottawa, ON: Health and Information Highway Division, Health Canada. 27 Jan. 2005. <<http://www.hc-sc.gc.ca/hcs-sss/pubs/ehealth-esante/2005-pancanad-priv/index-eng.php>>.

*Personal Information Protection and Electronic Documents Act*. Ottawa, ON: Department of Justice. 2000.

*Province of Alberta: Health Information Act*. Edmonton, AB: Legislative Assembly of Alberta. 2010.

Rindfleisch, Thomas C. "Privacy, Information Technology, and Health Care." *Communications of the ACM* 40.8 (1997): 93-100.

- Romanow, Roy J. *Building on Values: The Future of Health Care in Canada*. Canada: Commission on the Future of Health Care in Canada, 2002.
- Rozovsky, Lorne Elkin, and Fay Adrienne Rozovsky. *The Canadian Law of Patient Records*. Toronto, ON: Butterworths, 1984.
- R v. Crown Zellerbach Canada Ltd.*, [1988] 1 S.C.R. 401.
- R v. O'Connor*, [1995] 4 S.C.R. 411.
- Schneider v. the Queen*, [1982] 2 S.C.R. 112.
- Schoen, Cathy, Robin Osborn, Michelle M. Doty, David Squires, et al. "A Survey Of Primary Care Physicians in Eleven Countries, 2009: Perspectives On Care, Costs, And Experiences." *Health Affairs* 28.6 (2009): w1171-83.
- The Care Record Guarantee: Our guarantee for NHS Care Records in England, version 5*. London, UK: Department of Health, United Kingdom. 2011.
- The NHS Constitutions: the NHS Belongs to us all*. London, UK: Department of Health, United Kingdom. 2010.
- The Relationship between Electronic Health Records and Patient Safety*. Toronto, ON: iCare, Canada Health Infoway and the CPSI. 2007.
- Toward Electronic Health Records*. Ottawa, ON: Office of Health and the Information Highway, Health Canada. 2001.
- U.S. Department of Health and Human Services (FDA). "21 CFR Part 11 Electronic Records; Electronic Signatures; Final Rule Electronic Submissions; Establishment of Public Docket; Notice." *Federal Register* 62.54 (1997): 13430-66.
- U.S. Department of Health and Human Services (FDA). *Guidance for Industry: Computerized Systems Used in Clinical Investigations*. United States: U.S. Department of Health and Human Services. 2007.
- Wallace, Gordon. "Information Technology and Telemedicine." *CMAJ* 165.6 (2001): 777-79.
- Willison, Donald J. *Use of Data from the Electronic Health Record for Health Research- Current Governance Challenges and Potential Approaches*. Ottawa, ON: Office of the Privacy Commissioner of Canada. 2009.
- White Paper on Information Governance of the Interoperable Electronic Health Record (EHR)*. Canada: Canada Health Infoway. 2007.

Young, David. "Privacy Interview with Experts: Legal Issues Related to Electronic Health Records." *Nymity*. April 2009. 01 Jan. 2011  
<[http://www.nymity.com/Free\\_Resources/Privacy\\_Interviews/2009\\_David\\_Young.aspx](http://www.nymity.com/Free_Resources/Privacy_Interviews/2009_David_Young.aspx)>.