Improving Usability, Safety and Patient Outcomes with Health Information Technology
F. Lau et al. (Eds.)

doi:10.3233/978-1-61499-951-5-413

Privacy and Policy Implications for Big Data and Health Information Technology for Patients: A Historical and Legal Analysis

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Abstract. The consideration of privacy and policy implications for big data is essential to designing patient-centered health technology. A literature review demonstrated a significant gap to moving forward with information technology in healthcare. Ovid Medline and Google Scholar were searched to identify papers related to health technology, patient outcomes, and policy implications of Big Data. The findings of this research showed that despite a robust legal framework and clear outline of the legislation, there exists an innovative opportunity for health technologies to evolve and become patient-centered by integrating privacy and policy knowledge in health information technology. This historical legal analysis is valuable to health system leaders, decision-makers, health technology companies that are creating innovative platforms, and clinicians in both Canada and the United States.

Keywords. big data, privacy, health technology, patient outcomes, data linkages

1. Introduction

A core feature of a learning health system is the health data associated with in and around that system. The application of Big Data to health systems performance can improve health quality and is central to a learning healthcare system [1,2]. With the creation of a variety of health technologies including electronic health records, patient portals, mobile health applications, and artificial intelligence, this paper considers the health policy implications of integrating health care IT structures in hospitals, clinics, and homes. The intersections between the fields of big data, health law, and privacy legislation have allowed health services scholars to examine the applications of big data for patient safety and optimal patient outcomes. Health technology is an outlet that can provide a solution through user interfaces and interoperable systems to better connect health care sectors such as home care, community care, primary care, and hospitals.

Big data is the collection, storage, and analysis of large amounts of data in order to leverage existing trends within health systems performance. Defined in terms of the 3V's: volume, velocity and variety, big data can create linkable datasets, which

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traditionally have been unavailable in traditional health care delivery and processes [3]. This paper reviews current privacy legislation within the United States and Canada with regards to the application of big data. The heterogeneity of big data and its potential use within a new context of electronic health records, administrative data sets and patient-facing technologies calls into question whether current privacy legislation in Canada and the United States requires modernization in our current decade of digital health information age. Given that the law is a venue for health technology developers, clinicians, and policymakers to work with, we explore the application of big data to health technology development in the context of current legislation. In a fair and just civil society, the construct of case law in relation to the development of health technology should be considered by health technology developers, implementation specialists, patients, and health care providers.

2. Methods

This study adapted a scoping review framework approach using the Arksey & O'Malley in that a systematic, transparent and reproducible review of the academic and grey literature was undertaken [4,5]. The academic databases Ovid Medline, specific health law and policy journals, health law & ethics: Journal of Medicine Law and Ethics, Health Law and Policy, Annual Reviews of Medicine, and the grey literature consisting of Google Scholar and were searched. Authors used a combination of keywords and MeSH search terms including: "big data", "health law", "privacy", and "legislation". Academic databases and other review sources were searched in order to cast a wide net to retrieve credible studies and to minimize bias in the literature search. As per the Arksey & O'Malley framework, additional government publications were included to provide a historical analysis of the timeline for the development of privacy legislation.

3. Findings

3.1 Historical Analysis of Privacy Legislation in correlation with Health Technology considerations: Modernization of Privacy Legislation

A historical analysis of the legislation showed that the United States passed the *Electronic Communication and Privacy Act* (ECPA) in 1986 after Canada passed the *Privacy Act* of 1985. Specific to health information, the *Health Insurance Portability and Accountability Act* (HIPAA) was introduced in 1996 [5]). Canada recently amended *the Personal Information Protection and Electronic Documents Act (PIPEDA)* to include digital health records [6,7]. When considering privacy legislation and data sharing between Canada and the United States, within the legislation, there exists the possibility to create data sharing agreements between both countries for cross-comparative health services research studies [7,8]. An example of a research study that required data linkages across Canada is outlined in the paper by Chiu et al., where they describe immigration patterns, refugee, citizenship, and Canada's permanent resident data and vital statistics to Ontario's administrative datasets [9]. Health technology researchers, developers, and professionals can implement large scale, cross-comparative studies that utilize current data assets within North America.

There are differences in American and Canadian perspectives on the privacy legislation. Canadians typically trust the idea that the system protects their medical information and respects their privacy. Americans on the other hand have a heightened awareness of their data privacy laws, which may vary according to the state [10]. In an era where health technology innovations and electronic information sharing has dramatically increased over time, data is a public asset that can be used to improve the population health and the well-being of society. While policy development occurs at a more macro or health systems level, positive patient-centered outcomes are the goal of every health care professional. Technology can be a positive catalyst for improving health outcomes for patients.

3.2 The Canadian Perspective: Privacy Policy Development

In Canada, the *Privacy Act* of 1985 imposed obligations for 250 federal government departments to collect, use, and disclose personal health information. This health policy outlines the collection of personal health information that is stored in protected facilities, such as hospitals or other health care organizations [11]. It also considers public opinion and the ethical use of personal health information for purposes of research and advancing sciences [9]. The 2004 update of the *Personal Health Information Protection Act (PHIPA)* policy included a revision for health technology considerations. The legislation is different from PIPEDA as includes not only electronic health information but also external information as well [10]. According to this Act, there are ongoing audits by the privacy commissioner. For example, the update includes giving permission to prescribed entities-for example, the Canadian Institute for Health Information (CIHI) and the Institute Clinical Evaluative Sciences (ICES), Cancer Care Ontario (CCO)-to receive de-identified health data for the purposes of health systems planning, delivery, and design [10]. This legislation further outlines the role responsibilities which hospitals, primary care providers, and other interdisciplinary professionals have in protecting information in patient records.

In Canada, the *Personal Information Protection and Electronic Documents Act* (PIPEDA) of 2005 outlined the role of health records and technology such as the use of electronic documents and electronic payment options. It requires organizations to obtain consent from patients prior to the storage of their electronic medical record. Under this legislation, organizations can conduct data linkages while also protecting the privacy of patients and families through the process of re-identification of personal health information [7]. Organizations such as the ICES, Health Quality Ontario (HQO), CCO, CIHI, and other federal and provincial non-governmental agencies are governed under this federal legislation. In Ontario, health technology companies and private businesses are also governed by this legislation if they are creating linkages between data sets. Core elements of this legislation include: ensuring data is de-identified, small cell counts are suppressed, and that personal health information is not identifiable by a member of the public. As new health technologies modernize over time, it will be important from a patient-centered care perspective to ensure that health technology companies are in accordance with their local privacy legislation.

3.3 The United States: Considering Health Technology Developments and Integrating them into Health Policies and Legislation

Within the United States, the process of the development of health technology and their privacy legislation occurred earlier in comparison to Canada. The *Electronic Communication and Privacy Act (ECPA)* of 1986 states that Americans are protected from unreasonable search and seizure of data that is transmitted through new "emerging technologies" such as pagers, email, and cell phones [12]. This privacy policy was created to ensure that citizens are protected from unreasonable searches of their personal communication devices. This policy assisted organizations such as hospitals and primary care facilities in the management of their own health data. The implications of this legislation included the possibility of allowing organizations to aid in the process of health data management. It continues to evaluate new and novel technologies such as iPads and other devices for sharing and storing data. This legislation is monitored on a regular basis and there is ongoing policy evaluation conducted by the Privacy Commissioner.

There are several ethical implications of the *ECPA* of 1986. This legislation requires modernization to reflect the variety of current technologies that are used in health care. For example, how can technological innovators design and implement new technologies such as iPads, and encrypted technologies that meet privacy standards [12]. Also, how are these health technologies currently being used in hospitals across North America to ensure that they are both safe for patients, families, and health care providers in preventing privacy breaches? The current political climate in the United States impacts how legislation is operationalized at the front lines. The ECPA has many implications for the integration of new, emerging, and innovative health technologies in the health care sector.

4. Conclusion

Both the United States and Canada have had their own journey as two modernized, high income nations. This paper draws inspiration from two nations in their journey towards designing innovative health technologies in the context of existing privacy legislation. It presents a historical perspective in the evolution of the privacy legislation, the ethical implications, and highlights how key privacy legislation can be considered in the process of health technology development. This legislation has implications for both for-profit and not-for-profit industries and specialties such as digital health and mobile health.

Despite the evolution of this legislation over time, the law within both countries has not yet evolved to incorporate advances in health technology. Co-designing technologies that pool health information such as monitor health apps, remote monitoring devices or larger electronic health datasets can lead to a more patient-centered and family-centered health care system for all Canadians. Engaging clinicians, policymakers, and patients through organizations such as the Canadian Medical Association, Canada Health Infoway, and others can ensure that that there is synchrony with the common values of professional institutions, government, for-profit and not-for-profit companies, which include creating a patient-centered health care system.

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