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FIVE POLICY RECOMMENDATIONS FOR THE CANADIAN FEDERAL GOVERNMENT TO ACCELERATE THE GROWTH AND IMPACT OF DIGITAL HEALTH

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SUMMARY

The COVID-19 pandemic offered Canadians a glimpse of the digital health-care system we could have here if we are willing to clear away the traditional roadblocks that stand in the way. However, as the pandemic slowly recedes, the opportunity to keep moving forward, with a health-care system that fully embraces digital, will likely require the federal government asserting itself as a leader in a policy area that falls within provincial jurisdiction, despite the controversy and contention that federal intervention would arouse.

The pandemic's urgent demands on the health system forced jurisdictions to clear many barriers that have impeded digital-health innovation until now. Within weeks of the onset of the pandemic, virtual care exploded to previously unimaginable levels, with health-related telephone and video calls rapidly rising from less than two per cent of all ambulatory visits at the beginning of 2020, to as high as 70 per cent by mid-May the same year. The bureaucracy around procurement, privacy and security was reduced, while digital-health innovators were given the opportunity to take a larger role in the health system.

Digital health care is much more than just a doctor making a Zoom call, however. Seizing the momentum to realize broader change will require a national approach. This should include several policies, many requiring federal

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leadership, such as enshrining digital care within the definition of “medically necessary” care, insured under the Canada Health Act.

Digital health also includes giving patients ownership of their personal health data, while ensuring data interoperability across Canada. The current, fragmented, provincial approach to health care is a drag on innovation, creating barriers to the efficient procurement of technologies, interoperability and data sharing. Our heavily siloed system disadvantages not only the health-care system and patients, but Canadian digital-health companies who, because they are unable to scale up in Canada, will find it hard to compete in the growing global digital-health industry.

The federal government can show leadership by innovating with digital health policy for those citizens that fall under its health-care purview, such as Indigenous Canadians and members of the Canadian Armed Forces. Ensuring that Canadians everywhere realize the benefits of digital health care, however, will require Ottawa taking a more active role in breaking down barriers between provinces and territories, making it clear that our slow-to-innovate health-care silos are no longer sustainable in a digital world.

GENERAL INTRODUCTION

In 2017, the federal government took a new approach to that taken in the early 2000s to move forward on health system priorities. The government worked with the provinces and territories (PTs) to identify shared health priorities for federal investments, develop common areas of action within these priorities through an FPT framework, and then negotiated bilateral agreements with each PT. COVID-19 has highlighted the need for resilient health care systems that will continue meet the needs of Canadians today and in the future.

It is in this context that in April 2021, the School of Public Policy convened a group of health policy experts to develop research papers on various aspects of the evolution of health care in consultation with Health Canada. These experts have a diverse range of perspectives on issues related to Canadian health systems. Health Canada was consulted on the list of topics, but the orientation of each paper, the methodology, as well as the substance of the recommendations were left entirely to the discretion of the authors.

We are proud to share the result of this process. Each paper in this series of eight was subject to the intense scrutiny, and discussed extensively following detailed roundtable presentations. Two eminent health policy experts were also asked to conduct a careful double-blind review of the papers, with a special focus on rigor, readability, and relevance. We believe these policy briefs offer a rare combination of original thinking, deep subject expertise, and technical feasibility: a perfect balance between the very practical needs of the end users of the research and the independent and innovative spirit that pervades all the work originating from the School of Public Policy.

INTRODUCTION

This paper provides a series of recommendations for the government of Canada's role in sustaining and advancing digital health in Canada.

Digital health is an increasingly essential component of a high-performing health-care system. There are important distinctions between digital health and virtual care in Canada. Canada Health Infoway (Infoway) describes digital health as "the use of information technology/electronic communication tools, services and processes to deliver health-care services or to facilitate better health" (Canada Health Infoway 2021c). Virtual care is "any interaction between patients and/or members of their circle of care, occurring remotely, using any forms of communication or information technologies." Virtual care is a subset of digital health that includes provision of care over many media, including video, audio, and asynchronous messaging (Jamieson et al. 2015).

This paper details five digital-health policy positions:

1. <u>Patient data access is essential</u>: Patients should own their own data. They must be given access to their data upon request in a computable format, without charge or delay.
2. <u>Data movement and data sharing is imperative</u>: Digital data sharing is both a key component of digital health and a crucial enabler of digital health, but it is currently poorly supported. Canada must develop a uniform data-interoperability strategy aligned with international standards.
3. <u>Digital health is care</u>: The provision of digital health is now embedded in our health-care delivery. Canada must formalize the inclusion of digital health as an essential element of our public health system.
4. <u>Digital health must be inclusive</u>: All Canadians are entitled to an equal opportunity to participate in digital health.
5. <u>A federal approach is critical</u>: We need a national, collaborative approach to solve the innovation drag caused by our approaches to evaluation, procurement, and privacy and security. Our current siloed approach disadvantages the Canadian health-care system, the Canadian population, and Canadian industry.

Digital data is perhaps the most crucial aspect of digital health. The ability to share and use patient data in care delivery and health promotion is of paramount importance. Increasingly, digital health has become more focused on the individual: patients use wearable devices to keep personal records of their health data; they use mobile apps to be active participants in their day-to-day care; and they leverage advanced modes of communication, such as video and secure text, to communicate with their care teams. More and more these workflows are supported by tools that are acquired directly by the patient in a highly dynamic and fast-paced consumer marketplace. Patients increasingly expect to use their own smartphones and tablets, augmented with self-management and tracking apps, which are linked to devices such as scales, glucometers, Fitbits, and exercise equipment, to manually and automatically record symptoms and physiological parameters such as pain scores, mood, step counts, or blood-pressure data. On the horizon are home networks, including tools such as chat bots that facilitate medication reordering from pharmacies, cameras that can detect falls, and bathroom mirrors with heads-up displays (Fingas 2019; Miotto et al. 2018; Shu and Shu 2021). The commercialization of health that results from this individual focus has greatly expanded the types and volumes of data that exist. With that data come new and exciting opportunities for innovation in the realms of new apps, machine-learning insights, or "internet of things" networks of tools.

The pandemic exposed many of the challenges that digital-health innovation has encountered for years. Our inability to seamlessly move data across silos was, yet again, a significant vulnerability. This initially impeded our ability to understand our inventory of personal protective equipment (PPE) and to rationally procure it. It prevented us from understanding the true rates of COVID-19 spread in our communities. We were unable to have testing results transparently available to patients, practitioners, and government agencies. There was no way to load-balance clinical-care components (such as surgical wait lists) across jurisdictions, to compensate for reduced capacities. Most recently, we have had to understand who has been vaccinated where and with which vaccine to facilitate a return to normal. We saw a significant exacerbation of pre-existing issues in Indigenous and racialized communities in their ability to access health care, even with the rise in virtual care, further exposing the so-called digital divide. A rise in cybersecurity incidents through the pandemic also emphasized that a "low-rules" environment that promotes data sharing cannot lead to a "no-rules" environment that threatens patient data security. Key assurances regarding the security of patient data and the digital tools that leverage them remain an ongoing requirement for our system.

Canada's inertia in the realm of health-care innovation is well documented (Naylor et al. 2017; Goel 2021). Many of the root causes will be referenced here, including unco-ordinated approaches to vision, procurement and implementation, and the failures to spread and scale. The COVID-19 pandemic allowed us to see a glimmer of a system that could occur without our traditional hindrances. The demands on the health system wrought by the pandemic forced jurisdictions to clear many roadblocks that had impeded digital innovation. Within weeks of the onset of the pandemic in early 2020, virtual care, through the use of telephone and video visits, exploded to previously unimaginable levels, rapidly rising from less than two per cent of all ambulatory visits around the start of 2020 to as high as 70 per cent by mid-May that same year (Bhatia et al. 2021).

With this rise came opportunity for innovation. Several Canadian vendors, institutions, and provinces leveraged a rather "low-rules" environment. Reduced bureaucracy around procurement and privacy and security, combined with billing codes to support payment for virtual care, allowed digital-health vendors to increase their footprints significantly and rapidly. The pandemic has been a coming-of-age event for our digital-health industry, replete with IPOs, new business models, acquisitions, and unimagined growth. The combined market capitalization of the Canadian digital-care and virtual-care industries is now estimated to be in the range of $15 billion to $20 billion (Falk 2021).

A NATIONAL APPROACH TO PROBLEM SOLVING

The federal government has an important role to play in promoting both equitable access to and a thriving marketplace for digital-health innovation. We acknowledge the considerable work that has already occurred or is underway, such as:

- Foundational support from the federally funded Canada Health Infoway on the development of interoperability standards and frameworks (Canada Health Infoway 2021a);
- Funding by Infoway of key strategic projects (Canada Health Infoway 2021b);
- The creation of the nascent CAN Health network that provides innovators with access to all important clinical spaces (CAN Health 2021);
- The initiation of work around a pan-Canadian data strategy (Goel 2021); and
- The work of Health Canada to modernize its regulatory standards to meet the needs of a new era of digital tools and algorithms (Health Canada 2018).

It is important to acknowledge, however, that on the last point, the work of Health Canada will apply predominantly to higher-risk medical technologies, such as Wi-Fi-connected implanted defibrillators, or algorithms providing autonomous guidance. Most digital-health tools will not fall within the purview of this important regulatory update, including applications that provide decision-support guidance to clinicians, or wearable devices that capture physiological information for tracking purposes only (Jogova, Shaw, and Jamieson 2019). Our recommendations apply largely to these more numerous and less regulated kinds of tools.

In this paper, we provide guidance on how the federal government can play a critical role in the system changes needed to support digital health. Our first three recommendations are direct. Our final two are, admittedly, less so. These two are challenges for which considerable work needs to be done, and we suggest possible avenues to a successful outcome. These final two are no less urgent, however, and a deliberate and timely process to address these problems must be commenced soon and with vigour. Across all five, we suggest tangible next steps that leverage data to improve care, promote access for those who need it most, and help Canada become a world leader in digital-health innovation that directly benefits Canadian residents and grows our digital-health industry.

RECOMMENDATION 1: ENSURE PATIENTS HAVE ACCESS TO A COMPUTABLE COPY OF THEIR DIGITAL DATA WITHOUT CHARGE OR DELAY BY 2023.

Central to any patient-centred health system is the ability for patients and their designated caregivers to access, learn from, and make use of their personal health information (PHI) as full partners in their care. More than 10 years ago, social-media savvy "ePatients" elevated this ask into a movement (HIT Consultant 2014). They poignantly articulated the flaws of a system built around access restrictions and administrative delays, with arbitrary administrative fees. These cumbersome processes ultimately led to the acquisition of less than useful data, often contained in a non-machine-interpretable folder of PDFs or view-only portals, and consisting mostly of "coding" information, such as insurance diagnostic codes. Over the last decade, we have seen the rise of the "open notes" movement and a further push by patient advisory groups, such as the Canadian Patient Advisors Network, for patients to have greater access to and control over what is widely understood to be a patient's proprietary health information (Maybee and Chandani 2019). Clinical concerns, for example the worry that a patient's anxiety will rise should a diagnosis (like cancer) be discovered in advance of a physician's visit, have not borne out in practice. In contrast, this information allows patients to feel more in control of their care and to feel more engaged with the plan of care. This access has also demonstrated particular benefits for the traditionally underserved, including non-English speakers (Walker et al. 2019). In fact, preventing this access has been described by some as fundamentally unethical (Blease et al. 2021). The recently released data strategy of the National Health Service in the U.K. includes a commitment to enable everyone in Britain to have access to their personal health-care data by 2022 (Department of Health and Social Care 2021).

Recently, the U.S. has taken a lead in promoting patients' access to their own data through a series of legislative updates in the 21st Century Cures Act, which became law in 2016. The Final Rule came into effect in 2020, which requires industry to support application programming interface (API) functionality by 2022 (Mandl and Kohane 2020; Department of Health and Human Services and Office of the Secretary 2020; Majumder et al. 2017). Under this act, all certified health information technology must be able to provide patients a copy of their "Electronic Health Data" in a *digital and computable* format. This ensures that third-party tools can read the exported data. This is fundamentally different from the idea of a national consolidated single personal health record. Rather, it speaks to how patients can access their own data and consolidate it using third-party tools as they require and desire.

Historically, if patients wished to aggregate, track, search, reorganize, or share their health information, it would have to be done either on paper or through a painstaking, item-by-item manual upload into various digital charting systems (e.g., the Google Personal Health Record). These tools, owing to the effort involved, saw limited success. For many patients who lack the time, knowledge, digital literacy, or access to infrastructure, completing such a task is all but impossible. However, we now see the rise of a new model: well over 500 organizations across the U.S. facilitate live, real-time export of patient information to third-party tools such as Apple's Health Records tool (Apple Inc. 2021), eliminating these manual processes. With the 21st Century Cures Act, access to personal health data will certainly grow, to the benefit of patient empowerment. It will also benefit third-party innovators in the space. Meanwhile, similar Canadian innovators such as Dot Health (which seeks to allow Canadians to receive and share their personal health records via a mobile app) will continue to face restrictions that limit their growth at home. Patient-controlled third-party tools also have the benefit of including patient-generated data, such as from people's own personal wearable devices or observations, into a personal, portable, and comprehensive health record.

To accomplish similar usability of personal data, Canada must leverage this right of access alongside interoperability enabled by standardized APIs (see Recommendation 2).

Such government involvement is critical to achieving the aims of portability under the Canada Health Act (CHA) in the 21st century. There is a significant opportunity to support portability for two populations under the federal health-care purview: members of the Canadian Armed Forces and their families, and Indigenous communities. These groups, particularly those Indigenous communities whose ancestral nations straddle provincial boundaries, often move between the defined provincial boundaries to seek health care. A person who lives in an Indigenous community on the border of Manitoba and Ontario may need to seek emergency care in Winnipeg but could receive regular health-care services as an Ontario resident. Members of the military and their families frequently change postings and can receive care in New Brunswick one month, and then be off to Alberta the next. The burden for continuity of care for our military families is borne by the families. As they move from province to province, family members must not only keep track of their health information, but also their original health-card numbers in each province to reactivate if they return for a reposting. In both instances, the health-care system depends critically on patients' ability to be the hub for their PHI. Such individuals must be able to easily acquire a copy of their health information and carry it with them, in a digital format, and they should also be able to easily share that information with others — something we further address in Recommendation 2. This advanced digital portability has secondary quality and safety benefits for all patients who move or travel between provinces, whether for work or education, and whose PHI is crucial for the care assumed by new clinicians.

A key additional consideration is that the ownership of such data by the patient, by necessity, frees that data from many of the constraints that current health information custodians (HICs; e.g., hospitals) must follow. While this has the potential to expose patients to the risk of "bad actors" and cybersecurity breaches (Cohen and Mello 2019; Taralunga and Florea 2021), this cannot be turned into an insurmountable obstacle, and rules can be established to mitigate the risk. Data risks in the consumer space extend far beyond the boundaries of digital health, and indeed, the risks of data insecurity are likely higher in other non-health-care domains. We would not advocate for additional regulation of consumer health data alone, and, rather, would suggest that any desire to tighten the controls in the consumer space be done within a more expansive construct, like Europe's General Data Protection Regulation (GDPR). However, whether or not to pursue such changes is a much more expansive question that remains outside the scope of this discussion.

For health care specifically, it is critically important for consumers to be informed about what it means to remove their data from the regulated custodians in advance of a data transfer. As a measure of quality for such a data transfer from a HIC to a patient, there should be a requirement that such a transfer is done with full transparency of risk and informed consent of the patient or legal delegate (Halamka 2021). We must also avoid the issues of the lengthy and incomprehensible "terms of service." Sayeed and colleagues recently put forth a model to address these issues that leverages standards we further discuss in Recommendation 2. Specifically, they advocate for a model leveraging the SMART App Launch Framework on Fast Healthcare Interoperability Resources (FHIR) authorization routines, which essentially are the technical handshakes between apps requesting data from HICs, such as hospitals, and the HICs' digital systems. Under their model, the HIC-side system, as part of the authorization routine, would request basic and specific information from the app, including information about that app's data (storage, usage, sharing, and selling) and consent practices. The HIC would then display that information in an easy-to-consume format to the user in advance of the data transfer, allowing the user to review, and then either approve or deny the request (Sayeed et al. 2021).

There are multiple mechanisms to achieve the aim of giving patients the ability to access their PHI in a computable format without charge and without delay (Bari and O'Neill 2019; Bhatia and Falk 2018; Jaana 2021). The federal government can consider legislative changes to laws such as the Personal Information Protection and Electronic Documents Act (PIPEDA). PIPEDA could be amended to explicitly require organizations that are subject to the legislation to provide people digital access to their personal information, including their PHI, in a computable electronic format without undue cost or delay. This would be in line with similar rights under Europe's GDPR and the California Consumer Privacy Act, and it would extend beyond the public sector and beyond health (Van der Auwermeulen 2017). It would also apply to any organization or corporation subject to PIPEDA that collects personal information, such as phone apps, federal ministries, non-government organizations, and more. Important caveats to that approach would be health privacy legislation in Ontario, New Brunswick, Nova Scotia, and Newfoundland and Labrador, which has been deemed substantially similar to PIPEDA. These apply to health data in lieu of PIPEDA in these provinces. However, if those laws fail to keep pace with new major provisions of PIPEDA, that similarity may no longer hold. As well, there would be the potential for expansive effects beyond health care. With the increasing extension of health workflows into the consumer space through integrated HIC and consumer-acquired third-party tools, addressing data access rights beyond HICs is essential for health care (McGraw and Mandl 2021).

Alternatively, we could achieve the aim of patient data access through a process of accreditation or certification, as in the U.S., whereby certified tools must provide the ability to usefully export data as a condition of certification. It could also be achieved by provincial consensus. Infoway could be a key stakeholder in weighing various options to determine which approach is best suited to achieve this aim. However, for maximum utility, and particularly for groups under federal purview, this must be done nationally.

Recommendation 1: Actions	**Time Frame**
Enact a Canadian version of the 21st Century Cures Act, leveraging PIPEDA, that legislates patient rights to their data in a computable digital format without charge or delay.	12–18 months
Ensure a choice of portable digital health records for patients under federal purview (First Nations and Armed Forces and their families) that is low-effort for patients to maintain, due to advanced data exchange with health systems.	18–24 months

RECOMMENDATION 2: MANDATE THAT DIGITAL TOOLS RECEIVING PUBLIC SECTOR SUPPORT OR FUNDING SHARE PATIENT DATA THROUGH INTERNATIONALLY ACCEPTED APIs BY 2023.

Ensuring that patients have access to their digital health data is only the first step; it is critical that the data also be shareable between institutions, easy for patients to access, and useful both by patients and different HICs.

Both public and private institutions serving our health-care system have artificially siloed and segmented patient data. To date, in Canada, we have no cohesive approach to mandate data exchange. Patients need their data to be shared across entities to ensure appropriate care. This requires data interoperability.

Solving data interoperability is not a trivial undertaking. However, Canada can benefit from considerable work already done in this space by Infoway and in the U.S. The U.S. 21st Century Cures Act outlines legislative changes to promote greater standardization of data exchange. The act has laid out a model for interoperability. Under the act, certified health information technologies must: 1) provide API-enabled "read" services that meet certain FHIR standards, and 2) have the ability to export the U.S. Core Dataset for Interoperability (USCDI) (The Office of the National Coordinator for Health Information Technology 2021). The USCDI defines a core data set of clinically relevant information, including laboratory investigations, allergies, medications or patient demographics, and specifies the international standard to which they should conform on export. The USCDI is also being updated to include important standards for the exchange of social determinants of health-related information, which is key for equity.

Canada must similarly establish a common framework for interoperability and ensure that health information technologies, across primary care, acute care, and home and residential care, support digital export conforming to a common standard. We strongly recommend that Canada adopts the same standard as set out in the 21st Century Cures Act*,* as it will serve both our health-care system and the growth of our health-care industry in Canada. Our health-care system can take advantage of the changes the U.S. technology vendors will be making, many of whom are already well established in the Canadian acute-care and home-care domains. It will require effort to bring our Canadian vendors in the primary-care and ambulatory-care spaces into such a model. Ultimately this will benefit both patients, and our Canadian vendors, where the latter will have the opportunity to expand across Canadian jurisdictions, and into the U.S. marketplace, without major rework.

The combination of patients having access rights to their data (Recommendation 1), coupled with the establishment of a common framework for interoperability, would provide significant advantage to digital-health innovation across Canada. Allowing patients to access an interoperable copy of their data empowers patients to be the data broker for their own PHI. Interoperability clearly supports portability. Ideally, the groundwork should be laid such that a patient could share their digital health record with, for example, a new primary-care practitioner, digitally and seamlessly. This would be enabled because both the prior and new primary-care practitioners' electronic medical records would support the same interoperability standards as the third-party personal health-record tool of the patient's choosing.

Currently, the U.S. rules only speak to the *export* of PHI (i.e., a patient asking for a copy of their data), but work is underway to develop similar rules for the *import* of PHI (i.e., a patient sharing their data through uploading into systems run by traditional custodians). Similar rules will be important to future-proof the Canadian system. Another provision of 21st Century Cures Act prohibits developers from limiting data flow to other systems explicitly — otherwise known as "information blocking" (Department of Health and Human Services and Office of the Secretary 2020). Essentially, vendors and institutions cannot limit a patient's ability to hold, control, and share their data with other third parties (who may be direct competitors to the original software where the data was housed). Without such rules, Canadians will trade one set of silos for another.

Under such rules, patients can also share data with, and benefit from, a variety of third-party tools. Currently, most digital-health vendors are dependent on developing relationships with specific individual hospitals and clinics to access patient data. This artificially limits the size of the market they can realistically access, as they must establish unique integrations and data-sharing agreements with each institution. Thus, digital-health integration work is a collection of non-scalable, non-transferable, one-off and costly customization exercises as it pertains to data-sharing agreements, procurement requirements, or interoperability standards. Small vendors work with institutions to build an integration that works only in that institution, with significant business risk and minimal payoff. Large vendors often fail to see the business case to provide integrations for a single site and simply refuse the business. Patients, on the other hand, can share an aggregate copy of their data at will, removing many of the complex bureaucratic steps for these tools to access data. This also makes the patient the decision-maker with regards to who has access to their data and for what purposes.

Given the size of our marketplace (which is small on a global scale), this work must be co-ordinated on a national scale (Canadian Medical Association, The College of Family Physicians, and Royal College of Physicians and Surgeons of Canada 2020). While provincial standards would reduce some of the drag on innovation, different standards among the provinces and territories would divide Canada into rather small markets for vendors in an industry that is increasingly global and competitive. By allowing different standards, the system forces region-based customization by vendors where, depending on the size of that region, small vendors consume non-transferable effort and larger vendors determine that the market is not worth their time. This is such a critical point that one could certainly make the case that these are primarily matters of national commerce and trade more than they are matters of health care. As such, they could be viewed (perhaps controversially) as falling within the federal purview.

In addition to the patient-level information, there is enormous value to the system in the population-level data that would be more easily leveraged with shared interoperability standards (Hintze 2018). We note that within the provisions of the U.S. legislation, there are rules around the support of APIs for the bulk transfer of information. Admittedly, those rules exist primarily to support an institution's right to switch vendors without anticompetitive consequences pertaining to data migration. However, we recognize the value of such APIs to potentially feed population health registries or databases as part of a learning health system. Further, Canadian data sets for use by machine-learning researchers would prevent the current situation where researchers are forced to use international or artificial data sets that poorly reflect the Canadian population and are often subject to systemic biases.

Working with Infoway, our health system would benefit from developing a mechanism to ensure such standardization across sectors and provinces. To maximally benefit patients' use and ownership of their data and to make Canada a viable market for digital-health innovators, we must adopt the interoperability standards set out by the U.S. We recognize the important work already underway by Vivek Goel and colleagues to develop the Pan-Canadian Health Data Strategy. We encourage such work to strongly examine, in partnership with Infoway and the Canadian Institute for Health Information, the potential benefits of such bulk transfer APIs in Canada, and how their aims can be furthered by existing work, including the European GDPR, the 21st Century Cures Act and the NHS Digital Strategy, as well as the technologies supported by these initiatives. As a first step, an interoperability-readiness assessment of each province, according to the model developed by the Health Information Management and System Society (HIMSS), could be performed immediately (Health Information Management and System Society 2020). As mentioned previously, it is critical to recognize that this data-interoperability strategy must have a parallel plan to mitigate cybersecurity risks posed by consolidating previously siloed data, which is a system function Infoway could be positioned to address.

Recommendation 2: Actions	**Time Frame**
Perform an interoperability-readiness assessment for each province and territory using the model developed by HIMSS.	Immediate
Establish requirements for national APIs and interoperability that are aligned directly with the standards set forth by the U.S.	12–18 months
Continue the important work on the development of the Pan-Canadian Health Data Strategy.	18–24 months

RECOMMENDATION 3: CARE IS CARE. CLARIFY THE INTERPRETATION OF THE TERM "MEDICALLY NECESSARY" UNDER THE CANADA HEALTH ACT AS BEING MODALITY-NEUTRAL.

The CHA requires that provinces insure services that are "medically necessary for the purpose of maintaining health, preventing disease or diagnosing or treating an injury, illness or disability" (Legislate Services Branch 2017). Both federal and provincial governments can interpret what constitutes a "medically necessary" service. Thus far, no government in Canada has explicitly made the decision to interpret virtual care as "medically necessary" under the CHA, despite temporary extensions to virtual-care coverage during the pandemic. Clinicians are delivering necessary services virtually on a large scale, with essential medical care provided via telephone, video conferencing, and secure texting platforms (Bhatia et al. 2021). Additionally, the important adjunct care of remote monitoring, critically leveraged during the pandemic to monitor COVID-19 patients from home, is not explicitly insured, despite growing evidence of value for conditions such as congestive heart failure or a number of mental health disorders (Watson, Wah, and Thamman 2020). As with physical care, there are many instances where the same service can be viewed as completely necessary on one hand and as completely inappropriate on another. A key recommendation of the position paper by Falk was the need to do a “specialty-by-specialty review to determine which services are appropriate to conduct virtually,” which is something we certainly support (Falk 2021). However, it is important not to sacrifice short-term necessity for fear of inappropriateness while waiting for such a review. Patients requiring care must have access to it — irrespective of modality.

Interpreting “medically necessary” services to be modality-neutral means that public health insurance must have a plan to cover physician services independent of whether they are delivered by phone, video, messaging, or in-person. This availability is critical for equitable access. Long before the COVID-19 pandemic, patients experienced many challenges with in-person appointments, including costs (on average $100 out of pocket), transportation, child care, and time off work, not to mention the infection risk of physical contact (Kelley, Phung, et al. 2020; Falk 2021; Bhatia, Shojania, and Levinson 2021). Digital health can reduce many of these.

Until recently, virtual visits and telemedicine were synonymous with video visits. Experience during the COVID-19 pandemic and the explosion in telephone visits taught us further lessons in the need for modality neutrality. Patients for whom in-person visits present the biggest challenges are often the same patients who lack appropriate private space for video calls, supporting technologies for video calls, or the digital literacy to use them. Forcing patients to go in person to see their practitioner for simple check-ups and prescription renewals has always been more than an inconvenience — it is a barrier to receiving care. Forcing them into a position where video is the only alternative creates a similar set of problems. Need should determine how care is delivered.

Modality neutrality is also advantageous for clinicians. It allows them to consider their patients’ personal and medical circumstances. Picking and choosing which modalities are publicly insured (e.g., reimbursing video visits but excluding phone visits) limits this ability and introduces workflow inflexibility. It forces clinicians to consider technical issues in their clinic planning, such as initiation time, training and tech support, and possible connection issues, even in cases where a phone visit would serve just as well as a video visit. This may incentivize clinicians to offer in-person visits only, because it means less disruption to their workflow.

Failing to insure services such as secure text or email messaging encourages clinicians to offer them through private pay-per-use platforms. These services are often accessible 24/7, unlike much of the public health-care system. Those who can pay will use them, but key information will not necessarily follow them through their care trajectory and back to their primary-care practitioners. Insuring such services helps ensure against creating a parallel and disconnected system. In 2021, we should be dismantling silos — not creating conditions that foster the development of new ones.

Ultimately, the choice of modality should be a shared clinical decision between the clinician and the patient. To prevent selective funding of virtual modalities, or exclusion of funding overall, we must explicitly recognize all virtual modalities as covered under medically necessary physician services under the CHA (Dorn 2021). This is the type of action that could be done immediately through a letter of interpretation by the minister of health.

Recommendation 3: Actions	Time Frame
Interpret the term "medically necessary" under the CHA to be modality-neutral through a letter of interpretation by the minister of health.	Immediate

RECOMMENDATION 4: ENGAGE AND CREATE A PARTNERSHIP STRATEGY WITH COMMUNITIES TO HALT, NARROW, AND ULTIMATELY ELIMINATE THE DIGITAL DIVIDE.

Digital health has the potential to improve equity but only if approached with intention. We must ensure that geography, race, income, education, language, digital literacy, and disability are not significant barriers to accessing care (Cukier 2020). The federal government must make it a priority to facilitate meaningful efforts to engage and collaborate with communities around the design and implementation of digital-health solutions. This work can start in a network of communities, including Indigenous communities, that represents the major groups often left behind by digital. This process must engage the many organizations that are already active in these spaces. Coming to a community with a fully baked solution or message, often designed from an external position of privilege, will only lead to a repeat of the many pitfalls that we have seen during the various phases of the COVID-19 pandemic. Designing tools for certain populations without full consultation and co-design can harm more than help, and risks reducing engagement and trust. Communities must be true co-design partners in how their populations access health care digitally. We recommend starting by identifying a key set of issues, in partnership with these communities, and then funding dedicated work around solving these problems. For example, can we deliver an effective, culturally safe model of remote patient monitoring to low-income Indigenous patients who have suboptimal internet access, some level of disability, or who operate primarily in a language other than English or French?

Some aspects of this work must be started immediately. For example, the ability for Canadians to access reliable high-speed internet at an affordable cost is essential and must be extended to all Canadians through whatever means are required (e.g., broadband expansion, satellite, etc.) — that is a given that requires no consultation. It would be wrong, however, to assume that internet access alone is sufficient. Access to health care requires not only the internet, but also devices that can support advanced digital workflows (e.g., smartphones, home networks of devices and tools), access to affordable data plans, and digital literacy for their use. The federal government must lead in developing the infrastructure and planning to ensure full access to wireless and data infrastructure, ensuring cost-effective access to those services, and facilitating the technology and training necessary for all (Latulippe, Hamel, and Giroux 2017; Veinot, Mitchell, and Ancker 2018). Further, in-person care must continue to be a core part of all clinical practice to promote high-quality care, particularly for those with lower digital literacy and access. The existence of a virtual model to provide necessary access and coverage to an underserviced region should not be viewed as justification to stop the hard work of ensuring appropriate in-person coverage. Both models of care will be critical.

In alignment with such efforts, certain funding for digital health provided by the Canadian Institutes of Health Research and the Canada Foundation for Innovation should specifically be allocated for work with populations subject to the digital divide, including those who are racialized, are of low socio-economic status, are not fluent in either English or French, have low digital literacy, or have disability.

Recommendation 4: Actions	Time Frame
Convene representative stakeholders across major communities impacted by the digital divide (Indigenous and racialized, low socio-economic status, English/French as a second language, those with disability) to develop partnered approaches to addressing the digital divide across Canada.	Immediate
Create pilot programs working with a sample of Indigenous communities that identify their infrastructure requirements, including internet, devices, and training.	12–18 months

RECOMMENDATION 5: BUILD ON AND EXPAND THE SCOPE OF CURRENT NETWORKS TO DEVELOP A NATIONAL APPROACH TO ELIMINATING DRAGS ON INNOVATION, INCLUDING INEFFICIENCIES IN EVALUATION, PROCUREMENT, AND PRIVACY AND SECURITY ASSESSMENT.

While acquisition of digital health largely remains in the purview of the provinces and territories, aspects of that acquisition must be supported nationally to streamline innovation and define a common marketplace for digital health that allows our innovators to succeed both locally and internationally. It is essential that we do not waste resources on repeating the same exercises in each organization, health authority, province, and territory. Yet when it comes to evaluation, procurement, privacy and security assessments, and certifications, that is exactly what we do. As is the case with interoperability standards, siloed approaches to these procedures locally, or even provincially, effectively create a set of small markets where vendors must engage with each institution in long, complex processes to satisfy a collection of regional interpretations and idiosyncratic rules. Large vendors do not see the business case in those small markets, and small vendors absorb huge business risk by needing to rework their products again and again across jurisdictions.

Another important reason for such work to be done nationally is one of scale, especially as it relates to some of the multinational vendors that exist in the digital-health ecosystem. The foundational premises of this paper owe themselves to the openness of the internet that came through hard-won battles in the mid-1990s. These included the U.S. Department of Justice's campaign against Microsoft's alleged attempt to "embrace, extend, and extinguish" open internet standards in order to ultimately exert an anticompetitive level of control over the internet ("Embrace, Extend, and Extinguish" 2021). This was not a campaign that could have been successfully waged by an entity smaller than a federal government. Today, many of the large corporations increasing their footprints in health, such as Amazon and Google, and here in Canada, Telus and Loblaws, are rationally pursuing strategies rooted in data. However, some strategies, such as the pursuit of corporate "walled gardens," silo and restrict the very data that earlier recommendations spoke of freeing. Limiting those siloes forms much of the basis for the information-blocking restrictions in the 21st Century Cures Act. Other strategies raise the spectre of what has been called "surveillance capitalism," whereby data is mined to predict and shape consumers' behaviours, often without their knowledge (Zuboff 2019). On the other hand, we must acknowledge the great digital strides that these corporate innovators have allowed, and to ignore or deny their potential role in health would be a significant error. However, only the federal government has the size, and the appropriate leverage to influence such massive companies when required, and also to partner with them as appropriate, to ensure the integrity of a digital-health system that works optimally for the benefit of Canadian consumers and vendors.

As vendors and innovators would ultimately be major beneficiaries of such efforts, such work should seek funding partnerships with major industry organizations (e.g., Medtech Canada) and be aligned with parallel support efforts for small and medium-sized enterprises through programs such as the National Research Council Industrial Research Assistance Program.

We focus on three priority areas: 1) evaluation, 2) procurement, and 3) privacy and security.

1) Evaluation fuels scale, yet trustworthy and repeatable evaluations are rare.

As access to digital care continues to expand in Canada through interoperability and reimbursement for virtual care, it will become increasingly difficult for clinicians to know which tools are reliable (National Institute for Health and Care Excellence 2018). It may be tempting to apply a heavily regulated approach to all digital health, even those tools that would not meet the definitions of a high-risk medical device, and are thus already regulated by Health Canada. However, doing so would be imposing a significant burden — on both the innovators and the regulators — that would stifle the innovation we hope to promote. For many lower-risk devices, the fundamental question is one of "value" rather than one of "risk" or "safety," with the notable exception being growing issues with cybersecurity and data privacy. As we detail below, we prefer that these issues be managed through a process of certification, allowing for the elimination of current redundancies while simultaneously promoting informed purchasing and acquisition.

There is a need to robustly and effectively evaluate a subset of digital-health tools in a clinical setting to understand their impact on clinical value, patient safety, equity, cost-effectiveness, clinician workflow, and more (Sikka, Morath, and Leape 2015). However, there are significant administrative and financial barriers to conducting these evaluations (Kelley, Fujioka et al. 2020). The work is expensive and time-consuming, which strongly disincentivizes such evaluations. Health-care institutions in Canada do not have the dedicated resources that the private sector drug companies have, nor do they have budgets focused on research and development. The government must provide dedicated funding to mitigate these costs for institutions to participate meaningfully. Otherwise, good tools will never be evaluated, and bad tools, because of sunk costs, will become permanently entrenched into systems.

We should perform these pilots and evaluations in a timely way, incentivizing pilot institutions to hit aggressive targets for implementation and first-patient use (e.g., 90 days) for such work to maintain relevance against the exponential growth of digital and consumer health tools.

To promote trust and appropriate knowledge translation, we require a common national framework for digital-health evaluation that is repeatable and trusted across organizations. Like other high-quality evaluation endeavors, it should be built fundamentally around solid methodology, standards for evidence appraisal, key agreed-upon outcomes of interest, and reporting guidelines. A national evaluation network is already being funded by the federal government in the form of the Canadian Network for Digital Health Evaluation (CNDHE). This organization has been tasked with developing common, adaptable frameworks for evaluation specific to the nuances of digital health. Such an effort, for it to have maximal value, must be linked to implementation. True-to-life implementation is a necessity for an evaluation to generate the real-world evidence required to generate trust and to inform scale (Desveaux et al. 2017). Implementations and local complexities also represent a key set of variables that impact the success or failure of any digital effort. It is critical to understand not only if a tool does or does not “work,” but under what conditions (funding, operational support model, integrating and competing digital tools, user characteristics, clinical model, relevant local policies and procedures, etc.) (Sittig and Singh 2010; Greenhalgh et al. 2017).

A provincial model attempting to blend evaluation, implementation and scale is the Alberta Health Services (AHS) Strategic Clinical Networks, which aims to spread innovation across the province by testing emerging solutions using a novel and standardized process (Yiu, Belanger, and Todd 2019). This standardized approach has enabled the AHS to increase the speed and consistency of decision-making for implementation (Ambler, Leduc, and Wickson 2019).

2) *Procurement is often siloed and ignores the flexibility of software.*

Finding solutions to manage public procurement presents challenges that are well known across the country (Snowdon et al. 2019). Procurement rules were established to create fair opportunities and manage risk through documented processes and transparency. However, procurement processes can also create unintended consequences, adding costs and time to acquisition. A Canadian network such as CAN Health, already funded to improve innovation opportunities in health for Canadian vendors, should be further tasked with developing a shared, value-based model for the procurement of digital-health tools across its partners. Such a model must recognize the inherent benefits of software for flexibly responding to complexity through pivots and lateral application to new problems.

Digital health brings its own set of challenges to procurement. Lengthy procurements in a rapidly evolving digital marketplace often result in a "solution" that is out of date before the purchase cycle is complete. Yet the investments and contractual obligations of procurement force organizations to stick with the outdated solution. Contemporary procurement processes rarely support the complexity of software solutions that must be co-designed by the industry and the consumer, or versatile apps that have the flexibility to provide unanticipated solutions. They cannot factor in the flexibility of software to be repurposed to meet new needs and support continuous quality improvement once procured. For example, Unity Health Toronto acquired Verto's software to assist with patient flows in its diabetes clinic. When the pandemic hit, Unity was able to partner with Verto to rapidly deploy a solution to schedule COVID-19 tests and vaccinations, which, because of the relatively low-rules and high-needs environment, ultimately scaled up rapidly to fill a critical need across many sites in Ontario. This lateral use of software was quick and cost-effective. There is a growing notion that effective procurements will need to shift from something that is less tool- and requirements-based, to something that is more about relationships with reliable and responsible entities, and leads to the creation of value. This is something the U.S. Food and Drug Administration is attempting to address with its precertification procedures (FDA Office of the Commissioner 2020) and that is increasingly recognized as critical for the burgeoning artificial-intelligence industry (Roski et al. 2021).

3) *Privacy and security assessments are often highly redundant due to a failure of trust, and due to a lack of standardized approaches.*

The privacy and security of PHI is a significant concern when collecting, storing, and sharing data (Insurance Bureau of Canada 2021). During the pandemic, we have seen a major escalation of cybersecurity events, with new and challenging issues on the horizon given the greater use of third-party digital solutions. Varying approaches to privacy and security assessment have resulted in delays and wasted efforts that ultimately hinder the spread and scale of digital-health solutions. Considerable duplication of effort occurs not only because the rules vary by site or jurisdiction, but often because there is no trust framework or shared approach (Bhatia and Kelley 2019). Additionally, sites may lack significant privacy and security resources, and are hard-pressed to evaluate many contemporary digital applications.

A national network should develop a shared approach for the privacy and security assessment of digital-health tools that can effectively function as a privacy and security certification mechanism beyond such a network (Bhatia et al. 2020). Ideally, participants in a federally funded network would come to a shared agreement around privacy and security — one that is thorough enough to deal with looming cybersecurity threats — and then to explicitly trust each other's work. This should be a fresh evaluation specifically designed to reduce overly risk-averse and impractical interpretations (Falk 2021). It will reduce or even obviate the need for other sites to engage in wasteful, duplicative, and time-consuming activities, while also providing a critical mass of first movers to allow for new interpretations. Such certification could, in parallel, address other technology provisions of digital-health tools that are also critical in health care, for example the existence of appropriate downtime procedures, data retention policies, and backups. Infoway and CAN Health are existing programs that could be leveraged to develop this common framework.

Recommendation 5: Actions	**Time Frame**
Develop a common and repeatable framework for digital health evaluation through a federally funded pan-Canadian and representative network, such as the CNDHE.	6–12 months
Have Infoway, in partnership with an existing innovation network such as CAN Health, develop a shared standard for: 1) value-based procurement of digital tools that appreciates and leverages the strengths and flexibility of software; and 2) privacy and security assessments of digital-health tools that acknowledges emerging digital health workflows and cybersecurity risks.	12–24 months
In partnership with major industry organizations, and in order to encourage timely innovation and evaluation and mitigate “sunk costs,” develop a “first-mover” bonus covering the majority of implementation costs for network sites who are willing to: (a) assume the risks of being an early adopter of technology; (b) commit to an aggressive target for implementation and first-patient use (e.g., 90 days, with decremental bonus thereafter); (c) perform the work according to the developed standards for procurement, privacy and security assessment; and (d) submit to a separately funded, third-party evaluation of the effort, according to the standards set forth by the evaluation network.	12–24 months
Develop a process to build up the base infrastructure at participating network sites to ensure an equal opportunity across provinces and territories to access “first-mover” bonuses.	12–24 months
Grow the above standards into a certification mechanism for digital-health tools that can be leveraged by sites within and beyond the network.	24–36 months

CONCLUSION

There are five major areas of change that the federal government can support to promote the use of digital health in a way that improves care for the Canadian population.

First, data must be freed to move around the system. This means that patients must have the right to access their PHI from any health-care institution or digital solution that collects it. This information must be provided without charge, without delay, and in a computable format, by which we mean sharable with and readable by third-party tools.

Second, the computable format should follow a standardized, national interoperability framework using common APIs that mirrors the U.S. approach. This will craft a single market where Canadian innovators can develop tools that can scale across North America. The ongoing work to develop a pan-Canadian data strategy should continue, and should consider how the bulk transfer of de-identified PHI could support research, development, and evaluation of new and existing health-care interventions.

Third, we must ensure that virtual care does not become artificially segmented from in-person care. Care is care, whether it is provided in-person or virtually. The interpretation of “medically necessary” in the CHA must be modality-neutral.

Fourth, we must ensure a digital-health ecosystem in which all Canadians have an equal ability to participate. Deliberate community engagement to develop models to reduce the digital divide must be developed, not unlike the work that had to occur to ensure a comprehensive roll-out of vaccines during the pandemic.

Finally, we must absolutely get down to the business of reducing the common drags on innovation, including challenges with evaluation, procurement, and privacy and security. We must establish mutual trust and collaboration and shared interpretations that allow us to safely push the boundaries of what is possible.

No single province or territory has the reach to facilitate the changes we are recommending without the federal government assuming a role. While we have made recommendations that recognize the boundaries between the federal government and the provinces and territories in health care, a harmonized national approach is the only approach that moves Canada forward. This work is imperative; without strong leadership and collective action nationwide, our patients and our innovators will fall behind. The five recommendations will help us establish, embrace, and encourage digital-health innovation for our nation’s population and for the Canadian industries that will deliver these innovations.

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