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Background Paper

The LCO and IP Osgoode have prepared this Background Paper for discussion purposes in connection with the roundtable discussion on eHealth to be held on January 28, 2010. This paper is intended to provide background information for roundtable participants. It also sets out consultation questions on which we are seeking input from roundtable participants.

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1. Introduction

1.1. Background on Initiative

The Osgoode Hall Law School Law Commission of Ontario Scholar in Residence program provides release to faculty members at Osgoode to permit them to contribute to the LCO's work. In some instances, the Scholars assist with projects that the LCO has already undertaken. In other cases, the Scholars bring their projects with them and the project does not proceed through the LCO's usual Board approval processes. Professor Pina D'Agostino, selected as one of the OHLS LCO Scholars in Residence for 2009-2010, falls into the latter group. Her application to the Scholar program included a project proposal that the LCO considered merited development, even though not an "official" LCO project: the interrelationship of intellectual property, ethics and privacy issues arising from electronic medical records.

The LCO is a partnership among the Law Foundation of Ontario, the Attorney General of Ontario, Osgoode Hall Law School and the Law Society of Ontario, all of whom provide funding to the LCO, and Ontario's other law schools. Its function is to recommend law reform measures to enhance the legal system's relevance, effectiveness and accessibility; improve the administration of justice through the clarification and simplification of the law; consider the use of technology to enhance access to justice; stimulate critical legal debate; and study areas that are underserved by other research. The LCO is independent of government and selects projects that are of interest to and reflective of the diverse communities in Ontario.

The LCO is pleased to provide support for Professor D'Agostino's work on electronic medical records which it considers may contribute to critical legal debate in this significant element of Ontario's legal system.

1.2. Purpose of the Roundtable

We are seeking your views on issues concerning the governance of eHealth in Ontario. Specifically, we are interested in obtaining feedback on whether the current legal framework and practices should be altered to better bring our health records in the wired world.

1.3. Purpose of the Background Paper

The LCO and IP Osgoode have prepared this Background Paper for discussion purposes in connection with the roundtable discussion on eHealth to be held on January 28, 2010. This paper is intended to provide background information for roundtable participants. It also sets out consultation questions on which we are seeking input from roundtable participants.

1.4. Background of the Study

The development and implementation of Electronic Health Records (EHRs) in Canada is not a simple endeavour. The sheer enormity of the Canadian Health System is indicative of this monumental task. In fact, millions of healthcare encounters occur each day. According to the Auditor General of Canada's 2009 report, annually there are 440 million laboratory tests performed, 382 million prescriptions filled, 322 million visits to doctors' offices, 35 million diagnostic images taken and 2.8 million hospitalizations.¹ The vast majority of health information collected upon each healthcare encounter is still recorded on paper or other media, such as x-ray film, and is then physically stored.² In his 2002 report entitled, "The Future of Health Care in Canada",³ Commissioner Roy Romanow emphasizes the importance of health information and technology as the foundations of healthcare reform.

1.5. The Electronic Health Record: Definitions and Uses

An Electronic Health Record (EHR) may be defined as, "a longitudinal collection of personal health information of a single individual, entered or accepted by healthcare providers and stored electronically."⁴ The longitudinal nature of an electronic health record is its defining characteristic. Unlike paper records, an

¹ The Auditor General of Canada, *Report of the Auditor General of Canada to the House of Commons, Chapter 4 – Electronic Health Records* (Report on Matters of Special Importance) (Ottawa: Office of the Auditor General of Canada, 2009) at 7 [Auditor General of Canada, "Chapter 4: Electronic Health Records"].

² The Auditor General of Ontario, *Ontario's Electronic Health Record Initiative* (Special Report) (Ontario: Office of the Auditor General of Ontario, October 2009) at 5 [Auditor General Ontario, "Ontario's EHR Initiative"].

³ Commission on the Future of Health Care in Canada, *Building on Values: The Future of Health Care in Canada* (Ottawa: National Library of Canada Cataloguing in Publication Data, 2002), online: Government of Canada Publications <<http://publications.gc.ca/pub?id=237274&sl=0>>.

⁴ Anthony Morris. "The Electronic Health Record in Canada: The First Steps" (2005) 14:2 Health Law Review 14 at 14.

EHR is a comprehensive compilation of a person's healthcare history.⁵ An EHR may include summaries of physician visits and care provided in hospital or other facilities, medical test results, allergies, x-ray images, as well as prescription drug and immunization histories. EHR systems enable an individual's health and care histories to be accessible electronically to authorized health providers at various sites of care.⁶

The interoperable nature of electronic health record systems enable coordinated care between caregivers and across geographic locations, improve patient diagnosis and treatment through the linkage of personal health information with clinical support tools, and augment health record accuracy.⁷ The adoption of electronic health record systems also has important implications for the patient or health-system user. There is growing discussion that in order for healthcare users or patients to be true partners in their healthcare, they must have access to their personal clinical information.⁸ Access to personal health information is a fundamental right supported by law. In Ontario, for instance, the *Personal Health Information Protection Act*⁹ allows individuals to request access to their personal health information held by health information custodians operating within the province of Ontario. Systems such as patient portals or patient health records (PHRs) capture either elements of data or all data stored in EHRs, and can be accessible to the patient-consumer via the EHR network.¹⁰ Patient health records can also incorporate data entered by the patient themselves.¹¹ Such accessible electronic solutions enable patients to play a more active role in medical decision making. At the same time, the abundance of information housed within electronic health records is of value to parties that may be categorized as secondary users. The medical information housed within EHRs has considerable commercial value¹² for purposes such as marketing, quality assessment, employment insurance, prescription medication and medical research.¹³

⁵ Nola Ries and Geoff Moysa. "Legal Protections of Electronic Health Records: Issues of Consent and Security" (2005) 14:1 Health Law Review 18 at 18.

⁶ The Auditor General of Ontario, *Ontario's Electronic Health Record Initiative* (Special Report) (Ontario: Office of the Auditor General of Ontario, October 2009) at 5.

⁷ Elaine Gibson. "Jewel in the Crown? The Romanow Commission Proposal to Develop a National Electronic Health Record System" (2003) 66 Saskatchewan Law Review 647 at 650.

⁸ Sara Urowitz. "Is Canada Ready for Patient Accessible Health Records? A National Scan" (2008) 7 BMC Medical Informatics and Decision Making 33 at 34.

⁹ *Personal Health Information Protection Act*, S.O. 2004, C. 3, Schedule A.

¹⁰ Urowitz, "Is Canada Ready?", *Supra* note 8 at 34.

¹¹ *Ibid.*

¹² Mark A. Hall. "Property, Privacy and the Pursuit of Integrated Electronic Medical Records" (2009) Wake Forest Univ. Legal Studies Paper No. 1334963. Available at SSRN: <<http://ssrn.com/abstract=1334963>> [Hall, "Property, Privacy and the Pursuit of Integrated EHRs].

¹³ Patricia Kosseim and Megan Brady. "Policy By Procrastination: Secondary Use of Electronic Health Records for Health Research Purposes" (2008) 2 McGill Journal of Law and Health 5 at 6.

Questions:

- *The use of electronic record systems to support service delivery may be an emerging health care solution; however, similar technologies have been utilized in other industries for a number of years. What can the health sector learn from other sectors (e.g. the banking industry) about the adoption of information technologies in a manner that encourages client buy-in and maintains client trust?*

1.6. Establishing Rights: The Doctor - Patient Relationship

In *McInerney v. MacDonald*,¹⁴ the Supreme Court of Canada elevated the legal protection of medical information by recognizing the doctor-patient relationship as a special relationship of trust.¹⁵ For the Court, the doctor is the owner of the actual physical record. Despite the doctor's ownership interest, however, the patient maintains a trust-like, "beneficial interest" in her health information. As a general rule, therefore, the patient maintains a right to access the health information she confided in the doctor for medical purposes, as does the doctor have a corresponding duty to provide it.

While the ownership and access interests of the doctor and patient in closed environments, such as the isolated medical clinic, is arguably established with relative ease, this is not so in increasingly interconnected computing environments like the EHR. Since the interoperable electronic health record is collaborative across networks containing thousands of patient records, there is the potential for multiple creators and owners, subjects and users, each with layered rights and varying types of protection. While patients hold privacy and associated rights in their records, the question remains: who "owns" their health records? The unaddressed ownership issues central to effective governance were first flagged in a UK study which observed that, "a lack of clarity on complex questions relating to ownership and control of data may potentially lead to either a

¹⁴ *McInerney v. MacDonald* [1992] 2 S.C.R. 138.

¹⁵ *Ibid* at para 19.

complete unwillingness to share data, or conversely to costly litigation when conflicting claims come to light.”¹⁶

Questions:

- *Patient access rights are the same in both paper and electronic environments. In your opinion do electronic health records facilitate or hinder patient access?*

¹⁶ G. D’Agostino *et al.* “On the importance of intellectual property rights for e-science and the integrated health record” (2008) 14:2 Health Informatics 95 at 96 [D’Agostino, “On the Importance of IP”].

2. The Role of Intellectual Property

2.1. Intellectual Property and Electronic Health Records

The intellectual property implicated in electronic health records are mainly the copyrights and patents. Most contentious, however, are the copyrights as they directly relate to issues relevant to medical record ownership, and are often the most ambiguous. Copyright protection arises automatically upon fixation of a tangible original expression, arising from an author, and requiring some intellectual effort. Section 5(1) of the *Copyright Act*¹⁷ stipulates that copyright shall subsist in Canada for original literary, dramatic, musical and artistic works.¹⁸ In the EHR context, a single medical scan (e.g. MRI) is protected under copyright law as an artistic work, and the radiologist's notations on the medical record are protected as literary works. In addition, Section 2 of the Copyright Act protects compilations or, "works resulting from the selection or arrangement of literary, dramatic, musical or artistic works or parts thereof, or of data."¹⁹ Databases, or in this case the electronic medical archive may, therefore, be protected as compilations should the gathering and sorting of data involve original and creative selection and arrangement.

Although medical information is not considered intellectual property, the expression of these records in a fixed form is. Healthcare providers who possess and compile medical records may own their tangible embodiment.²⁰ The EHR context, however, presents a unique scenario as several healthcare providers may have contributed to an individual's health record. Consequently, there may be several owners with proprietary interests in different pieces of a patient's medical history. Furthermore, when records are linked through EHR systems the number of potential authors or creators increases exponentially.

¹⁷ *Copyright Act*, R.S.C. 1985, c. C-42 [Copyright Act].

¹⁸ *Ibid* at s. 5(2).

¹⁹ *Ibid* at s. 2.

²⁰ Hall, "Property, Privacy and the Pursuit of Integrated EHRs", *Supra* note 12 at 13.

2.2. Determining Copyright Ownership

Central to the ownership question of the EHR is determining who the owner is for copyright purposes. The first owner of copyright is typically the creator, but there are exceptions. One of the main exceptions particularly relevant to the EHR deals with employees. Whilst independent contractors retain copyright over their works (unless an express or implied contract provides otherwise), employees' copyright ownership of their works resides with their employers pursuant to the "course of employment" doctrine²¹. Contract law governs the management of copyrights. In the context of the EHR, most of the radiographers or technicians who scan and/or annotate the images are employees of the clinics or hospitals. Because of the absence of any contractual agreement, all intellectual property generated by them belongs to the respective employer institutions. However, some healthcare professionals might not be employed but have independent contractor arrangements, and unless there is a contract or clear policy clarifying these rights, ownership will reside with these individuals or at best be ambiguous. As uncovered in the noted UK study on point, the results can be devastating as there is confusion on ownership and consequently, the inability to properly manage (and share) the data with other collaborators.²²

Questions:

- *To what extent is determining ownership of EHR data important? Consider the interests of each stakeholder group: healthcare professionals, patients, government, the public, innovators and other groups.*
- *Do you think that the uncertainty with regards to who owns and controls what could hinder the benefits of eHealth?*
- *Would this uncertainty compromise the forming of public-private partnerships that drive innovation and research in Ontario?*

²¹ In Canada, *Copyright Act* RSC 1985 c C-42 s 13(3); in the UK, *Copyright, Designs and Patents Act* 1988 c 48 as amended ('CDPA') s 11(2); in the US, *Copyright Act* 1976 17 USC s 101 'works made for hire'.

²² D'Agostino, "On the Importance of IP", *Supra* note 13.

3. Privacy and Electronic Health Records

3.1 The Protection of Personal Health Information

Personal health information is the most private form of information due to its highly sensitive nature, and the circumstances of vulnerability and trust under which it is confided or collected.²³ In Canada, the protection of personal health information is regulated by various federal and provincial privacy laws that establish standards for patient privacy rights.²⁴ The freedom of information and protection of privacy statutes in most provinces protect personal health information in the custody or control of public or government bodies.²⁵ Public bodies encompassed by such legislation include hospital and regional health authorities, as well as health agencies. In addition, the federally regulated public sector has privacy legislation in place to cover both personal information and personal health information in the custody and control of federal government bodies (i.e. the *Privacy Act*²⁶ and *Access to Information Act*²⁷). The Personal Information Protection and Electronic Document Act (*PIPEDA*),²⁸ governs the private sector, and applies to both federal and provincial private entities, unless the provincial privacy statutes have been deemed substantially similar.²⁹ *PIPEDA* extends to information collected, used or disclosed in the course of commercial activities. In the healthcare context, *PIPEDA* applies to entities such as private pharmacies, laboratories and healthcare providers operating private practices.

²³ Canadian Medical Association, *CMA Health Information Privacy Code* (Ottawa, ON: The Board of Directors, 1998) at Principle 2, online: CMA Information Privacy Code < http://www.cma.ca/index.cfm/ci_id/3216/la_id/1.htm >

²⁴ B.C.: *Freedom of Information and Protection of Privacy Act*, R.S.B.C. 1996, Chapter 165; Alberta: *Freedom of Information and Protection of Privacy Act*, R.S.A. 2000, c. F-25; P.E.I.: *Freedom of Information and Protection of Privacy Act*, R.S.P.E.I. 1988, c. F-15.01; Nova Scotia: *Freedom of Information and Protection of Privacy Act*, S.N.S. 1993, c. 5; Saskatchewan: *Freedom of Information and Protection of Privacy Act*, S.S. 1990-91, c. F-22.01; Manitoba: *Freedom of Information and Protection of Privacy Act*, C.C.S.M. c. F175; Ontario: *Freedom of Information and Protection of Privacy Act*, R.S.O. 1990, c. F.31.

²⁵ *Ibid.*

²⁶ *Privacy Act*, R.S.B.C. 1966, c. 373.

²⁷ *Access to Information Act*, R.S.C. 1985, c. A-1.

²⁸ *Personal Information Protection and Electronic Documents Act*, S.C. 2000, c.5.

²⁹ *Ibid.*

3.2 Health Information Specific Legislation

The sensitive nature of personal health information has prompted several provinces to enact health information specific legislation. Manitoba, Saskatchewan, Alberta, Newfoundland and Ontario are the legislative pioneers in this regard.³⁰ The statutes apply broadly to the collection, use, disclosure and retention of personal health information by healthcare providers.

There is, however, significant variation in privacy laws and data access policies nation-wide.³¹ This is evident when comparing consent frameworks employed by provincial health information legislation. For instance, the *Saskatchewan Health Information Protection Act (HIPA)* follows a deemed consent model.³² Here, an individual's consent is deemed to exist where personal health information is required to provide health services.³³ Alternatively, Ontario's *Personal Health Information Protection Act (PHIPA)* has adopted an implied consent model for the collection, use or disclosure of health information.³⁴ Here consent is implied if health information is disclosed for purposes of providing healthcare or assisting in providing healthcare.³⁵

The consent provisions specifically relevant to electronic health records also show a lack of uniformity. Manitoba regulations permit disclosure without consent for certain EHR purposes,³⁶ while Ontario's leaves the specific rules regarding EHRs to be established in regulations.³⁷ Should these regulations conflict with more specific health information relevant legislation in other provinces, challenges will emerge as EHR data moves from one jurisdiction to another.

Prompted by provider feedback, Alberta and Saskatchewan have already altered their health information legislation, as healthcare providers found EHR relevant provisions to be too cumbersome

³⁰ Manitoba: *Personal Health Information Act*, C.C.S.M 2005, c. P33.5; Ontario: *Personal Health Information Protection Act*, S.O. 2004, c. 3, Sch. A; Newfoundland and Labrador: *Personal Health Information Act*, S.N.L. 2008, c. P-7.01; Saskatchewan: *The Health Information Protection Act*, S.S. 2003, H-0.021; Alberta: *Personal Information Protection Act*, S.A. 2003, c. P-6.5.

³¹ Canada, Standing Senate Committee on Social Affairs, Science and Technology. (2002). *The Health of Canadians – The Federal Role, Vol. 1-6*. Ottawa: Standing Senate Committee on Social Affairs, Science and Technology.

³² Saskatchewan: *The Health Information Protection Act*, S.S. 2003, H-0.021, s. 27(2).

³³ *Ibid* at s. 27(2)(b)

³⁴ *Personal Health Information Protection Act*, S.O. 2004, c. 3, Sch. A, s. 18 (2).

³⁵ *Ibid* at s. 18 (3).

³⁶ *Personal Health Information Act*, C.C.S.M 2005, c. P33.5, s. 21 (d).

³⁷ Nola Ries. "Patient Privacy in a Wired (and Wireless World): Approaches to Consent in the Context of Electronic Health Records" (2005/06) 43 *Alberta Law Review* 681 at 696.

to be applied³⁸ When first implemented, Saskatchewan's *HIPA* gave individuals the right to direct that a trustee not store their specified information in the Saskatchewan Health Information Network (SHIN).³⁹ Today, an opt-out method is employed, as individuals must indicate in writing if they do not wish to be included. Alberta legislation underwent a similar change in 2003, as the provision that required consent from individuals before information could be disclosed electronically was removed.⁴⁰

Questions:

“Differences in rules on how the scope of purpose is defined, the form of consent required, the conditions for substitute decision-making, the criteria for non-consensual access to personal health information, periods for retention of data, and requirements for destruction, to name but a few, must be seriously addressed in order to enable the development of EHR systems.”

(Canada, Standing Senate Committee on Social Affairs, Science and Technology, 2002)

- *Should provincial privacy legislation be aligned to facilitate a national electronic health record that enables the transfer of information across borders?*
- *If so, how can these inconsistencies be reconciled?*

³⁸ Ries, “Patient Privacy in a Wired and Wireless World”, *ibid* at 697.

³⁹ *Ibid* at 698

⁴⁰ *Ibid*.

4. Canadian Investment in Electronic Health Records

4.1 Canada Health Infoway

Established in 2001, Canada Health Infoway Inc. (Infoway) is a non-profit corporation tasked with leading the nation-wide EHR initiative. In the eight years since its establishment, Infoway has supported almost 300 EHR projects nation-wide.⁴¹

Infoway recognizes that although each province and territory will have an EHR system that meets their specific jurisdictional needs, provincial and territorial systems should be based on a core set of principles and characteristics and promote interoperability.⁴² But according to a 2009 Auditor General of Canada report on Electronic Health Records, although Infoway takes steps to ensure that EHR projects align with certain privacy and security requirements, it has no responsibility for ensuring that systems comply with privacy laws.⁴³ Further, Infoway has not followed up with provincial and territorial partners on conformance test results, nor has a plan been fully developed to deal with EHR project variances.⁴⁴ Importantly, Canada Health Infoway strategies and published reports do not adequately address its vision for governance as it relates to the ownership of electronic health records.

⁴¹ Canada Health Infoway, "Open Letter to Canadians" online: Canada Health Infoway < <http://www.infoway-inforoute.ca/about-infoway/news/open-letter-to-canadians>>.

⁴² Auditor General of Canada, "Chapter 4: Electronic Health Records", *Supra* note 1 at 8.

⁴³ *Ibid* at 9.

⁴⁴ *Ibid* at 21.

Questions:

- *What are the potential short-term and long-term implications of Infoway failing to ensure that EHR projects nation-wide comply with privacy and security standards?*
- *Given the Auditor General of Canada's unfavourable review of Infoway, what can be done if any, to improve its functioning, specifically as these relate to its constitution, governance and objectives?*
- *Is there another alternative to Infoway?*

4.2 eHealth Ontario

Several Canadian provinces have restructured healthcare delivery in ways that are intended to enhance the role and responsibility of electronic health information technology.⁴⁵ Established in September of 2008, eHealth Ontario is charged with harnessing information technology and innovation to support the provincial health strategy.⁴⁶ The agency's key priority is to have an electronic health record in place for Ontarians by 2015.⁴⁷ The Ministry consolidated provincial eHealth efforts with eHealth Ontario: the Ministry replaced Smart Systems for Health Agency (SSHA), that had been tasked to develop the technical infrastructure, and the Ministry of Health, tasked to formulate the overall EHR strategy.⁴⁸

A recent Auditor General of Ontario report confirms that Ontario trails behind its provincial eHealth counterparts.⁴⁹ SSHA's \$800 million dollar investment utilized has reaped little value: although a network is in place, it is underutilized as there is insufficient health-information contained within the system.⁵⁰ The documented poor coordination between SSHA and the Ministry's eHealth Program Branch, and delay in the development of an eHealth Ontario strategic plan have contributed to the poor return on investment to date, and slow EHR project progress.

⁴⁵ Patrick Powers. "HIMSS Analytics Column: Growing E-health Information Technology Partnership: Canadian Healthcare and HIMSS Analytics." 7:4 Electronic Health-Care 122 at 122.

⁴⁶ eHealth Ontario, *Ontario's eHealth Strategy* (Toronto, ON.: eHealth Ontario, 2008) at i., online: eHealth Strategy <<http://www.ehealthontario.on.ca/micro-pdfs/eHealthStrategy.pdf>>. [eHealth Ontario, "Ontario's eHealth Strategy"]

⁴⁷ *Ibid* at ii.

⁴⁸ Auditor General Ontario, "Ontario's EHR Initiative", *Supra* note 2 at 6.

⁴⁹ *Ibid* at 25.

⁵⁰ Auditor General Ontario, "Ontario's EHR Initiative", *Supra* note 2 at 9.

eHealth Ontario has released a three-year strategic plan.⁵¹ The strategy focuses upon three clinical priorities meant to provide significant clinical value to both patients and physicians, and includes diabetes management, medical management and wait-times management.⁵² Although the three-year plan provides concrete targets and deliverables on each of the key EHR components, it appears to de-emphasize the eHealth Ontario goal of delivering an EHR by 2015.⁵³ Last, eHealth Ontario appears to postpone addressing strategies adhering to *PHIPA* and does not at all seem to consider ownership issues.⁵⁴

Questions:

- *Ontario has chosen to utilize the clinical priority of diabetes management as a springboard to the creation of a province-wide EHR. What are the implications of choosing this arguably narrow starting point rather than establishing a basic EHR infrastructure for all patients?*
- *During the current 3 year strategic plan period, eHealth Ontario plans to develop a comprehensive strategy for managing consent in compliance with PHIPA. What are the implications of not having a consent strategy at the outset of eHealth's strategic plan?*

⁵¹ eHealth Ontario, "Ontario's eHealth Strategy", *supra* note 45.

⁵² *Ibid.*

⁵³ Auditor General Ontario, "Ontario's EHR Initiative", *Supra* note 2 at 20.

⁵⁴ eHealth Ontario, "Ontario's eHealth Strategy", *supra* note 45 at 25.

5. International EHR Comparisons

The design and implementation of EHR systems extends beyond Canada to a number of international jurisdictions. Countries around the world are engaged in projects to develop infrastructure for national health information. Both New Zealand and Denmark have experienced successes in implementing integrated electronic solutions in the healthcare context.

5.1 New Zealand

In 1992, the New Zealand government initiated three strategies that set the stage for the development of its EHR infrastructure.⁵⁵ These strategies included the creation of a national health identifier database, the development of a health information privacy code, and an agreement with private sector organizations to develop and deliver information services to the sector.⁵⁶ This strategic coordination showed tremendous foresight, as the establishment of private sector agreements and privacy codes at the outset of a strategy provided a solid foundation for the development of eHealth projects.

Six years later, the New Zealand government granted general practitioner (GP) offices a one-off grant of approximately \$NZ 5000 to purchase computers, and mandated that electronic billing be compulsory.⁵⁷ This initiative was remarkably successful. Within two years of its onset, more than 95% of GPs used a computerized billing and appointment system, and more than 50% utilized this system for capturing clinical information during patient consultations. Today, as electronic billing is now compulsory, 100% of general practitioners have a computerized system. In addition, 75% of general practitioners take advantage of the system's clinical functionality.⁵⁸

⁵⁵ Denis Protti *et al.* "Adoption of Information Technology in Primary Care Physician Offices in New Zealand and Denmark, Part 2: Historical Comparisons" (2008) 16 *Informatics in Primary Care* 189 at 2. [Protti, "Adoption of IT in New Zealand and Denmark"]

⁵⁶ *Ibid*

⁵⁷ *Ibid* at 3.

⁵⁸ *Ibid*

Currently, HealthLink, a privately-owned company, is the sole provider of all healthcare related electronic services in New Zealand.⁵⁹ The services utilized by HealthLink to communicate with GPs are government-funded. Any additional services provided by HealthLink are paid for by the healthcare providers that utilize them such as laboratories, hospitals and general practitioners.⁶⁰ In recent years, however, the New Zealand government appears to be discouraging this monopoly by supporting the formation of competing services.⁶¹

5.2 Denmark

The automation of physician offices in Denmark commenced in a similar fashion to New Zealand. As early as the mid-1980's, Danish primary care physicians received a small financial subsidy to send floppy disks of their medical claims to the public health insurance body.⁶² This process stimulated the purchase of a single administrative computer for use in physician's offices, and created the early infrastructure necessary to facilitate the use of computers for clinical purposes.⁶³ By 1990, the MedCom project was launched which connected two primary care physicians on one system with a hospital system and laboratory system. Two years later, lab results and discharge letters were being transmitted electronically to a number of primary care physician practices, and the emergence of electronic medical records (EMRs) became a reality. In addition, paper prescriptions were replaced by electronic prescription transmission from primary care physicians to pharmacies.⁶⁴

Unlike New Zealand's for-profit HealthLink, MedCom is the Danish non-profit equivalent. The mission of MedCom is to contribute to the development, testing, dissemination and quality assurance of electronic communication and information in the healthcare sector in order to enable coherent treatment, nursing and care.⁶⁵ In carrying out its mission, MedCom develops messaging software, as well as core infrastructure and services used to securely exchange healthcare messages.⁶⁶

⁵⁹ Protti, "Adoption of IT in New Zealand and Denmark", *Supra* note 54 at 3.

⁶⁰ *Ibid.*

⁶¹ *Ibid.*

⁶² *Ibid* at 4.

⁶³ *Ibid.*

⁶⁴ *Ibid.*

⁶⁵ *Ibid* at 2.

⁶⁶ *Ibid.*

5.3 Health System Integrators

Both MedCom and HealthLink are examples of health system integrators (HSIs), a specialized information technology company that has expertise in integrating supporting messaging, online communications and security systems.⁶⁷ There are several benefits to an HSI model in the delivery of electronic solutions in the healthcare context. Health system integrators provide unambiguous interest in increasing the use and value of eHealth services across the sector. Also, HSIs must adhere to an explicit contractual commitment to standards and external governance as established by government. They are required to support the use of all national data-communications standards, to interconnect with other HSIs and to defer to a national governance framework.⁶⁸ The enforcement of these standards is essential to the efficient and effective operation of the health system. In New Zealand, should HSIs fail to meet a range of government-imposed and monitored safety and security standards, accreditation is withdrawn.⁶⁹

As described earlier, Canada Health Infoway has attempted to act in a similar capacity to health system integrators, however, to a certain extent has been unsuccessful. The enforcement of standards has not been achieved as conformance testing and processes to address policy breaches are not in place. Furthermore, although Canada Health Infoway has the mandate of coordinating the national EHR strategy, healthcare delivery is within provincial jurisdiction. Infoway for instance is not responsible for ensuring that privacy laws or any other provincial policies/ regulations are adhered to. The key distinction, therefore, is that Canada's eHealth strategy is not under the power and influence of a single unifying body. The fragmented jurisdictional model currently in place has fuelled the isolated and disjointed development of EHR initiatives in Canada.

Questions:

- *The effective and efficient uptake of electronic health solutions in Denmark and New Zealand is markedly different from the slow progress in Ontario. What characteristics of the eHealth strategies in these two countries do you feel have contributed most to this success?*
- *New Zealand and Denmark have selected a sole-provider model to govern eHealth services. What are the advantages and disadvantages of such an approach?*

⁶⁷ Protti, "Adoption of IT in New Zealand and Denmark", *Supra* note 54 at 5.

⁶⁸ *Ibid.*

⁶⁹ *Ibid.*

6. EHR Governance Strategies

Inconsistencies in federal or provincial legislation and regulations threaten the interoperability of the electronic health record. In devising potential governance models, it is necessary to consider the interests of each stakeholder group, and balance the interests of society in promoting medical research, and the diagnosis, treatment and prevention of disease. Drawing from a previous study,⁷⁰ there are at least three potential governance models: hospital/clinic-centred governance, patient-centred governance and an independent organization model.

6.1 Hospital / Clinic-Centred Governance

The hospital/clinic-centred governance model most resembles the status quo. As a deemed owner of the IP, the hospital would retain local control and responsibility for protecting data. This model would leave patient EHR interests such as access rights unchanged.

A policy document would be required for all hospitals specifying the permitted uses of the IP in the data. Under this model, the hospital would remain one of the beneficiaries of any database created using its data. Researchers seeking to utilize the EHR data would negotiate with each individual hospital to obtain required data. An alternative, although perhaps more ambitious scenario would see hospitals adopt an open access approach, implemented through creative commons or public licence-type contracts.

There are both advantages and disadvantages to the hospital-centred governance model. This approach is the least disruptive, as it requires little or no legislative changes. There would, however, be no central control. Consequently, the previously addressed issue of multiple owners and creators would remain.

6.2 Patient-Centred Governance

Considered a radically different model, patient-centred governance would allow patients to own the IP in their medical records. Contracts between all parties could be standardized to assign all IP to patients. Similarly, legislation amendments could vest all IP in the context of medical data to patients. As in the music

⁷⁰ D'Agostino, "On the Importance of IP", *Supra* note 13.

industry, a collecting organization could be established to manage patients' new rights and act as a conduit. In addition, patients could be obliged to license their data through compulsory licensing.

This proposed model represents a substantial change from the status quo, as currently patients have no ownership rights in the EHR. Granting patients ownership rights runs contrary to the default state of the law, and therefore may be met with scepticism. In addition, a patient-centred governance model may make it difficult to establish research projects and commercial partners. This concern is further augmented if only a limited sample of patients permit the use of their health data for secondary purposes despite the potential monetary gain. Indeed, the very idea of patients making money from their data in a public healthcare system is undesirable. Furthermore, patient desire for such a model may not exist. Some patients have suggested that ownership is not needed provided there is a sufficient safeguard in the law to regulate the use and dissemination of data, and in particular to ensure that data remains sufficiently anonymized.

6.3 Independent Organization Governance

The third and seemingly most promising model proposes to assign IP rights in the EHR to a central organization. Medical records could be created as the result of clinician's work at multiple healthcare sites, researchers might draw on records originating all over the country, and the exploitation of these records could then be handled by a single national body. It may be possible to implement this model using contracts; however, a more compelling alternative would be legislative reform, where for example a sui generis law on medical data in research collaborations could vest ownership in a national body. Although legislative reform is complicated and often cumbersome, a centralized governance model delivered by a neutral body would render the EHR more accountable and transparent. Furthermore, this model would best address the complexities that arise when multiple parties have ownership interests in the EHR. The drawbacks of this model are notable and namely, agency capture as seen with the failings of Ontario's eHealth initiative. If more accountability and transparency were enforced, then this model might hold greater promise.

Questions:

- *What are the implications of each of the pre-described governance models for clinicians, patients, researchers, private entities and other stakeholders?*
- *What policy goals should the ideal model strive to attain? How should these be prioritized?*
- *Given the current EHR landscape in Ontario and nation-wide, of the three governance strategies proposed, which would most facilitate Canada's goal of an interoperable electronic health record?*
- *Are there other models that should be considered?*

7. Concluding Observations

A governance model vigilant of the ownership and privacy questions concerning the electronic health record in Canada is required. This model should benefit patients, and remove legal ambiguities for clinicians, researchers and industry to help advance research, diagnosis and treatment of patients and ultimately save lives. In evaluating the various governance possibilities, the interests of each stakeholder group must be considered, and balanced against the interests of society as a whole in promoting medical research, and the diagnosis, treatment and prevention of disease.

This paper has illustrated the significant complexities that surround the design and implementation of the electronic health record. Although the potential benefits of the EHR are indisputable, legal implications must be considered thoughtfully. This is especially important given the interoperable nature of the EHR, and consequent sharing of medical data on large-scale electronic networks.

Certainly issues of privacy, confidentiality and security cannot be ignored. As illustrated in this paper, the harmonization of privacy legislation nation-wide will be essential to the sharing of electronic health information across borders. In addition, questions concerning the secondary or non-clinical uses of EHR systems should be more adequately addressed. The clarification of ownership, control and access issues subject to intellectual property protection is essential. The prevailing uncertainty as to who owns or controls what will very likely hinder the benefits of eHealth and present disadvantages to forming the type of public-private partnerships that drive innovation and research in Canada.