Mobile Health Technologies that Enable Patient-Physician Interactions: Public Policy Perspectives

by

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Abstract

Canadians are fast adopting mobile devices and health apps, and surveys suggest that Canadians want to engage with their health provider using these technologies, yet they are seldom able to. This study seeks to understand why health apps are seldom jointly used between physicians and patients and explore policies that would allow us to leverage these tools within British Columbia's health care system. Critical discourse analysis and case examples are used to identify key issues and inform the policy analysis. Policy options are evaluated according to effectiveness, implementation ease and equity. In the near term, I recommend the development of a directory of health apps reviewed by patients and medical experts according to an agreed-upon framework and criteria. Longer term, more rigorous processes of certifying or licensing health apps may encourage adoption of more sophisticated, high quality health apps. However, government funding may be needed to stimulate the development of apps that can satisfy more rigorous validation approaches.

Keywords: mobile health technology; health apps; patient-physician interactions; public policy

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Executive Summary

Canadians are fast adopting mobile devices and health apps, and surveys suggest that they want to engage with their health provider using these technologies, yet they are seldom able to. The overall aim of this research is to understand why health apps are seldom collaboratively used between physicians and patients and explore policies that would allow us to better leverage these tools within British Columbia's health care system.

Health apps downloaded to smartphones or tablets can be used for a variety of purposes, including basic functions (such as tracking fitness and calories) to more sophisticated functions involving analysis of patient-supplied data, which can be transmitted to a care team. Expert opinion and some research suggest that mobile health technology can improve patient engagement, quality of care and bring about certain efficiencies to the health care system. Yet, many of these benefits are not being fully realized.

There is a lack of high quality (i.e. secure, clinically safe and effective) health apps that can be collaboratively used between patients and physicians. Specific concerns associated with health apps include factors attributable to the app's content (e.g. accuracy, quality of information) and the development process (e.g. privacy protections, involvement of medical experts or credible health bodies). Further, patients and physicians are challenged to identify appropriate and effective health apps given the sheer number on the market for most health categories.

In order to understand how current policies may be impacting on the use of mobile health technology in BC, I undertook a critical discourse analysis of 11 policies of provincial government, medical associations and governing bodies. This analysis highlights important barriers to mobile health adoption including factors attributable to the health system (e.g. its complexity and diversity of stakeholders) and policy (e.g. lack of policy focused on mobile health, provider- and system-centric discourse).

I also examine practical applications of m-health in Canada, Europe and the United States and find that various forms of reviewing or approving health apps are underway. The strategies reviewed are all partially or fully funded by government, and are motivated by a recognized need to facilitate the identification and use of high quality apps and even stimulate the development of such health apps.

In order to stimulate the development and adoption of high quality health apps I consider the following policy options: 1) development of a health app directory; 2) establishing a process for certifying health apps; and 3) regulatory licensing of health apps. The criteria used to assess the policy options include effectiveness, implementation ease and equity.

Based on the analysis of policies, I recommend in the near term the development of a directory of health apps reviewed according to an agreed-upon framework and criteria. The directory that I have proposed would establish a coherent strategy and address some of the issues identified with health apps. Compared to the other policy options, this option better suits the low-cost business model of current apps.

Longer term, a more rigorous process of validating the security and clinical safety of health apps through a certification and labelling program will encourage the development and adoption of safe, high quality health apps, and provides better assurances to physicians and patients compared to a directory of reviewed apps. Regulatory approval and licensing is also appropriate for the highest hazard health apps. However, given the current low-cost business model app developers are currently operating in, government funding is likely needed to stimulate the development of apps that would satisfy certification or regulatory requirements.

In time, all three policies could be implemented as complements to each other. A directory would feature apps that perform basic but still useful functions; a certification scheme would provide assurances for health apps that do not meet the threshold of a medical device but that still benefit from formal assessment. Regulatory oversight would be reserved only for the highest risk health apps.

Chapter 1. Introduction

In Canada patients have relatively limited opportunities to connect with health care providers or health services more generally using modern forms of monile information and communication technologies (e-health). While federal and provincial governments have long invested significantly in e-health, the technologies implemented to date are generally provider-centric. They are typically designed for and used by health care providers and primarily enable information sharing between providers but not patients and providers.

Canada lags behind other countries in the adoption of technologies that enable patients to connect with the health care system. Eleven percent of primary care physicians in Canada answer medical questions via e-mail compared to 34 percent in the United States and 68 percent in Switzerland (Schoen et al., 2012). Seven percent of Canadian physicians allow patients to request an appointment or referral online compared to 30 percent of US physicians and 66 percent of Swedish physicians (Commonwealth Fund, 2013).

There is also a significant gap between the number of people interested in connecting with the health care system using e-health tools and those that can (Zelmer and Hagens, 2014). Ninety percent of Canadians would like to request prescription renewals online (Ipsos-Reid, 2010); however, only 6 percent of Canadian physicians allow this function (Commonwealth Fund, 2013). Fewer than 10 percent of adults in Canada have consulted a health provider, booked an appointment or viewed their health records through remote means (Ipsos Reid, 2010 and 2013). For all groups, actual use is below the number of respondents who indicated they would like to be able to use these services (Ipsos-Reid, 2013).

This gap is becoming more salient as technologies are increasing marketed to – and used by – health consumers. Health apps and mobile digital devices are two

examples of such technology, are the focus of this study. As of 2015, 68 percent of Canadians have a smartphone (up from 55 percent in 2014) (Catalyst, 2015). And as this market has grown, so too has interest in using the tools for health purposes (Ho, 2013). As of 2013, approximately 97,000 apps are listed under the mobile health section of the top two platforms (Apple and Android) (a doubling since mid-2011) (research2guidance, 2013). Health apps downloaded to smartphones or tablets can be used for a variety of purposes, including to track fitness and calories or to aid in the management of chronic conditions such as heart disease or diabetes (Ho, 2014). Some apps perform patient-specific analysis of health data which can be transmitted to a care team.

Most studies show that the use of health apps is widespread among consumers and physicians; however, their usage is "siloed" – that is, physicians and patients use these tools independently of one another and patients are seldom able to integrate their use of the tools in their interactions with physicians (Snowdon et al., 2014:30). The overall aim of this research is to understand why health apps are seldom jointly used between physicians and patients and explore policies that would allow us to better leverage these tools within British Columbia's health care system. I focus on mobile digital devices (smartphones and tablets) and health apps that allow patients to collect, store and transmit important health information to physicians. The study is focused on British Columbia (BC) but the lessons learned here should be useful across Canada.

Given the unprecedented rate of growth in health apps and mobile digital technologies, the question is probably not whether health care will change but how the changes will be managed and who will provide leadership. Change happens slowly in health care systems and the benefits and drawbacks of these tools along with ideal implementation strategies are important topics that reasonable people may well disagree on. I hope this study provides valuable insights.

1.1. Study Overview

This study is guided by the following research questions:

1. Why is there relatively little interaction between patients and physicians using mobile health technologies (m-health)?
2. To what extent are current policies impacting the use of health apps and mobile digital devices in BC's health care system?
3. What policies would enable effective use of health apps between physicians and patients in BC?

Chapter 2. Background

In this chapter, I outline the current use of mobile health tools in Canada and provide an overview of the research on the benefits and concerns associated with health apps. I also discuss relevant legislation with emphasis on privacy laws and medical device regulations. The chapter concludes with a synthesis of the main findings from this literature.

2.1. Mobile Health Technology in Canada

2.1.1. Use of Health Apps and Mobile Digital Technologies

The use of mobile digital tools is high among patients and health care providers. A survey of Canadian medical students, residents and faculty (n=1,210) found that 93 percent own a mobile device, 42 percent own both a smartphone and tablet and 37 percent have purchased 1-4 health apps or other medical resources for their mobile device (Boruff and Storie, 2014). A majority of respondents use the devices to find drug information, perform clinical calculations and find clinical practice guidelines. A survey of Canadian dietitians (n=139) in various practice areas (e.g. hospitals, long-term care, private practice) showed that 69 percent of respondents currently use smartphones and/or tablets in their practice and 57 percent use health apps in their practice (Lieffers et al., 2014). Eighty-four percent of respondents not currently using apps for work purposes expressed an interest in future use of such software.

Survey data also show that Canadians are strongly interested in using mobile health technologies that enable remote connection to the health care system (see Table 1). In 2012, Canada Health Infoway consulted 500 Canadian patients, health care providers, government representatives, vendors and national health associations to better understand which digital technologies could best support future health care needs.

Bringing care closer to home (e.g. access to personal health information, patient monitoring) and providing easier access to health care (e.g. e-visits, e-scheduling) were among the top five priorities (Infoway, 2013).

Table 1 Preferences among Canadian Adults for Consumer Digital Health Solutions

	Percent desiring the solution	Percent selecting as single most valued solution
Request prescription renewal	90	26
View laboratory results	88	20
Make appointments with providers	87	15
Consult securely with providers online without having to phone or visit office	79	10

Adapted from Ipsos Reid (2010)

2.1.2. Benefits of Mobile Health Technology

Improved Patient Engagement

Health apps, in addition to other forms of m-health and traditional interventions, are seen as promising tools for engaging patients in self-management and behaviour change between in-person appointments with physicians (Singh et al., 2016). This is significant when considered in the context of the growing body of research that shows health care is more "efficient and effective when patients are actively engaged in their treatment" (Singh et al., 2016:1).

In the context of chronic disease, patient engagement includes patient's knowledge of the condition, their confidence and self-management skills and willingness to adopt new health promoting behaviours such as medication adherence, physical activity and compliance to nutrition recommendations (Simmons et al., 2014). According to Singh et al. (2016) the advantage of health apps is they can be designed to support patients at any level of engagement – for instance, apps that provide education or reminders for patients who are less engaged and apps that enable active participation, rewards and information exchange for patients who are more engaged. Health apps are

also an intervention that many patients are highly motivated to use in part due to the popularity of smartphones and tablets (Snowdon et al., 2014; Singh et al., 2016).

The issue with the current usage of health apps (whereby patients primarily use them independently of their physicians) is that patients are engaging in self-management without the benefit of a physician (Snowdon et al., 2014). One reason for the siloed way in which patients and physicians currently use health apps may be that most health apps are developed *either* for physicians or patients. Snowdon and colleagues (2014) undertook an analysis of the most popular health apps available for iPhone and Android platforms in June 2013. Twelve hundred apps were analyzed for content and categorized by cost (paid or free) and purpose (medical or health and fitness). Apps for professionals were primarily for diagnosis and treatment, evidence-based practice and information on anatomy and physiology; by contrast, apps for consumers were primarily focused on health and wellness (Snowdon et al., 2014).

Improved Quality of Care

Most experts agree that there is great potential for mobile health technology to improve health outcomes and quality of care by opening up new channels of patient-physician communications and enabling earlier and less costly health interventions (Cortez et al. 2014). Health apps, as a specific example of m-health, can enable better and more frequent analysis of patient data, and this aspect is thought to be particularly advantageous for many chronic diseases which benefit from increased monitoring (Cortez et al., 2014).

While research on the effects of mobile digital technologies on disease management and health outcomes is somewhat limited (Free et al., 2012; Fiordelli et al., 2013), some research suggests that health apps and associated devices can improve health outcomes without increasing medical time or the time burden for patients. In a six-month randomized trial involving people with chronic, poorly managed diabetes Charpentier et al. (2011) found statistically significant improvements in metabolic control in treatment groups using Diabeo (a diabetes management software uploaded to a smartphone) and bi-weekly teleconsultations compared to the control group (quarterly visits to a health care provider). Treatment groups using Diabeo and undergoing

quarterly visits showed intermediate improvements in metabolic control. The authors noted that the extent of improvement in metabolic control using the Diabeo system was greater than what has been achieved in other telemedicine trials involving diabetes patients that generally show non-significant improvements or more modest changes compared to their study. Charpentier et al. (2011) proposed that the Diabeo system offers important features compared to standard monitoring protocols or devices. The app allows for real-time, validated calculation of insulin dose and allows for the transmission of more complete data to a health expert. Further, the app allowed for more brief teleconsultations as the health care provider had reviewed the data in advance of the call and the Diabeo-teleconsultation group did not have to miss work to attend in-person visits with a health care provider (Charpentier et al., 2011).

Improvements in Operational Efficiencies

Some research suggests that mobile digital technologies can result in cost savings and/or operational efficiencies at the health system level. For example, hospital readmissions are common and costly – in Ontario, one study found that 21 percent of patients discharged from an internal medicine ward are readmitted within 90 days of discharge (Gruneir et al., 2011) and hospital readmissions cost the Ontario system $700 million annually (Eng, 2011). Hospital readmissions are often avoidable, and in many jurisdictions efforts are being made to reduce their incidence.

In a Canadian trial (Semple, 2013), patients who had undergone breast reconstruction surgery were provided with a mobile phone at the time of discharge and asked to use an app to complete a recovery questionnaire and take daily pictures (for 30 days) of their surgical incision using the device's camera. Both the pictures and recovery information were reviewed remotely by surgeons. In this study, post-operative length-of-stay was reduced from four days to 18 hours, and surgeons were able to reliably assess patient recovery and intervene early (Semple, 2013). The authors also noted that the intervention was associated with reduced hospital readmissions and emergency department visits, and was viewed positively by participants.

Outside of the peer reviewed literature, experts have proposed that health apps and associated devices that transmit health data in real time to health care providers

would allow for clinical problems to be identified sooner thereby potentially defraying costs of treating more advanced cases (Infoway, 2014).

2.1.3. Concerns Associated with Mobile Health Technology

Lack of Safe, High Quality Health Apps

Concerns about accuracy and validity of health apps are often cited among health care providers and these concerns negatively impact their willingness to recommend or encourage patients to use them (Cortez et al., 2014; Lieffers et al., 2014). For example, if the algorithms used to perform analysis of patient supplied data contain errors or the app otherwise fails to measure health inputs accurately, the app may mislead the user (Ho, 2013; Cortez et al., 2014).

The lack of validation in health apps ought to be considered in the context of the number of apps currently on the market. As mentioned at the outset of this study, one estimate suggests that there are approximately 97,000 health apps listed by the top two platforms (research2guidance, 2013). Evaluating the quality of health apps is, therefore, difficult at the level of individual patients or physicians as well as at a health system or organizational level (Cortez et al., 2014; Powell et al., 2014).

Providers have also raised concerns about the lack of involvement by credible organizations in the development and/or approval of apps (Lieffers et al., 2014). Indeed, several analyses of currently available apps suggest that many are developed without input of physicians or other medical experts (Cortez et al., 2014; Gagnon, 2014), are not consistent with evidence-based guidelines (Cortez et al., 2014), and are of limited usefulness to patients (Singh et al., 2016).

Many currently available apps have not been formally studied, particularly those with more sophisticated functions. Fiordelli et al. (2013) undertook a review of literature on mobile health published between 2002 and 2012 and found that most studies evaluated basic mobile phone features (such as text messaging) rather than the more sophisticated capabilities of newer technologies. In addition, the authors found that the

few studies involving smartphones were of an app created for research purposes rather than of publicly available apps.

Equity Considerations

Concerns about equity have been raised perhaps mainly because health literacy and access to technology are known to be correlated to income. Yet, opinions vary on the potential equity effects with some arguing the tools may improve equity (by reducing the need to take time off work or pay travel costs, as examples) and others pointing out that cost of the devices and data plans may disproportionately affect lower income populations (Zelmer and Hagens, 2014). Hoff et al. (2012) were able to target and effectively reach minorities and women of lower socio-economic status in an experimental study involving "text4baby" (a mobile app that sends pregnant women and new mothers information on their health, infant health and availability of resources via text message). Yet several other studies reveal an income effect. For example, a systematic review of studies published through 1999-2010 found evidence that the use of patient portals was lower among certain racial and ethnic groups and those with lower literacy or education levels (Goldzweig, 2012).

Other equity issues may arise based on user's age and skill level. Most experts agree that among elderly patients, whose health needs are significant, literacy skills need to be considered, and, in the context of m-health, include literacy in computer, health, and reading and writing skills (Infoway, 2014). Elderly or disabled patients may also have physical impairments making it challenging for them to successfully use these tools; however, their informal caregivers may well be capable (Infoway, 2014).

Nine in 10 Canadian adults indicate that they would be moderately or extremely comfortable using consumer health solutions if available to them (Ipsos Reid, 2013). However, the same survey revealed that self-reported comfort levels tend to be higher among those living in a city, in the middle-income category (household income $40K–$80K) and under the age of 35. Mehrotra et al. (2013) found that younger patients and those with longer travel distance were more likely to opt for e-visits.

Privacy Concerns

Privacy and security concerns have been raised by consumers and health care providers. Approximately 10% of survey respondents who said that they were uncomfortable using consumer health solutions most often cited concerns about privacy and security of data (Ipsos Reid, 2013). Health care providers also express concern about privacy of patient information stored in health apps (Whittaker, 2012; Lieffers et al., 2014).

2.2. Brief History of E-Health in Canada

2.2.1. Role of the Federal Government

The federal government began making significant investments in e-health in 1997, and early funding was dedicated to establishing a modern, pan-Canadian information and communications technology network that would support subsequent e-health strategies (Health Canada, 2007). Since then, federal funding has focused on increasing the availability and use of electronic health records and electronic medical records and improving telehealth capability particularly in rural and remote communities.

Health Canada has focused its efforts on integrating e-health services across the system, measuring progress and addressing policy issues (Health Canada, 2010). As an example, Health Canada undertook a review of federal statutes and determined that regulations under the *Food and Drugs Act* and *Controlled Drugs and Substances Act* do not impede electronic prescribing (Health Canada, 2010).

In 2001, the federal government established Canada Health Infoway (hereafter Infoway) to coordinate and accelerate the adoption of e-health technologies across Canada. Infoway is an independent, non-profit corporation whose members include the federal government and the provincial and territorial ministers of health. The corporation has collaborated with provincial and territorial funding partners on more than 390 projects mostly involving electronic records and telehealth (House of Commons Canada, 2013). Infoway also performs certification services for various e-health technologies to

verify conformance to Canadian and international standards for privacy, security and interoperability (Infoway, n.d.).

With the establishment of the Emerging Technology Group in 2011, Infoway has been allocating resources to newer technologies or mature technologies that are underutilized in the health system. The Emerging Technology Group has been directed to monitor and study a number of technologies including mobile computing devices, and share information with health organizations through white papers and webinars.

2.2.2. Role of the BC Government

Similar to the federal government, the BC government has invested significantly in e-health technologies with particular emphasis on electronic records and telehealth. As this project is focused on BC, I analyze major policies and strategic plans of the provincial government (through critical discourse analysis) in Chapter 4.

2.3. Current Policy Landscape

E-health technologies are often described as presenting a challenge to policy makers who are ultimately managing what has been described as “competing social benefits” (BC Medical Association [BCMA] et al., 2009:5). Health information and communication technologies greatly enhance access and exchange of information; this improves patient care but also introduces new privacy issues to manage (BCMA, 2009; Infoway, 2014). Mobile health technologies must obviously be safe and effective but these objectives must be achieved without stifling innovation in the sector (Williams and Weber-Jahnke, 2010). In the section that follows, key federal and provincial legislation is summarized in the context of the health sector.

2.3.1. Federal Legislation

While provincial governments hold significant policy-making authority in health care, two federal statutes of concern are the *Personal Information Protection and Electronic Documents Act* and the *Medical Devices Regulations*.

Personal Information Protection and Electronic Documents Act

The *Personal Information Protection and Electronic Documents Act* applies to the private sector and federally regulated organizations and establishes a regulatory framework for how personal information is collected, used and disclosed for commercial activities (Office of the Privacy Commissioner of Canada [OPCC], 2015). Under the law, individuals are also empowered to access their information and request corrections where appropriate (OPCC, 2015). Personal information is defined as "any factual or subjective information, recorded or not, about an identifiable individual" with addresses, medical records and income being a few examples (OPCC, 2015:3).

The Act requires that organizations have consent from individuals whose information they collect, use or disclose and use that information only for the purposes for which it was collected (unless additional consent is obtained) (OPCC, 2014). Organizations must also take steps to protect the information in their custody – the Act is not prescriptive as to safeguards (broadly, they can include technological, physical or organizational measures) and accepts that safeguards can be proportional to the sensitivity of the information (OPCC, 2014).

In provinces where the privacy legislation is deemed "substantially similar" to the federal statute, the provincial legislation prevails except in cases of interprovincial or international exchanges of information (OPCC, 2014). In BC, for instance, organizations governed by the provincial *Personal Information Protection Act* are exempt from the federal Act (BCMA et al., 2009).

Food and Drugs Act – Medical Devices Regulations

In Canada, medical devices are regulated at the federal level through the *Food and Drugs Act Medical Devices Regulations*. Medical devices are classified (from I - IV) based on their purpose, invasiveness and degree of harm that would result if the device failed (Williams and Weber-Jahnke, 2010). Class II, III and IV devices are subject to a licensing system and must meet applicable regulatory requirements which include safety and effectiveness testing, post-market problem reporting and labelling restrictions (Squire, n.d.). Class I devices are exempt from licensing requirements; however, the

manufacturer must ensure that the requirements outlined in the regulations are met (Health Canada, 2011).

In 2011, Health Canada issued guidance stating that software would be regulated as a medical device if it: "(1) provides the only means and opportunity to capture or acquire data from a medical device for aiding directly in the diagnosis or treatment of a patient; or (2) replaces a diagnosis or treatment decision made by a physician" (Health Canada, 2011:1).

Software used by a patient in any location external from health care settings would be a Class II medical device if the software "is intended for analyzing device-provided data for the purpose of directly aiding in treatment or diagnosis" and would be Class I if the software "only transmits and stores the data." (Health Canada, 2011:1). Further, "Software that is intended to be used to view images, or other real time data, as an adjunct to the monitoring device itself, for the purpose of aiding in treatment or diagnosis of a patient, would be Class I medical devices" (Health Canada, 2011:1).

Canada's medical devices regulations are considered comprehensive and even influential (Williams and Weber-Jahnke, 2010). However, some question whether the approach historically taken in Canada will continue to be effective as mobile health tools become increasingly sophisticated (Infoway, 2014). Currently, however, the vast majority of health apps perform basic functions (Infoway, 2014) and are low risk (Cortez et al., 2014) and therefore do not fall under regulatory oversight.

2.3.2. Provincial Legislation

Like other provinces, privacy legislation in BC has evolved alongside fast evolving information technologies. A suite of privacy legislation is in place in BC and is discussed below.

Personal Information Protection Act

Enacted in 2004, the *Personal Information Protection Act* governs private and non-governmental organizations in the collection, use and disclosure of personal

information (Office of the Information and Privacy Commissioner for British Columbia [OIPC BC], n.d.]). It therefore applies to private physician offices and private laboratories, as examples. Personal information includes that which identifies a person (e.g. name, home address) or that relates to the identifiable person (physical description, blood type) but does not apply to anonymized aggregated information (BCMA et al., 2009).

Core principles of this legislation include: (BCMA et al., 2009)

- Personal health information should not be collected, used or disclosed without patient consent. (In rare cases, such as when consent cannot be obtained in a timely way, this principle does not apply.)
- Consent can be implicit or expressly given but must be informed (e.g. physicians should explain their privacy protocols to patients) and patients must know of their right to withdraw consent.
- Patients own their information; physicians are custodians of the information they have collected.
- Safeguards must be implemented (by physicians or others covered by this Act) to protect the information they have collected regardless of how it is stored (i.e. paper, digital, or electronic), the technology used to access it (e.g. laptop, mobile digital device) or location (e.g. within the office or through remote means)
- Information collected should be limited to only what is necessary relative to the purpose for which it is collected

Freedom of Information and Protection of Privacy Act

The *Freedom of Information and Protection of Privacy Act* establishes the rules under which public organizations (e.g. hospitals, health boards) collect, use and disclose personal information (OPIC BC, 2015). This legislation also empowers individuals to gain access and request corrections to the information that has been collected about them by public organizations (OPIC BC, 2015).

The e-Health Act

In 2008, the "e-Health Act" (*Personal Health Information Access and Protection of Privacy Act*) came into force. The e-Health Act is more specific in scope compared to other privacy legislation: it outlines the rules under which public bodies such as Health Authorities can collect personal health information for specific "Health Information Banks" (databases that can support information sharing in the provincial Electronic Health Record) (BCMA et al., 2009). This law also establishes a process to review requests for secondary access to information in an Electronic Health Record and allows individuals to block access to some or all of their information stored in centralized repositories (BCMA et al., 2009).

2.4. Section Summary and Discussion

Physicians and patients generally use mobile health solutions independently of one another and there is a significant gap between the number of people interested in connecting with the health care system using newer technologies and those that actually can. The literature reviewed offers important insights on these issue (discussed below and summarized in Table 2).

There is good agreement that m-health technologies offer important benefits to the health system and individual patients. However, the nature of these benefits is often prospective. Research evidence is somewhat lacking, and this is likely an impediment given the strong emphasis on evidence-based interventions in the health system. Concerns associated with health apps include factors attributable to the app's content (e.g. accuracy, quality of information) and the development process (e.g. privacy protections, involvement of medical experts or credible health bodies). Physicians and patients are challenged to select safe, useful apps given the sheer number of currently available apps.

Table 2 Summary of Factors Impacting Joint Use of Health Apps between Physicians and Patients

Driving forces	Restraining forces
Factors attributable to the technology	
Popularity of apps and mobile digital devices among patients and physicians	Lack of involvement of medical experts or credible bodies in app's development
Strong interest among patients	Privacy and security concerns
	Accuracy issues and lack of validation
	Design is often either for patients or physicians
Other factors	
	Research evidence is somewhat lacking

Chapter 3. Methodology

3.1. Research Questions and Methods

As previously outlined, the overall aim of this research is to better understand the opportunities and risks of health apps and identify policies that would support effective use of these tools in BC's health care system. In particular, my aim was to address the following research questions:

1. Why is there relatively little interaction between patients and physicians using mobile digital technologies?
2. To what extent are current policies impacting on the use of health apps and mobile digital devices in BC's health care system?
3. What policies would enable effective use of health apps between physicians and patients in BC?

The literature reviewed as part of *Chapter 2 – Background* offered some important insights on the first question. However, there is obviously a need to delve further into this question particularly in the context of BC's health care system. A critical discourse analysis of several policies relevant to BC was done to gain insights on the first two research questions. I also examined examples of mobile health tools in practical settings. In what follows, my methodology is described in greater detail.

3.2. Critical Discourse Analysis

Critical discourse analysis has been described as "an analytical framework for studying connections between language, power and ideology" (Fairclough, 1995:23). In this form of analysis, spoken and written communications are critically examined within their political, historical, social and cultural contexts (Fairclough, 1995).

Critical discourse analysis is increasingly used in policy studies to better understand the political and organizational objectives expressed in policy texts (Taylor, 2004; Jacobs, 2006). It has also been used in health research, for example to study discourses underpinning compassionate care (Whitehead et al., 2014) and telehealth and telemedicine (Greenhalgh et al., 2012).

The goal of the analysis I conducted was to examine policies (defined broadly to include not only policies but also strategic plans and position statements) to better understand how these may be impacting the use of m-health in BC. My aim was to identify dominant discourses but also gain insights on the marginalized discourses or what Taylor (2004:4) refers to as “silences” in the policy texts.

Government of BC policies were identified by doing an advanced search in Google using the site operator and search terms such as “e-health policy”, “mobile health” and “mobile health policy”. This approach meant that all Government of BC websites (i.e. ministries and central agencies but not crown corporations) were searched. The list of documents produced from the search was then screened and I selected five documents that represent the current thinking of the Ministry as it relates to general provincial health policy along with policies specific to e-health. The selected public policy documents are listed in Section 4.1.

To identify relevant policies of medical associations and governing bodies, I consulted organization websites. For Doctors of BC (www.doctorsofbc.ca), I selected the “Health Policy” page and scanned all policy papers and policy statements. The same approach was used to search for policies of the College of Physicians and Surgeons of British Columbia (www.cpsbc.ca), and the Canadian Medical Association (www.cma.ca). I selected materials that discussed e-health technology involving patient-physician communications and that were published after 2010 as these were more likely to discuss the newer technologies that are the focus of this study. One document published in 2005 was included in the analysis as it was reviewed in 2012 and is still in use. The six medical association policies selected are listed in Section 4.1.

The analysis of the identified policies was accomplished using the following steps:

- Each document was read it its entirety to become familiar with its content. General notes about the purpose of the documents were recorded in an Excel spreadsheet to organize the data.
- Each document was then read more closely and key excerpts were extracted and pasted into the spreadsheet. The excerpts were then reviewed and notes were made in a separate column to denote relevant ideas, observations and dominant discourses.
- These notes, along with the excerpts, were then considered together and an initial list of topics and corresponding discourses was created.
- I then read the excerpts multiple times using Fairclough's (1995) approach to critical discourse analysis. This involves analysis of textual practice (i.e. linguistic features of the text such as key words and metaphors); the discursive practice (i.e. the way references, warrants and evidence are used to form an argument or otherwise persuade); and social practice (i.e. ideology and power relations revealed in the text).
- Finally, the excerpts were reread to verify that the analysis represented the full scope of discourses and the list of topics and corresponding discourses was refined.

3.3. Analysis of Case Examples

A second component of this research was to examine, in closer detail, practical applications of m-health. The examples studied focused on ways of reviewing or validating health apps. The goal of this analysis was to gain insights on strategies that may address problems, identified in the literature, related to the quality of health apps and how this appears to be impeding effective use of health apps between patients and physicians. To familiarize myself with these initiatives, general information was found by doing an Internet search for relevant documents and reviewing relevant websites. I chose one example from Canada, Europe and the United States to obtain a broad understanding of different approaches taken nationally and internationally.

Chapter 4. Findings from the Critical Discourse Analysis

In this chapter, I begin with a broad overview of the documents selected for the critical discourse analysis. Following this, the findings are presented and I end with a summary and discussion of key findings.

4.1. Documents Analyzed

The following policies were included in this analysis:

- British Columbia Medical Association[1] (2012) Policy Statement – Email Communication with Patients
- Canadian Medical Association (2005 [last reviewed 2012]) Physician Guidelines for Online Communications with Patients
- Canadian Medical Association (2011) Principles for the Protection of Patients' Personal Health Information
- College of Physicians and Surgeons of British Columbia (2013a) Professional Standards and Guidelines – Emailing Patient Information (a guideline)[2]
- College of Physicians and Surgeons of British Columbia (2013b) Professional Standards and Guidelines – Telemedicine (a standard)[2]
- Doctors of BC (2014) Policy Statement – Telemedicine in Primary Care
- Ministry of Health (2010) Innovation and Change Agenda
- Ministry of Health (2011) British Columbia's 2010/11 - 2012/13 Provincial Health Sector Information Management and Information Technology Strategy

[1] Note: In 2013, the BC Medical Association changed its name to Doctors of BC.

[2] As outlined by the College of Physicians and Surgeons of BC, a guideline is a recommendation of the College; a standard reflects either a legal requirement or minimum expectation of professional behaviour and ethical conduct of physicians.

- Ministry of Health (2014a) Setting Priorities for the BC Health System
- Ministry of Health (2014b) 2014/15 - 2016/17 Service Plan
- Ministry of Health (2015a) Enabling Effective, Quality Population and Patient-Centred Care: A Provincial Strategy for Information Management and Technology

4.1.1. Overview of Professional Association Policies

The Canadian Medical Association provides leadership and guidance to physicians and advocates for high quality health care on behalf of physicians and patients. The General Council is the governing and main policy-making body of the association (Canadian Medical Association, n.d.).

The College of Physicians and Surgeons of BC regulates the practice of medicine under the authority of provincial legislation. The College has published a number of Professional Standards and Guidelines – while several of the College's Professional Standards and Guidelines focus on e-health, only a few are concerned with communications between patients and physicians.

Doctors of BC represents the interests of its members on a number of policy areas in health and works collaborative with its members and other stakeholders to uphold high standards of patient care. The association periodically produces policy papers and statements developed by its Board of Directors or committees representing the Board (Doctors of BC, n.d.). Policy statements represent the official position of the association and are reviewed periodically (Doctors of BC, n.d.).

4.1.2. Overview of Provincial Government Policies

In 2010, the provincial health ministry published the *Innovation and Change Agenda*, an overarching framework for the BC health system developed by the government with input from provincial health authorities and other allied health organizations (Ministry of Health, 2010). The Agenda is unique provincially (a first-ever

framework for coordinated action across the health sector) (Ministry of Health, 2014a). It was intended to drive fundamental change across BC's health system in the following priority areas:

> 1. Providing effective health promotion, prevention and self-management to increase the health and wellness of British Columbians
>
> 2. Meeting the majority of health needs with high quality primary and community based health care and support services
>
> 3. Ensuring high quality hospital services are available when needed
>
> 4. Improving innovation, productivity and efficiency in the delivery of health services
>
> (Ministry of Health, 2010:4)

The Innovation and Change Agenda remains an important directional document and has informed several subsequent planning and policy documents (Ministry of Health, 2014a).

In 2011 and 2015, the Ministry of Health published provincial information management/information technology strategies which outline the information management and technology initiatives that will be used to support the goals identified in other planning and policy documents. There are a number of IM/IT initiatives in BC; the strategies focus on initiatives that apply across the system.

In 2014, the Ministry of Health published two key documents also included in this analysis: *Setting Priorities for the BC Health System* and the provincial *2014-15 - 2016/17 Service Plan* which outline the broad policy goals and objectives of the Ministry and, in the case of the service plan, the performance measures for the health system.

4.2. Discourses

I have presented the excerpts below in a way that highlights the three main aspects of the critical discourse analysis using an approach adapted from Fairclough

(1995); Jacobs (2006); and Callender and Sixsmith (2014). Textual practices are **emboldened,** social practices are <u>underlined</u> and discursive practices are *italicized*.[3]

4.2.1. Topic: Personal Health Information

Discourse: Confidentiality and Trust

The importance of protecting personal health information was strongly emphasized throughout the policies. In discourses of confidentiality and trust, health information is considered highly sensitive and its protection paramount. Within medical association policy, confidentiality and trust are additionally framed as among the foundational principles in medicine and essential to a well-functioning patient-physician relationship.

> **Privacy**, **confidentiality** and **trust** are **cornerstones** of the patient-doctor relationship. Health information is highly sensitive and is confided or collected under circumstances of **vulnerability** and **trust**. Trust plays ***a central role*** *in the provision of health care and treatment*; fulfilment of physicians' fiduciary obligations *enables open and honest communications and fosters patients' willingness to share personal health information*. (Canadian Medical Association Code of Ethics, 2004: Article 31 cited in Canadian Medical Association, 2011:1)

In some medical association policies, discourses of confidentiality and trust framed the protection of personal health information as a challenge in the context of modern modes of communications. The benefits of the technology were accepted and their use encouraged yet it was acknowledged that online communications between patients and physicians is limited and privacy and security were suggested as among the factors impeding such communications.

> The digitized nature of e-communications facilitates rapid and easy sending, storing, sharing and searching. However, these inherent benefits

[3] As outlined in Chapter 3 - Methodology, textual practice includes key words and metaphors; social practice involves the ideology and power relations revealed in the text and discursive practice involves the way references, warrants and evidence are used to form an argument or otherwise persuade. (Fairclough, 1995)

> create **challenges related to the preservation of privacy and confidentiality**. (Canadian Medical Association, 2005:1)
>
> Currently physicians and patients, as with the majority of Canadians, use email for a variety of reasons, but the extent that they are using it to communicate with one another is limited. In order to facilitate and *encourage this mode of communication*, **barriers relating to privacy and security**, *legal issues*, and compensation must be addressed. (BC Medical Association, 2012:2)

Discourse: Physician Responsibility

Discourses of physician responsibility were prominent within the broader context of personal health information. Physicians have significant responsibilities to protect patient information regardless of the technology or mode of communication used.

> The role of the College is to regulate physicians, not technology, and to remind physicians that the use of technology does not alter the ethical, professional and legal requirements around the provision of appropriate medical care. (College of Physicians and Surgeons of BC, 2013b:1)
>
> When transmitting patient information electronically, security and patient confidentiality must be **maintained** and **guarded** *in the same way as traditional paper medical records are protected.* (College of Physicians and Surgeons of BC, 2013a:1)

The Canadian Medical Association's *Physician Guidelines for Online Communications with Patients* (2005) provides a comprehensive review of the considerations physicians should or must make prior to communicating online with patients. The 11-page policy advises physicians to develop a protocol for online communications (10 considerations); decide on the purposes for which online communications with patients will be used within the practice (20 uses are listed); plan for managing patient expectations (9 strategies offered) establish conditions for patient use (12 conditions proposed); and establish protocols outlining who will have access to patient enquiries (with a minimum of 3 issues to be addressed). For specific technical

issues, a 37-point checklist of actions is provided to improve IT security within the office.[4] This policy is strictly focused on the context of physician-patient online communications; communications between physicians and other health care providers, government and other third parties are addressed in separate comprehensive policies.

While all personal health information must be protected, some of the policies express variation in the degree of sensitivity depending on the security of the technology, the nature of the information (e.g. appointment time versus adverse test results) and nature of the patient-physician relationship (i.e. existing patient, non-patient, prospective patient, purely online patient) (Canadian Medical Association, 2005). Sensitive information should be communicated in-person; having purely online patients is discouraged (Canadian Medical Association, 2005; BC College of Physicians and Surgeons, 2013a).

4.2.2. Topic: Quality of Care

Discourses of Patient Centred Care

Quality of care was described as a multidimensional concept, and, in recent discourse, patient centred care has been strongly emphasized by the Ministry as a core dimension of quality of care.

> In BC, we [BC Ministry of Health[5]] have adopted the approach used by the BC Patient Safety and Quality Council, which defines the dimensions of quality as including effectiveness, appropriateness, accessibility, safety and acceptability...**Underpinning** these dimensions of quality, we propose to add a **priority** to **consistently strive to provide patient-centred care**. (Ministry of Health, 2014a:12)

> Government is committed to ensuring that British Columbians both now and in the future have access to quality health services...This includes a **shared**, **cross-sector commitment** to providing **patient-centred care**, in

[4] Note: the checklist provided is an abridged version of an OECD document "Information Security Issues and Resources for Small and Entrepreneurial Companies - a Business Companion to the 2002 OECD Guidelines for Security of Networks and Information Systems prepared by the International Chamber of Commerce.

[5] My addition in brackets.

> which **care is about the patient** and responsive to their **individual needs and values**. (Ministry of Health, 2014b:3)

In these discourses, the patient is positioned at the centre of the health system and patient centred care involves consideration of the individual needs and values of patients. Patient centred models of care were explained by contrasting them favourably compared to models of care that are designed around the provider, system or disease.

> While many health organizations assert they put patients first, there is an *overwhelming consensus* that the health care system in many jurisdictions (including Canada) is **built** around the needs of providers. In any true **patient-centred** care delivery model, the **primary driver** of priorities is the patient as opposed to the setting where the care is provided or the experience from the provider perspective. (Ministry of Health, 2014a:12)

Interestingly, patient centred care is depicted in the discourses as both a component of quality care but also as a shift in culture that provides a *way* to improve quality and achieve other key health system goals.

> *In order to deliver responsive and effective health care services*, the Ministry and its partners aim to shift the **culture** of health care from being disease-centred and provider-focused to being **patient-centred**. This shift requires understanding and being responsive to **patient needs**, **values and preferences** as the **primary driver** of daily practice at all levels, from administration to front-line staff. (Ministry of Health, 2014b:12)

> **Underlying these goals** is the principle of **patient-centred care**: a sustained focus on shifting the **culture** of health care in B.C. to put **patients at the centre**, which will drive policy, accountability, service design and delivery in the coming years. (Ministry of Health, 2014b:10)

4.2.3. Topic: Technology

Discourse: Technology as an enabler

The role of technology as described in the policies is highly complex and multifaceted but, in the main, e-health technology is presented as an enabler for the broader health system goals and priorities. In these discourses, technology is linked to the sustainability of the health system, ensuring value for money, efficiency and improved quality.

> The health sector IM/IT vision is that health care information is accessible, when and where it is needed, to **support** personal health, health care decision making, and health system sustainability. (BC Ministry of Health, 2011:13)

> The mission of IM/IT resources within the BC health system is to **support** and **enable** the achievement of health system priorities and goals through the effective management of information and related information technologies. (BC Ministry of Health, 2011:13)

Provider- and System-Centric Discourses

Provider and system centric discourses were dominant within the broad topic of e-health technology. While the benefits of modern information technologies are described as accruing to both patients and physicians, the perspective that is directing implementation is most often that of the provider or health care system rather than the patient.

> The use of email by physicians can reduce non-essential office visits and save time otherwise spent communicating by phone..." Email follow-up allows retention and clarification of advice, creates a self-documenting written record, and is especially useful for information that the patient would have to commit to writing if given orally. (BC Medical Association, 2012:1)

> Physicians who choose to use email to communicate with their patients should consult the Canadian Medical Association's guidelines for online communication with patients to establish a protocol...The protocol should be reviewed with both staff and patients. (BC Medical Association, 2012:1)

The use of modern communications initiated by patients is discussed as something that must be managed and physicians are positioned as the authority in terms of technology usage.

> Patient expectations about how quickly a physician or the physician's office will respond to their enquiries online may be **unrealistic**. Physicians should determine how these expectations will be **managed** and communicate clearly to patients what the **office protocol** is with respect to response times. (Canadian Medical Association, 2005:3)

Of the 20 uses for online communications between patient and physicians described in *Physician Guidelines for Online Communications with Patients* (Canadian Medical Association, 2005) only four uses involve communications or actions initiated by the patient ("scheduling appointments", "online payments", "patient follow-up questions", "patient request for prescription refills") (p.2). Two of these are categorized as "Administrative uses" and two as "Patient Care"; none appear under "Education and Health Promotion" (p.2). The remainder of the uses for online communications are either silent as to whom is initiating communications (e.g. "monitoring") or articulate the uses from the physician perspective (e.g. "providing post-procedure instructions and follow-up") (p.2).

Provider- and system-centric discourses also extend to the exchange of patient information, which is often described as being exchanged across the system or between care providers and seldom from patient to provider or health services.

> ...modernize the health system through information management and technology by expanding the capability for **system interoperability** to enable **referrals**, improve **wait time management** and improve the exchange of patient information **across service areas** *to support inter-professional care teams in the delivery of high quality patient care while ensuring privacy*. (BC Ministry of Health, 2014b:17)

> The eHealth program has established a robust information technology infrastructure, creating and enhancing **information repositories** and building secure **information exchange services** that enable the exchange of health information (e.g., drug profiles, laboratory tests, medical imaging information). (BC Ministry of Health, 2014a:19)

Overall the review of policies, including forward-looking strategic plans, revealed relatively few instances where the technology is controlled by or mediated through the patient in meaningful ways. The extracts that follow are among the only articulations of patients having access to personalized health information and being empowered in meaningful ways in the context of e-health.

> ...IM/IT [Information management/information technology[6]] solutions **may** provide the patient access to their own health information to increase the

[6] My addition in brackets.

> ability to **participate** as a partner in their care team. (BC Ministry of Health, 2011:12)

> Increase information flow and **personal access to health data** to **empower patients** to be **full partners** in actively managing their health concerns. (BC Ministry of Health, 2014a:37)

The 2015 IM/IT strategy certainly places more emphasis on patient involvement calling for the development of a patient-centred IT strategy and acknowledging that the Ministry's patient-centred model requires, among other things, new technologies and services:

> This [patient-centred IT[7]] strategy will also contemplate how patients will use technology to access the health system in a more **patient centred** format, for example, by booking appointments online, tracking their spot on waitlists or using email and text to communicate with care providers. (BC Ministry of Health, 2015a:38)

4.2.4. Topic: Health System Change

Language on change was underpinned by discourses of change management considered most often at the health system level. Within these discourses, successful management and implementation of change was described as difficult and uncertain due primarily to the nature of the health system which was characterized as highly complex and slow to change.

> Implementing change in a **complex system** is **not only difficult**, it can also be **unpredictable**. Strategies and approaches that have proven effective in one setting may not work in another. (BC Ministry of Health, 2014a:iii)

> Some of the key **challenges** for the agenda [Innovation and Change Agenda[8]] were related to **change management** and the implementation of the strategy across a **complex sector**...There were also several service areas that remained **stubbornly problematic** and **resistant** to

[7] My addition in brackets.

> successful resolution, despite significant effort. (BC Ministry of Health, 2014a:2)

In the provincial policies and plans reviewed, discourses of drivers and barriers to change were also prominent. Many factors put forward as driving the need for change include changing demographics, increasing disease burden and other factors increasing the demands on the system or changing the nature of the demands on the health care system. In contrast to discourses of change management, factors driving change were often characterized as rapidly evolving. The first extract below illustrates this in the context of dementia, as an example that characterizes the discourse on the drivers for change.

> B.C. has the **fastest** growing population of seniors in Canada. *Currently, 16.9 per cent of our total population is 65 or older – a number that is expected to double within the next 25 years*...Rates of dementia are also rising **rapidly** and pose a challenge for the health system. As such, **the system must adapt** *to meet the* ***changing needs*** *of residential care users, in particular those with dementia.* (BC Ministry of Health, 2014b:8)

In terms of barriers, emphasis was given to the range of stakeholders within the health care system. Interestingly, the involvement of stakeholders was put forward as both a pre-requisite for change but also a barrier to change. The interests held by different stakeholders were framed as conflicting and this was linked to the difficulties of achieving successful, timely change across the health care system.

> The successful achievement of our strategic priorities includes **engagement and collaboration with our partners, including health authorities, physicians and health care providers, the Doctors of BC, unions and other stakeholders**, in shaping and implementing key actions. This **collaborative approach**, with a focus on population and patient needs, will allow us to enable effective change together... (BC Ministry of Health, 2014b:3)

> Challenges to making changes to health care are numerous – with often **divergent, entrenched viewpoints** and established ways of doing business overwhelming efforts to make significant transformational shifts. (BC Ministry of Health, 2014a:8)

4.3. Section Summary and Discussion

There is a dearth of policy focused on mobile health in BC. Further, among the policies and strategic plans reviewed, including forward looking documents, little attention is given to mobile health technologies, which have been marketed since about 2008 and are widely used by both physicians and health consumers.

Personal health information is considered to be among the most sensitive forms of information. Regardless of the technologies used, physicians have significant legal and ethical responsibilities to protect the privacy and security of patients' information. While there are several resources outlining best practices and requirements when implementing e-health technologies, their adoption may still represent a significant undertaking perhaps especially for private-practice physicians. While physician responsibilities were stressed throughout the policies, very little attention is given to the role that health consumers should play in protecting their own health information stored in personal mobile devices. As part of this analysis, a separate Internet search was conducted to identify resources designed to educate consumers on privacy risks or best practices when using modern technology for personal health purposes. The search revealed that such resources are lacking.

While the benefits of e-health for patients are recognized in important ways in the policies, discourses of e-health technologies tend to be provider- or system-centric in terms of who is benefiting and in terms of the perspective directing implementation. This approach is not likely sustainable as health consumers increasingly use mobile tools for health purposes and become increasingly keen to access health services using personal mobile devices (similar to how they remotely access other private or public services).

While providers and health system administrators will always have an important role in e-health technology, provider- and system-centric discourses that dominate in several policies are inconsistent with the Ministry's stated commitment to patient centred models of care. Further, since 2005, the BC government has required that its e-health strategies align with its broader health system goals. Personalized m-health solutions are among the technologies that align well with the Ministry's objectives, including

commitments to establish patient centred models of care. A very recent (2015) Ministry plan to develop a patient-centred IT strategy is an important new direction.

The BC Ministry of Health has signalled a need and desire for change and innovation in health care delivery but characterizes such change as having been very slow and difficult. The main barriers to system-wide change seem to be the complexity of the health system along with the often conflicting interests of diverse stakeholders in the health sector. Barriers to newer modes of communication between physicians include privacy and security concerns and physician compensation.

This analysis contributes further to our understanding of the barriers and enablers to m-health adoption by highlighting factors attributable to the health system and policy. These factors are summarized in Table 3.

Table 3 Summary of Health System and Policy Factors affecting M-Health Adoption

Driving forces	Restraining forces
Factors attributable to the health care system	
Technology viewed as an enabler	Highly complex and slow to change
	Diversity of stakeholders with often divergent views
Factors attributable to policy	
Technology must align with broader health system goals	Provider- and system-centric discourse dominant
	Limited focus on mobile health technology
	The need to overcome issues with confidentiality and security of data
	Physician compensation

Chapter 5. Findings from Case Examples

Chapter 5 details case examples that provide insights on initiatives in Canada, Europe and the United States to review or formally approve health apps. Consistent with other chapters, I conclude with a brief synthesis of the findings.

5.1. Practical Examples of Reviewing and/or Validating Health Apps

5.1.1. Health-e-Apps

In 2013, the University of British Columbia e-Health Strategy Office established the "Health-e-Apps" web resource with funding from the BC Ministry of Health (Ho, 2013). The goals of the project are to encourage the use of apps recommended by professionals and promote a more "synergistic use" of health apps between health care providers and consumers (Ho, 2013: 460). Apps are reviewed (but not endorsed) by Dr. Kendall Ho, M.D. and Director of the eHealth Strategy office. For each app reviewed, users can click on a link and watch a short (i.e. < 3 minute) video that provides user-friendly information on the purpose of the app, its advantages, cost and availability. The website and videos also encourage consumers and health care providers to share their input on the reviewed apps. As of 2016, nine apps had been reviewed.

5.1.2. European Directories of Health Apps

In 2012, the *European Directory of Health Apps 2012-2013* was published providing a comprehensive catalogue of 200 health apps (Patient View, 2012) reviewed by patient or consumer groups. The Directory was developed to create "some sense of order imposed on the chaotic, sprawling world of health apps" (Patient View, 2012:xxv).

Apps are categorized according to health topic (e.g. child health, cancer, anxiety), and information on cost, purpose, and patient reviews is available for each app included in the Directory. Where possible, the popularity of individual apps is noted (as measured by the percentage of patient group members who indicate they use the app). The data was gathered through research, online surveys and engagement through social media with patient or consumer groups (Patient View, 2012).

In 2015, a second edition was published titled *The Myhealthapps Directory 2015-2016,* which provides a catalogue of 450 health apps reviewed by individual patients or consumers or patient or consumer associations. This Directory acknowledges the need for "trustworthy and reliable health or wellness apps" as well greater transparency in the development of patient apps (Patient View, 2015a:v). The overall goal of the initiative is to help patients choose credible health apps and improve the quality of health apps (Patient View, 2015a).

The 2015 Directory divides reviewed apps into three broad categories: "disability"; "health, wellness and care in the community"; and "medical apps". Medical apps are defined as those associated with "clinical decision-making, diagnosis or treatment (Patient View, 2015a:xxxvii). The 2015 Directory covers the first two categories; a Directory of medical health apps is forthcoming (Patient View, 2015a). The information on each app is similar to that provided in the 2012 edition; however, the second edition includes information on the app developer and funder/commissioner. Involvement of medical advisors (either in the development or review of the app) and approvals the app may have been granted are also noted.

Both initiatives were supported by the European Commission Directorate General for Communications Networks, Content and Technology which recognized the benefits of health apps and need for an index of credible apps (Patient View, 2012, 2015a). In both directories, information is synthesized into a 1-page, user-friendly format.

5.1.3. Veterans Affairs Apps Compliance Review

In 2012, the U.S Department of Veterans Affairs implemented a comprehensive process to develop and approve health apps (U.S. Department of Veterans Affairs, n.d.[a]). The initiative is part of a wider strategy within the department to "improve the

health of Veterans by providing technologies that expand clinical care beyond the traditional office visit" (U.S. Department of Veterans Affairs, n.d.[a]). Health apps must undergo a rigorous validation and certification process in order to be listed as a VA approved app and use the VA logo. This process includes verification and validation against VA developed standards and a review of the software's coding. Apps that "handle clinical evidence" are also subject to an independent clinical review, which is arranged by the Mobile App Governance Board (U.S. Department of Veterans Affairs, n.d.[b]).

A "VA App Store" provides information and links to the thirty health apps that have been approved since the program launch in 2012. Approved apps include those focused on patient administrative functions (e.g. appointment requests), health (e.g. "Concussion Coach", "Stay Quit Coach") and mental health (e.g. "Mindfulness Coach", "Post-Traumatic Stress Disorder Coach"). Information on each app includes a description of the app's features, availability and important considerations for users.

5.2. Section Summary and Discussion

In Canada, Europe and the United States various forms of reviewing or approving health apps are underway. The strategies reviewed were all partially or fully funded by government, and are motivated by a recognized need to facilitate the identification and use of high quality apps and even stimulate the development of safe, credible health apps. Differences exist in the number of apps reviewed or certified and the rigour of the evaluation.

Chapter 6. Policy Options

The purpose of the next three chapters is to consider policy options that will help achieve the objectives outlined below in Section 6.1. In this initial chapter, I outline the options I consider and offer a brief justification for their inclusion as policy options.

6.1. Policy Objective

There is a lack of high quality, credible and safe health apps that can be synergistically used between patients and physicians. Further, patients and physicians are challenged to identify appropriate and effective health apps given the sheer number on the market for most health categories. These factors appear to be impeding use of this form of m-health between physicians and patients. How can government stimulate wider adoption of safe, high quality health apps so the potential of this technology is realized? In the sections that follow I outline three policy options.

6.2. Develop a Directory of Health Apps

The approach I envision for this option is adapted from review processes discussed in *Section 5.1.1 – Health-e-Apps* and *5.1.2 – European Directories of Health Apps*. In our context, the BC government would serve in a coordinating role to develop a directory of health apps reviewed by experts. The BC Ministry of Health would first establish a cross-discipline steering committee (i.e. patient advocacy groups, technology experts, researchers, and physicians) to develop a framework and criteria to guide the review process. Much literature exists that could be drawn upon in establishing a standardized framework and common criteria. For example, Singh et al. (2016) developed a framework for assessing mobile health apps according to quality (e.g. conformance to clinical guidelines, patient ratings, usability), safety (e.g. privacy

protections, how the app handles critical health information, such as low blood sugar) and the degree of patient engagement they enable.

Once a review framework and criteria are established, the Ministry would strike an expert panel of patient advocacy representatives and physicians with expertise in the main health specializations that are expected to be included in the directory. These experts would then review apps relevant to their area of specialization according to the framework and advise on a short list of apps to be included in the directory.

The information would then be compiled by a coordinator (Ministry of Health staff) and published thereby giving physicians and patients a repository of credible health apps. The directory would be updated approximately every 2 years depending on government resources and according to need (i.e. update the directory to include new apps that merit inclusion in the directory and exclude those that are no longer available).

The published directory will include a listing of experts involved (and their affiliations) along with the full process used to develop the directory. It is expected that each reviewed app would include the following information (adapted from Kamel Boulos et al., 2014 and Patient View, 2015):

- Name of the app and its availability
- A screen shot of the app
- Purpose and its functions/features
- Cost
- App developer and/or funder, including involvement of medical experts or a credible association
- Approvals or endorsements the app may have received
- Commentary on any privacy protections noted by the developer
- Reviewer comments with emphasis on quality of the information and usability relative to the intended users

According to Buijink et al. (2013) government has a role to play in the development of health app guidelines, and collaboration across stakeholders is likely to improve acceptance of the guidelines. With these types of review processes, there is an

acknowledged need to focus on a manageable number of the most popular and clinically useful apps in any one category (Singh et al., 2016).

6.3. Establish a Process for Certifying Health Apps

This option is modelled after the Veterans Affairs health app certification and approval process described in section 5.1.3. As such, it would involve the development of national industry standards and the establishment of a national certification process for health apps involving verification of the tool's privacy and security functions and conformance to standards in addition to an independent clinical review of the app's health information and functions. I suggest this policy be national in scope as the existence of multiple standards is generally not desirable for m-health vendors, health care professionals or end users (Infoway, 2014).

Voluntary certification is thought to be an appropriate approach for m-health solutions that do not meet the threshold of a regulated medical device (and therefore do not fall under federal licensing rules) but that still benefit from a formal assessment process (Infoway, 2014). This approach would also be consistent with US policy. The FDA's risk-informed regulatory framework is focused on clinical safety (i.e. the health hazard posed should the medical app or device fail to function as intended) and various approaches to curation and/or certification reside with industry (Powell et al., 2014).

Canada Health Infoway, which currently performs certification services for large-scale e-health solutions (verifying the solution's conformance to national and international privacy, safety and interoperability standards), is an example of a Canadian entity that could potentially take the lead in standards development and accreditation of health apps.

Health apps that meet all program standards would be granted certification and able to use a program logo on the app (which could link users to the program's website for information on the standards and certification process) (Kamel Boulos, 2014). Conflict of interest concerns (commonly raised in programs where the certification body is paid by the entities it certifies) can be mitigated by having an independent body

perform audits of the certification program to ensure the certification services are carried out according to its standards and operations manual.

The certification renewal schedule would depend on updates to program standards and the certified apps. On an annual basis, developers with certified apps would complete specific program forms intended to determine if the app has been changed or updated since its last certification. Apps that have not been updated need not renew their certification (unless that program standards had undergone revision). Apps that are updated would undergo a recertification corresponding to the nature of the update(s), i.e. it would undergo the independent clinical review if the update involved changes to clinical information or functions. The app would undergo a validation of the app's privacy and security functions if the update involved changes to how the app handles privacy and security of personal health information.

6.4. Regulatory Licensing of Health Apps

Option three represents a status quo option whereby software meeting the legislative definition of a medical device would be approved and licensed by Health Canada according to the federal *Food and Drugs Act Medical Devices Regulations*. As outlined in *Section 2.3.1 – Federal Legislation*, a risk-informed approach is taken in the regulations and medical devices are classified into one of four categories with class 1 defined as the lowest risk and class IV the highest risk.

Software is regulated as a medical device if it: "(1) provides the only means and opportunity to capture or acquire data from a medical device for aiding directly in the diagnosis or treatment of a patient; or (2) replaces a diagnosis or treatment decision made by a physician" (Health Canada, 2011:1).

Software used by a patient in any location external from health care settings would be a Class I medical device if it is used to view images or store and transmit data; software that is intended for analyzing device-provided data for the purpose of directly aiding in treatment or diagnosis would be Class II (Health Canada, 2011).

Class II, III and IV devices are subject to a licensing system and must meet applicable regulatory requirements which include safety and efficacy testing, reporting of adverse events and labelling rules (Squire, n.d.). Class I devices are exempt from licensing requirements; however, the manufacturer must ensure that the requirements outlined in the regulations are met (Health Canada, 2011). Table 4 highlights other differences between classes II-IV.

Table 4: Summary of the Main Differences in the Regulatory Requirements of Class II-IV Medical Devices

Selected Class II regulatory requirements	Selected Class III regulatory requirements	Selected Class IV regulatory requirements
(2)(a) a description of the medical conditions, purposes and uses for the device	(3)(b) a description of the features of the device that permit it to be used for the medical conditions, purposes and uses for the device	(4)(b) a description of the features of the device that permit it to be used for the medical conditions, purposes and uses for the device
(2)(b) a list of the standards complied to satisfy the safety and effectiveness requirements	(3)(d) a list of the standards complied with to satisfy the safety and effectiveness requirements	(4)(h) a list of the standards complied with to satisfy the safety and effectiveness requirements
(2)(c) an attestation by a senior official of the manufacturer that it has objective evidence to establish that the device meets the safety and effectiveness requirements	--	--
(2)(f) a copy of the quality management system certificate certifying that the quality management system satisfies required standards	(3) (j) a copy of the quality management system certificate certifying that the quality management system satisfies required standards	--
--	(3)(c) list of countries where the device has been sold, number of units sold, and a summary of reported problems and recalls	(4)(c) list of countries where the device has been sold, number of units sold, and a summary of reported problems and recalls
--	(3)(d) list of the standards complied with in the design and manufacture of the device to satisfy the safety and effectiveness requirements	(4)(h) list of the standards complied with in the design and manufacture of the device to satisfy the safety and effectiveness requirements
--	(3)(i) bibliography of all published reports dealing with the use, safety and effectiveness of the device	(4)(n) bibliography of all published reports dealing with the use, safety and effectiveness of the device
--	--	(4)(d) risk assessment comprising an analysis and evaluation of the risks and risk reduction measures to satisfy the safety and effectiveness requirements
--	(3)(f) a summary of all studies relied upon to ensure safety and effectiveness requirements met, and the conclusions drawn from those studies	(4)(i) detailed information on all studies relied upon to ensure safety and effectiveness requirements met, including (i) pre-clinical and clinical studies, (ii) process validation studies, (iii) if appropriate, software validation studies, and (iv) literature studies
--	--	(4)(l) a summary of the studies referred to in paragraph (i) and the conclusions

Excerpts from the Medical Devices Regulations (SOR/98-282) [last reviewed 2015-07-16].

Chapter 7. Criteria and Measures

In this chapter, I outline the criteria used to assess the policy options outlined in Chapter 6. The criteria present a consistent framework to assess the options and are intended to uncover trade-offs to inform the policy recommendations outlined in Chapter 8. The criteria, which are justified below, include effectiveness, implementation ease and equity. The criteria, and associated measures, are also listed in Table 6.

Table 5 Summary of Criteria and Measures

Criterion	Measure	Score	Interpretation
Effectiveness	To what extent does the policy lead to apps that achieve the following outcomes: - Secure (as to privacy) - Clinically safe - Clinically effective 0 point = does not achieve the outcome 1 point = achieves the outcome through subjective review 2 points = achieves the outcome through formal validation to a defined standard 3 points = achieves the outcome through experimental evidence	1-3 points 4-5 points 6-8 points	Low Medium High
Implementation ease	Does the policy require collaboration with multiple groups?	>10 groups 5-10 groups <5 groups	Low Medium High
	Does the policy require advanced analysis?	Yes No	Low High
Equity	Is the burden of costs shared equitably?	No Yes	Low High

For effectiveness, I consider the extent to which the policy leads to the development and adoption of apps that are secure (as to privacy), clinically safe and

clinically effective. These outcome measures were chosen given the research, outlined in *Section 2 – Background*, which suggest that the lack of safe, high quality health apps is a barrier to the use of these tools in practical settings.

I include privacy as a component of stakeholder acceptance as the critical discourse analysis of current policy revealed that health information is considered to be highly sensitive. Further, current laws, professional regulations and medical association policy place significant responsibility on physicians to maintain the privacy and security of health information. Survey data and other research, highlighted in Section 2, suggest that consumers also have concerns about privacy and security of health information stored or transmitted through various forms of m-health. Unless addressed, these concerns act as a barrier to wider adoption of m-health solutions.

An app's clinical safety or effectiveness can be assessed either by validating the content and functions of the apps against recognized standards (e.g. clinical guidelines) or based on formal research trials.

For implementation ease, I consider the number of groups that would need to collaborate and whether advanced analysis is required to implement the policy. Change management was a strong theme identified in Ministry of Health policies and strategic plans. The complexity of the health system and range of groups involved exist as barriers to successful adoption of innovations (Ministry of Health, 2014a). Therefore, new policies need to be carefully considered in this context.

I discuss equity in the context of whether the burden of costs is shared equitably (i.e. costs are concentrated to a few groups or more equitably dispersed). Where possible, estimations of actual costs of the policies are also considered.

Chapter 8. Policy Analysis

This chapter presents the results of the assessment of policies based on the criteria and measures outlined in the preceding chapter. Table 7 provides an overview of the results.

Table 6 Summary of Policy Analysis

Criteria	Directory of reviewed health apps	Certification program for health apps	Regulatory licensing of health apps
Effectiveness	Low (3/8 points – 1 for data security, 1 for clinically safe; 1 for clinically effective)	High (6/8 points – 2 for data security; 2 for clinically safe; 2 for clinically effective)	High (6/8 points – 0 for data security; 3 for clinically safe; 3 for clinically effective)
Implementation ease	1 Low (coordination of >10 groups), 1 High (does not require advanced analysis)	2 Low (coordination of >10 groups and requires advanced analysis)	1 High (coordination of < 5 groups); 1 Low (requires advanced analysis)
Equity	High (burden of costs is dispersed equitably)	Low (burden of costs is concentrated)	Low (burden of costs is concentrated)

8.1. Directory of Reviewed Health Apps

Effectiveness

In terms of effectiveness, this option is assessed a low score. The clinical safety and effectiveness review would be done by professionals with expertise in the specialization of app under review, and while credible, this is less rigorous than what can be accomplished through a formal certification or regulatory approval process. Further, only a modest level assessment for security is achieved (e.g. the app developer's privacy policy and any self-declarations are reviewed but not validated), and this is a significant deficiency given the security risks associated with personalized mobile technologies and the sensitivity of personal health information. Indeed, in 2013 the UK

National Health Service (NHS) launched an accreditation process for health apps as part of the agency's attempt to establish an online library of accredited apps (Huckvale et al., 2015). However, an independent evaluation, over a 6-month period, of the 79 health apps approved by the NHS found serious privacy and security non-compliances on a majority of approved apps calling into question the agency's approach to this component, which relied principally on vendor self-declarations (Huckvale et al., 2015). The authors concluded that, at a minimum, limitations of any review process should be clear to users and proper terminology used that accurately reflects the rigour of the process.

However, the directory would serve as a user-friendly guide of apps reviewed according to a credible framework and by organizations that are reputable in the eyes of physicians and patients. Given the number of health apps and lack of curation or accreditation process, physicians are challenged to guide inquiring patients (Cortez et al., 2014; Powell et al., 2014) and, anecdotally, report that they are either not able to assist the patient or are forced to undertake their own review of health apps. The directory offers efficiency improvements by bringing a degree of coordination to a process that is currently happening at the level of individual patients, physicians, clinics, hospitals and health associations.

Overall, the existence of a health app directory (developed with involvement of credible experts) would encourage the development of higher quality apps to at least some extent. The directory would also offer some clarity to app developers on the characteristics of health apps that are important to patients and the medical community. App developers would likely respond to this over time drawn to the prospect of their app being featured in the directory which would bring a degree of credibility to those apps.

Implementation Ease

From an implementation standpoint, this option involves coordination of a large number of different groups, and it therefore performs poorly on this aspect of implementation ease. In order to assess the number of organizations involved, I

consulted resources available on the European directories this option is adapted from. Early consultations on this initiative involved representatives from seven stakeholder groups: patient advocacy, healthcare professionals, app developers, policy, regulatory, mobile technology and academia (Patient View, 2015b). This listing is consistent with the stakeholders that should be involved in the development of health app guidelines proposed by Buijink et al. (2013). In terms of development of a framework that is credible and that is likely to be supported by stakeholders, representatives from these groups should be involved suggesting that for the preliminary stage of this option (i.e. the development of the review framework and criteria) at least seven groups would be involved.

To assess the number of groups to coordinate for the app review process, I consulted the *European Directory of Health Apps 2012-2013* and *The Myhealthapps Directory 2015-2016* and counted the number of health categories (e.g. diabetes, mental health) included in each directory. Based on this review, the development of the catalogue would involve coordination of at least an additional 16 associations (possible specializations are outlined in Table 8).

As for the second measure of implementation, sophistication of the analysis, this option is assessed a high score. As previously described, it is anticipated that the development of the framework and criteria can be informed by existing approaches in peer review literature thereby facilitating the development of an agreed-upon framework and criteria. The actual review of the selected apps will not involve highly technical analysis. As with the European directories, reviewers will primarily be reviewing information about the apps (e.g. involvement of medical experts, privacy declarations, the funder or commissioner and any approvals granted).

Table 7 Categories of health apps for the health apps directory

• Cancer • Informal caregivers • Heart, circulation and blood • Mental health • Nervous system and brain • Stomach, bowel and continence • Medications (e.g. reminders) • HIV/AIDS	• General wellness • Nutrition • Bones and muscles • Breathing and lungs • Diabetes • Kidney disease • Other chronic conditions • Dermatology

Based on The myhealthapps directory 2015-2016. Patient View. (2015). London, UK.

Equity

The catalogue option also performs well relative to equity in that the resources needed are dispersed across a number of interested groups which will all share the costs but also the benefits. Government funds would be needed to coordinate the project but experts reviewing selected apps would provide in-kind contributions.

8.2. Certification Program for Health Apps

Effectiveness

A formal certification process of health apps (involving third-party verification of privacy protections, clinically-relevant information, and software scans) provides a high degree of assurance relative to data security and clinical safety and effectiveness. Therefore, this option performs well for the effectiveness criteria.

This policy option would stimulate the development and adoption of higher quality apps by creating a rigorous assessment process that offers strong assurances to physicians and patients and also creates a marketing advantage for certified apps enabling their apps to be purchased more often and/or purchased at a higher price compared to uncertified health apps.

Implementation Ease

In order to assess the number of groups that would have to collaborate in the development of this policy, I consulted the Veterans Health Affairs website (U.S.

Department of Veterans Affairs (n.d.[b]) which details the departments involved in the VA's App Compliance Review. My review suggests that at least eleven VA departments are directly involved in the compliance process: verification and validation of software (5 departments); clinical review and patient safety (2 departments); data terminology (1 department); data security and privacy (2 departments); and branding (1 department).

However, because of the need for common set of national standards that complement or are consistent with international standards, collaboration with groups outside the certification body would also be necessary, including Health Canada (as the regulator of licensed medical devices) and international standards bodies (e.g. Continua Health Alliance and/or ISO Medical Device Standard) (Infoway, 2014). Given the number of groups that would need to collaborate (estimated to be at least 14), this option is given a low rating for this aspect of implementation ease.

This option also receives a low rating for the degree of sophistication involved in the analysis. The type of analysis involved in formal verification of software is highly technical (Mark Nenadovic, personal communication, April 1, 2016). The process is resource-intensive, involves a series of steps including analyzing the software coding which is a multi-day process and that also requires significant work in advance of the analysis (Mark Nenadovic, personal communication, April 1, 2016).

Equity

In terms of equity, this option also performs poorly given that the costs would be concentrated into fewer than five groups (i.e. the certification body, the app developer and government assuming some public funds would be provided towards standards development).

In the context of health apps, "there is definitely a role for certification but it has to be a different model than the one currently used for large-scale solutions where certification costs range from $20,000 – $100,000 (Mark Nenadovic, personal communication, April 1, 2016). *Happique,* a US health app certification service launched in 2013, with a certification fee of $3000 saw only modest interest in its certification services by industry (HIS Talk, 2014). *Happique* suspended its services shortly after its

launch, and the certification fee was thought to be among the potential causes; however, the certification body was also found to have failed to properly evaluate the security of its approved apps which significantly impacted its credibility (HIS Talk, 2014). The challenge with the certification of health apps is to find an approach that fits the low-cost model health app developers are operating in (Singh, 2015; Mark Nenadovic, personal communication, April 1, 2016).

8.3. Regulatory Licensing of Health Apps

Effectiveness

The regulatory option offers a high degree of assurance as to clinical safety and effectiveness given the requirements for effectiveness studies and post-market monitoring. In terms of clinical safety, a feature unique to this option are the mandatory reporting and recall rules should adverse events occur post-marketing. Recalls of regulated health apps have occurred in the US – for example, in 2012, a diabetes app developed by Sanofi Aventis was recalled when it was found that it was miscalculating insulin doses thereby putting diabetics at risk of serious health consequences (Cortez et al., 2014). Monitoring and recalling mechanisms for high risk apps is likely a model that would be supported by physicians.

However, the regulatory approach does not include any evaluation of the app's privacy and security features.

While regulatory approval may facilitate the use of high risk apps, the regulatory framework is very burdensome relative to the business model apps are currently developed under and may not stimulate the development of high quality apps. Unlike traditional medical device developers, app developers are not accustomed to regulation and have expressed concern that a burdensome regulatory environment will hinder innovation (Cortez et al., 2014).

Implementation Ease

From an implementation standpoint, this option involves coordination of only a few different groups, and it therefore performs well on this aspect of implementation ease. The approval, licensing and monitoring process involves coordination between the applicant and Health Canada (specifically, the Medical Devices Bureau of the Therapeutic Products Directorate – the governmental department responsible for regulating medical devices in Canada).

As for the second measure of implementation, sophistication of the analysis, this option is assessed a low score. Regulatory approval involves sophisticated scientific analysis, particularly for studies evaluating effectiveness. There are currently very few studies evaluating the safety and effectiveness of health apps in part due to the "significant resources " required to undertake such studies relative to the business model health apps are developed in (Kamel Boulos, 2014).

Equity

In terms of equity, this option performs poorly given that the costs would be highly concentrated among two groups (i.e. the app developer and the regulator).

8.4. Policy Recommendation

Based on the analysis of policies, I recommend in the near term the development of a directory of health apps reviewed according to an agreed-upon framework and criteria. There are examples of professional bodies, government and research groups reviewing apps; however, with the exception of the European directory approaches tend to be informal and modest in scope. The directory that I have proposed would establish a coherent strategy and address some of the issues identified with health apps. Compared to the other policy options, this option better suits the low-cost business model of current apps.

Longer term, a more rigorous process of validating the security and clinical safety of health apps through a certification and labelling program will encourage the

development and adoption of safe, high quality health apps, and provides better assurances to physicians and patients compared to a directory of reviewed apps. Regulatory approval and licensing is also appropriate for the highest hazard health apps.

How this landscape may gradually evolve is that all three policy options I've discussed would be implemented and complement each other. A health app directory would include apps that perform basic but still useful functions (e.g. apps that teach relaxation breathing techniques); a certification scheme would provide assurances for health apps that do not meet the threshold of a medical device but that still benefit from formal assessment. Regulatory oversight would be reserved only for the highest risk health apps (e.g. an app that allows a mobile digital device to perform electrocardiography). Overtime, with these policies in place, we may see a gradual shift away from our current state characterized by a very high number of apps most of which are low cost and low usefulness to a state where a fewer number of apps are available but most tend to be higher quality and higher price.

However, government funding is likely needed to stimulate the development of high quality apps that would meet certification or regulatory requirements. Credible concerns are raised in the literature on the viability of certification and licensing of mobile apps. Certification models in both Europe and the US were suspended shortly after implementation and it seems more work is needed to identify viable approaches. According to Nenadovic (2015) until workable models of certification can be established, peer review and recommendations from professional associations will continue to play a role in the use of trusted apps. Relative to the current business model apps are developed under, the costs and other burdens of certification and regulatory approaches may limit the number of app developers able to pursue these options.

Chapter 9. Other Recommendations

This study revealed a lack of guidance, directed to patients/consumers, on protecting personal health information stored or transmitted using mobile health technologies. I therefore recommend that the BC Ministry of Health convene discussions with provincial health stakeholders on the need for consumer resources on the privacy and security of personal health data stored or transmitted using health apps and mobile digital devices. My research revealed that much guidance and rules exist on physician responsibilities to protect patient health information; however, there is a scarcity of guidance targeted to health consumers. Surveys suggest consumers are not taking even basic steps to protect health information stored on personal mobile devices. A 2013 Consumer Report showed that only 36 percent use a screen lock with a greater than four digit password; only 31 percent back up their data; and only seven percent had installed remote erasure software (so that personal information could be remotely deleted from a lost or stolen smartphone or tablet).

The discussions should focus on potential privacy risks and simple strategies consumers can adopt to protect their information. Stakeholders should also outline a strategy for broad dissemination and clearly identify whose role it is develop and update patient resources. Beyond the Ministry of Health, stakeholders to involve in these discussions include health researchers, technology experts, physicians and patient advocacy groups.

As well, in the very long term – when health apps are certified or a greater number are licensed – there will likely be a need to consider physician compensation to support synergistic use of mobile health between physicians and patients (more specifically, to compensate physicians for reviewing patient data supplied through mobile apps).

BC's current billing codes (Medical Services Commission, 2016:7-30) include a "GP telephone/email management fee" of $15.00 "payable only to the family physician who commits to providing the majority of the patient's longitudinal comprehensive practice care…" This policy was introduced to encourage continuity of care between in-person visits for patients covered by specific billing codes also outlined in the payment schedule (e.g. complex care planning fee, mental health planning fee, annual chronic care bonus for COPD), and can be used up to five times a year per patient (Medical Services Commission, 2016:7-30). This billing code could be amended to also include remote analysis of patient data, transmitted via mobile health app, such that a physician could bill for five non-face-to-face encounters per applicable patient (for *either* telephone, email or analysis of data transmitted via health app). Physicians who review health app data as part of an office visit would not bill the medical services plan an additional fee (their review of health data in that case would fall under the office visit fee code). This represents a fairly straightforward future amendment to an existing billing code. Once there is a greater supply of certified or Health Canada approved apps, the amendment may well allow for a more effective intervention complementing in-person visits compared to e-mail and telephone.

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