Competition Bureau Market Study: Digital Health Care
Medtech Canada Submission

June 30, 2021

Medtech Canada is the national association representing Canada's innovative medical technology (medtech) industry. Representing approximately 100 medtech companies (ranging from Canadian-owned to multinationals), Medtech Canada works closely with government and healthcare stakeholders to deliver a patient-centred, safe, accessible, innovative and sustainable universal healthcare system supported by the use of medical technology.

INTRODUCTION

Dear Stephanie Gillespie and Kristen McLean,

On behalf of our member organizations, thank you for the opportunity to provide industry perspectives on how to improve digital health care in Canada. Medtech Canada strongly supports the Bureau's goal to encourage competition and digital innovation in the health care sector.

On the digital technology front, technology solutions from Medtech Canada member companies are enabling the collection of novel kinds of data, increasingly sophisticated data analysis, and augmented intelligence. Elements of health care powered or enhanced by these data capabilities include new insights into individual and population health; real-time, continuous, remote patient monitoring & remote medical interventions; care outside of traditional settings; advanced diagnoses through implantable technologies; and enhanced clinical decision support.

Medtech Canada's mission is to be a trusted partner in providing valuable outcomes and innovative health care solutions for Canadian patients & providers. To this end, Medtech Canada works closely with federal and provincial governments, health professionals and other eco-system stakeholders to deliver a patient-centred, safe, accessible, innovative and sustainable universal healthcare system supported by the use of medical technologies.

Throughout the COVID-19 pandemic, the adoption of digital tools to support the delivery of high-quality care has accelerated across the Canadian health care system. Increasingly, patients and clinicians are realizing the benefits of digital tools, while also confronting the challenges of the current landscape. In response to the evolving environment, Canada Health Infoway (CHI) sought to better understand Canadian's perspectives on the role of technology in the delivery of better health care. Through "A Healthy Dialogue"[1], CHI obtained feedback from over 58,000 Canadians and found that "92% of Canadians want technology that makes health care as convenient as other aspects of their lives, 84% of Canadians would use technology tools to manage their health, and 80% of Canadians believe investing in health technology should be a top government priority."

To fully realize the potential benefits of digital health care, Canada must develop national standards that support access, use and sharing of digital health data and information across and within jurisdictions. The current silos through which care is delivered (e.g., acute care, primary care, long-term care, home care, etc.) and the patchwork of regulations and policies (e.g., federal, provincial, territorial, regional, institutional, etc.) have resulted in inefficiencies and barriers to digital health transformation.

While we appreciate that the scope of the current consultation includes data and information, products and services, and health care providers, we have also included considerations regarding digital infrastructure and privacy of digital health data and information. Additional resources are also provided for your convenience and consideration.

Sincerely,

Brian Lewis, President & CEO, Medtech Canada

Raj Malik, Vice President, Federal Affairs & Health Systems, Medtech Canada

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[1] Canada Health InfoWay https://access2022.ca/section/a-healthy-dialogue

Data and Information

Barriers and Recommendations

The regulatory landscape in Canada is very complex, with 14 jurisdictions (1 Federal, 10 Provincial and 3 Territorial) with distinct regulations governing the use of data and information. As a result, digital health innovators must navigate 14 sets of regulations, that are outdated, and based on older technologies. Beyond consistency and clarity in regulations, barriers also include standards, disparate systems, cyber security, infrastructure, strategies and funding mechanisms, value proposition and access and quality. National standards for the digital health space are required.

Recommendations include:
- Develop a comprehensive digital health framework for all provinces and territories that allows for a robust domestic digital health market
- Encourage investment to ensure the success of the digital health framework
- Focus on outreach to patients, clinician groups, caregivers and the general public

Products and Services

Barriers and Recommendations

The length of time for Health Canada to grant approvals for new technologies delays access to and use of new technologies. Additional delays occur following Health Canada approval, as many new technologies must then go through provincial assessment processes to be considered in the digital landscape. Regulatory barriers also include exclusivity, market access, reimbursement and procurement, domestic experience, and open data.

Recommendations include:

- Adopt a strategic global vision for digital products and services
- Streamline and simplify the development and approval process
- Promote collaboration

Health Care Providers

Barriers and Recommendations

Privacy and scope of practice barriers limit the adoption of certain technologies among health care providers. Non regulatory barriers also include compensation, training, fear, technical limitations and increased responsibility.

Recommendations include:
- Billing codes or incentives that include the use of digital health technologies/solutions
- Transitioning from Fee-for-Service (FFS) model to newer models that promote integrated care delivery
- Medical schools and licensing bodies such as the Canadian Medical Association (CMA) or Royal College of Physicians and Surgeons of Canada need to incorporate basic requirements for digital proficiency and certification

DATA AND INFORMATION

Regulatory Barriers

The regulatory landscape in Canada is very complex, with 14 jurisdictions (1 Federal, 10 Provincial & 3 Territorial) with distinct regulations governing the use of data and information. As a result, digital health innovators must navigate 14 sets of regulations, wasting time and resources that could otherwise be devoted to supporting the scope and scale of adoption within the system. National standards to provide consistency and clarity across jurisdictions' regulations are needed to facilitate access to, use, and sharing of digital health data.

For example, there is a patchwork of legislation governing the rules related to privacy, storage, and access to personal information from outside of a province or outside of Canada. As the federal legislation that governs the private sector, *PIPEDA* (*Personal Information Protection and Electronic Documents Act),* sets out the ground rules for how businesses must handle personal information during their commercial activity. There is also similar provincial legislation around personal information protection, which sets out rules applicable to each province. Whereas industry is governed by federal laws and substantially similar provincial sector laws, customers of companies in our industry are governed by provincial personal health information legislation. There is an absence of meaningful government direction or guidelines as to how to navigate the different statutes and how to best share patient data between health information custodians (HICs) and industry.

In addition, these laws are outdated and based on older technologies. Today, the prevalence and benefits of cloud computing have completely changed the way personal information can be stored or accessed from other jurisdictions in the world, often with even more protection than through previous technologies. The lack of clarity on how to address technological advances has resulted in different interpretations within jurisdictions at an organization or point of care level. This means that digital health solutions are being inconsistently adopted within jurisdictions, limiting their utility, and preventing access to and use of health data beyond siloed institutions.

Consent - Private Sector laws are currently structured around consent as the principal gateway to accessing data.

Although there are limited exceptions to obtaining patient consent for data disclosure, such as for agency arrangements, the type of data sharing between industry and HICs, where the sharing not only permits the HICs to have third parties assist in the management of the data to advance patient care, but also allows use of the data for product development and innovation, is not adequately dealt with in the current regulatory environment.

We need to modernize the consent expectations to account for new digital realities that were not anticipated when these laws were built. There is a need to develop a framework for standards built on common principles to accommodate different situations. A greater

emphasis on education and understanding of meaningful consent amongst patients would support greater empowerment and autonomy for person-centred care.

Data Sharing – There are standard forms of agreements called Business Associate Agreements in the US, based on applicable US laws, which can be used in the various forms of data sharing with our customers but there is no comparable, clear legislative authority in Canada for such data sharing.

<u>Non-Regulatory Barriers</u>

Standards – Beyond consistency and clarity in regulations, national standards for the digital health space are required. Currently, standards are both evolving and incomplete, with variation across jurisdictions.

Standards for data and information collected are needed for, but are not limited to, the following: what data is being collected (ensuring consistency); standardized patient surveys to collect patient reported outcome measures (PROMs); and value impact (outcomes, cost avoidance, and patient and user satisfaction). In the future, data must be collected in a format and through a comprehensive method that will allow for insightful analytics, which in turn can uncover opportunities, trends, and drive measurable improvements to the system.

Disparate Systems – Within each jurisdiction, the fragmented accountability, funding, and decision-making across care settings (e.g., acute care, long-term care, primary care, home care etc.) has resulted in siloed systems that create barriers to access, use and sharing of health data. This challenge is compounded when considering how to access, use and share data for Canadians that move between jurisdictions. The existence of multiple platforms and a high inter and intra provincial variation is a significant challenge.

Cybersecurity – Cybersecurity and breaches also cause hesitation for both health care professionals and those receiving health care services. Breaches are managed differently, and rules vary from jurisdiction to jurisdiction. Cybersecurity guidelines for the provinces need to align with the Canadian Centre for Cyber Security's criteria such as business continuity, disaster recovery, crisis management and privacy and fraud. This will assist with building capacity for the organizations and public understanding.

Infrastructure – Today's clinical health informatics infrastructure is evolving at a much slower pace than the digital health industry, widening the gap between health care delivery and the evolution of digital health. Not only does this hinder the adoption of evidence-based technologies that can significantly help to drive improved outcomes, but it also places restrictions on how data can be used to better inform care. The lack of interoperability with Electronic Medical Records (EMRs), unclear policies on privacy/cybersecurity in health organizations, and the inability to leverage these significantly undercuts the value industry can compete for in the sector.

Cellular, broadband and satellite coverage and capabilities need to be improved to encourage better access for rural and remote communities.

For reference, the Healthcare Information and Management Systems Society (HIMSS) is a global advisor, thought leader and member association committed to transforming the health ecosystem. As a mission-driven non-profit, HIMSS offers a unique depth and breadth of expertise in health innovation, public policy, workforce development, research and analytics

to advise leaders, stakeholders and influencers from across the ecosystem on best practices. With a community-centric approach, this innovation engine delivers key insights, education and engaging events to healthcare providers, payers, governments, startups, life sciences and other health services organizations, ensuring they have the right information at the point of decision. HIMSS has served the global health community for more than 60 years, with focused operations across North America, Europe, the United Kingdom, the Middle East, and Asia-Pacific. The HIMSS Analytics Electronic Medical Record Adoption Model (EMRAM) incorporates methodology and algorithms to automatically score hospitals around the world relative to their Electronic Medical Records (EMR) capabilities. This eight-stage (0-7) model measures the adoption and utilization of electronic medical record (EMR) functions.[2]

Are we making progress?

United States EMR Adoption Model[SM]

STAGE	2017 Q1	2017 Q2
7	5.0%	5.3%
6	31.9%	32.4%
5	34.3%	34.1%
4	10.0%	9.8%
3	13.3%	13.1%
2	1.9%	1.9%
1	1.6%	1.6%
0	1.9%	1.8%
	N:5,479	N:5,478

Canada EMR Adoption Model[SM]

STAGE	2017 Q1	2017 Q2
7	0.2%	0.3%
6	1.2%	1.1%
5	3.9%	3.9%
4	1.4%	1.6%
3	30.6%	30.6%
2	29.6%	29.5%
1	15.6%	15.5%
0	17.6%	17.5%
	N:643	N:644

- Progression to HIMSS EMRAM Stage 4 and above is associated with improved care: quality, safety and value

  - Amarasingham R et al. Arch Intern Med 2009 169(2):108-14
  - 2006 HIMSS EMR Sophistication Correlates to Hospital Quality Data
  - 2012 HIMSS Analytics Report: Quality and Safety

- US has **12x** the proportion of sites at HIMSS Stage 4 and above vs Canada (81.6% vs 6.9%)

Strategies and Funding Mechanisms – Digital strategies are often targeted (and therefore have a narrow focus and limited funding). This approach hinders the adoption of disruptive technologies that offer broader benefits. To foster greater innovation and reap the potential benefits of digital health care, a systems lens is needed, which considers system-level funding (i.e., health human resources, infrastructure, technology, change management, etc.) rather than funding for technology alone.

Value Proposition – Social determinants of health are not accounted for in the Canadian Health Data Strategy. Moreover, it would be of benefit to advancing the health equity agenda and accessibility of services to understand and share quantifying data to assist with improving health outcomes for key under-serviced populations. This is also a case for data needs to be shared across silos and health service provider organizations.

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[2] North York General
https://www.ontarioshores.ca/UserFiles/Servers/Server_6/File/PDFs/BestPracticesConference/2018Presentations/Ontario%20Best%20Practices%20Lessons%20Learned%20HIS%20Conference%20-%20Theal%20Feb%2028%202018%20v3.pdf

Access and Quality – Data and Artificial Intelligence (AI) has many possible uses in the health field, both clinically and administratively. Although the potential of AI has been well documented and demonstrated by researchers and developers, concerns about data access, bias and integration continue to hinder the adoption of AI in health care. Barriers include:

- Difficulties in accessing sufficient and quality data can hinder innovation in this space.
- Available data may be biased which can reduce the effectiveness and accuracy of the tools.
- In addition to data access, problems of scaling and integration in health care organizations can also hinder the use of digital health and AI. Differences between the institutions and the patient populations they serve can make it difficult to not only implement, but implement on a large scale and thus export these tools outside Canada's borders.
- Data from jurisdictions outside of Canada will not be sufficient to support innovation from a Health Canada licensing perspective: For example, note the following excerpt from CADTH (Canadian Agency for Drugs and Technologies in Health) ISSUES IN EMERGING HEALTH TECHNOLOGIES Issue 174 September 2018 Informing Decision:

AI systems have the potential to remove human bias in decision-making, but there remains the risk that, depending on the data used for training algorithms, some models incorporate and reinforce biases from the demographics of the population used for their training. This bias can be challenging to detect and can unintentionally be incorporated into the logic systems of machine learning products. The data may not be representative of the target population in which it is being applied which could result in discrimination of legally protected groups in ways hidden from those tasked with making decisions from AI outputs. For example, an algorithm may work well in an academic or limited clinical setting, but may not be scalable to a real-world setting, and consequently has the potential to lead to misdiagnosis and harm to patients. This was demonstrated recently with machine learning software developed for stratifying cancer risk in pulmonary nodules detected with CT imaging. The software attained high performance on the training data set based on patients from the US National Lung Screening Trial but achieved lower performance when applied to patients at Oxford University Hospitals.[3]

What changes can be made to reduce barriers to the access, use and sharing of digital health data and information? How can this encourage more competition and innovation in digital health care?

To promote the use of digital health care and to support an integrated health care system (within and across provinces and territories) the regulations governing digital health data and information must be clear and consistent. Governments must prioritize and accelerate the development of national and provincial standards on: data integration, interoperability of provincial digital health assets and innovative digital health tools and technologies, and what types of digital health information is relevant for clinical support and for policy considerations. All governments should also be encouraged to adopt integrated health system planning.

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[3] CADTH https://www.cadth.ca/sites/default/files/pdf/eh0070_overview_clinical_applications_of_AI.pdf

Recommendations include:

1. Develop a comprehensive digital health framework for all provinces and territories that allows for a robust domestic digital health market

   - Work with multiple stakeholder groups to ensure data and information is collected consistently across jurisdictions through standardized laws, protocols, and processes

   - Build upon global acceptance and standards and learn from similar jurisdictions to assist with implementation and more frequent adoption of innovative technologies

   - Develop and promote ideal data sharing provisions

   - Within the framework, consider developing and promoting a principle for Cloud First technologies

2. Encourage investment to ensure the success of the digital health framework

   - Invest in a solid and stable infrastructure that can be used as a common platform for both primary care, long-term care, home care, pharmacy and hospital-based databases

   - Invest in data integration and predictive analytics to support smoother transition of information across systems, reduce redundancy and maximize efficient use of resources

   - Develop or expand a mechanism to access high-quality national and international data; industry requires access to high-quality data to train, adjust, evaluate and validate new innovations for the Canadian market

   - Advance the use of, and funding for, integrated business cases that promote innovation and broader change (rather than funding for individual 'widgets')

   - Promote point-of-care decision making to accelerate and facilitate adoption

   - Facilitate collaboration and encourage partnerships between digital health innovators, information and communications technology (ICT) providers and governments to enhance infrastructure

   - Ensure the implementation of cyber-safe fire walls for storage of digital patient data

3. Focus on outreach to patients, clinician groups, caregivers and the general public

   - Promote digital health literacy awareness through targeted campaigns; develop specific indicators to enhance the digital experience

   - Work with clinician groups to enhance participation in digital health care by promoting understanding of how digital health can inform health system needs, improvement opportunities, and support the collection of real-world evidence for use in studies with a scientific intent

PRODUCTS AND SERVICES

Are there barriers (regulatory or non-regulatory) that are restricting the range and scope of digital health products and services available for use by health care providers and patients? How have these barriers impacted the competitive landscape for digital health care?

Regulatory Barriers

The length of time for Health Canada to grant approvals for new technologies delays access to and use of new technologies. Additional delays occur following Health Canada approval, as many new technologies must then go through provincial assessment processes to be considered in the digital landscape.

Non-Regulatory Barriers

Exclusivity – Historically, digital health products and services have been limited in reach, developed to support only one patient population or therapeutic area. This fragmentation and the abundance of proprietary solutions have historically impeded wide scale adoption of digital technologies. Greater focus on and prioritization of integration and connectivity across care settings and jurisdictions is required to ensure data can be accessed at scale.

Market Access, Reimbursement & Procurement – There continues to be no direct pathway for high value digital health technologies to be developed and adopted in the Canadian health care system. In some jurisdictions, there is a predilection to proof-of-concepts/pilots/limited rollouts, without corresponding implementation plans that identify key metrics and outcomes to advance broad-scale implementation and committed funding. This delays widespread adoption and this lack of commitment and/or clear path to adoption can disincentivize industry to invest in research in Canada.

Where a procurement path exists, a focus on the lowest price or the immediate need, as opposed to the long-term opportunity, without consideration for innovation or quality, further erodes opportunities to advance digital health care. For example, procurement processes must be able to distinguish between different types and levels of products and services and consequently consider the comparative value provided by different offerings beyond the lowest price. Even under a quality-price formula regime, the weighting of the quality factor is often either too low or non-existent to have a real impact to promote quality, let alone innovation versus the lowest price.

There are innovative solutions that are not being used in Canada that have proven effective in other jurisdictions. The slow adoption of clinical health informatics infrastructure also hinders the adoption and use of existing informatics platforms and digital health technologies. The lack of a sound IT infrastructure with CPOE (Computerized Physician Order Entry), BCMA (Barcoded Medication Administration) and EMRs, limits the value industry can compete for in the sector. Innovation often does not come at the lowest price. On the other hand, the adoption of innovation most often results in a positive return on investment when measuring the impact to the health care system and/or patient care/outcomes. Several case studies highlight the benefits of using criteria other than price when selecting medical technologies.

For example, the 2014/24 European Public Procurement Directive encourages this smarter and more holistic approach to public procurement which, stimulates innovation and provides

the Most Economically Advantageous Tender (MEAT). A value-based procurement approach can help break organizational silos within health facilities, reduce inefficiencies and spur innovation-driven investments.

The potential of procurement to support Value-Based Health Care (VBHC) remains largely untapped in Canada. Value-based sourcing is only possible when transactions go beyond short-term cost savings to involve quality factors such as technical merit, accessibility, environmental features, and innovative features. By choosing the most valuable health care products, services and solutions, procurement has the power to move the needle to smarter, more cost-effective spending.

Domestic Experience – The need for domestic/local research that replicates outcomes achieved through international studies can sometimes delay or limit the scope, scale, and timing of adoption of digital solutions.

Open Data – While there is often a focus on domestic experience amongst decision makers when considering the value of digital technologies, Canadians have yet to adopt an open data/open science mindset. To continue to develop products and services that specifically take into account domestic experiences, there must be a willingness to engage in long-term and ongoing exchanges of research, training and knowledge transfer between health care providers and industry.

It is imperative to create opportunities and incentives between industry and research hospitals to enable the deployment of evidence/tools resulting from research collaborations in health systems. These collaborations stimulate the growth and adoption of new technologies/clinical procedures that mutually benefit the health system and the life sciences sector.

To advance this approach, as noted above, greater clarity is needed on how data can/should be managed, and the responsibilities associated with ownership of complex data sets. Patient consent/education on how data is shared and used is also needed to assist with implementation of digital tools and the rights patients have to control use of their information.

How do rules regarding the development and approval of digital products and services impact their availability and use? What steps can be taken to facilitate the development and approval of digital products and services?

The rules regarding the development and approval of digital products and services are often complex and time-consuming, resulting in long lead times for solutions. In some cases, this process can serve as a deterrent for innovators to bring solutions to the Canadian market.

Recommendations include:

1. Adopt a strategic global vision for digital products and services

   - Policies and programs (including financial incentives) must be both at a speed and scale that match the attractive offerings of competing jurisdictions, while identifying opportunities for international collaboration

   - Support the development of a value-based governance framework for innovation and procurement to move from innovation to commercialization and local adoption

2. Streamline and simplify the development and approval process
   - Review the Health Technology Assessment (HTA) process and create a fit for purpose system that allows for a prioritization with quality-of-care indicators along with the implementation of real world data to generate real world evidence (RWE)
   - Connect multiple stakeholders to create provincial toolkits to ensure a streamlined and consistent approval process for digital technologies in the healthcare space
   - Identify best practices from other jurisdictions to streamline and simplify the approval process
   - Consider utilizing a governing body like the Canadian Standards Association (CSA) for assessment and classification of products and services (similar to Health Canada's device classification of one to four)
3. Promote collaboration
   - Increase opportunities for collaboration between industry, academia, healthcare providers, and payers. Greater partnership will create shared accountabilities and facilitate the development of innovative solutions that meet collective needs

How do procurement and commercialization processes impact the ability for businesses to innovate and compete in the market for digital health care products and services? How can more innovation and competition be encouraged?

Broader Public Sector (BPS) adoption and guidelines are difficult to manage and the process to be included in lists for preferred vendors of records is not updated at the same speed by which services and innovations can be developed. The complex procurement processes in a publicly funded system often create an environment where large scale projects are required to justify the effort and resources required to procure new innovations.

Additionally, vendor of record (VOR) processes focus on cost, sometimes to the detriment of innovation and innovative thinking that industry leaders (at higher unit costs) bring to a particular problem. To promote innovation, consideration should be given to the value of partnerships and the ability to collaborate and innovate collectively over a longer-term.

Digital health care products and services should be complementary to existing services and products to not increase the total health care budget but rather contribute to higher efficiency such as time savings. Such savings should be considered in any procurement process as part of the evaluation framework.

RFP's could be drafted in such a way as to permit companies to provide digital offerings that complement the products being procured beyond "value-adds". Value adds can be challenging if they are requested in ways that are not compliant with our healthcare compliance guidelines. As such, ways in which digital services can be offered compliantly, potentially outside of the value-add portion of the RFP, could generate more innovative bid responses.

Innovation and competition can be encouraged through transparency and partnership with industry. Health system planners should work with industry to develop a long-term strategy for digital health, which articulates the system level goals and overarching approach to achieve greater integration and connectivity. The current environment fosters inefficiency and

redundancy. There is a need to create opportunities for public and private partnerships as an incentive towards the development of an integrated system. This will also allow for shared responsibility amongst the sectors and break down further silos. For example, defining the broad parameters through which digital health will be achieved will allow industry to focus efforts and develop solutions that are both competitive and compatible (as opposed to the competitive, stand-alone solutions developed today). To move forward, we must all be moving in the same direction - rather than what occurs today, where we veer left to right, and sometimes backwards before we can move forward.

HEALTH CARE PROVIDERS

Are there barriers (regulatory or non-regulatory) that are restricting the ability of health care providers to deliver digital health care to patients? How have these barriers impacted the competitive landscape for digital health care?

Regulatory Barriers

Privacy – While the protection for personal health information (PHI) is necessary, at times, the interpretation and/or application of regulations meant to protect PHI impede the ability for health care providers to share information. Careful review of how HICs are defined and clarity on the responsibilities and liabilities of HICs are needed to promote the use of digital tools.

Scope of Practice – In some cases, scope of practice regulations may limit the adoption of certain technologies amongst health care providers where their scope of practice would limit their ability to realize the full benefits of an innovation; thereby reducing the overall value proposition of the product.

Non-Regulatory Barriers

Compensation – The FFS compensation structure for many health care providers acts as a disincentive to adopt technologies that replace activities, particularly where an analogous fee-code for digital care does not exist. Fair physician fees/billing codes need to be available so that health care providers are encouraged to adopt digital health care services including diagnosis and remote management of patients.

Training – clinician comfort with technology, combined with the lack of clarity on roles and responsibilities, can impeded technology adoption. Health Care providers require training and education on how best to incorporate digital services into their practices.

Fear – many digital technologies can create efficiencies that may be seen to displace the need for health human resources. Fear of job loss due to changes to care pathways (e.g., movement of patients from hospital to home) and/or required qualifications can impede adoption.

Technical Limitations – Among other aspects, health care providers require solutions that are efficient and accommodate their workflows. The lack of interoperability with EMRs and clear policies on the adoption of new technologies, limit the provider's willingness to use and recommend digital health tools and resources to patients. These limitations pose a significant

threat to the industry's ability to spread and scale competing offerings to both providers and patients.

Increased Responsibility - The responsibility of the HIC can impact the landscape development. Responsible data management means that the collection and use of data is conducted in a lawful, fair, legitimate and ethical way, and always while respecting the privacy rights of individuals. It does not mean lack of transparency.

To unlock the value of digital technology and deliver better services, we need to review the role of an HIC and patient consent. There needs to be a focus on impact and connectivity as opposed to sheltering information between providers. This is key in the patient journey to align with multiple providers.

Obligation to share and changing the mindset is instrumental. Individuals have an obligation to recognize the importance of sharing data and information to benefit their own health and to benefit the public, such as research to improve publicly funded health services, while recognizing that custodians have a duty to respect, protect and fulfill personal health data rights.

How do billing codes and compensation mechanisms for health care providers impact the delivery of digital health care? What steps can be taken to facilitate digital health care delivery?

As noted above, FFS compensation structure is rigid and acts as a disincentive to the delivery of digital health care. If there are no billing codes nor incentives to change or evolve clinical practice that includes the use of digital health technologies/solutions (e.g., virtual care), then the adoption, utility and positive impact of value-based digital health tools/technologies/solutions cannot be fully optimized.

The FFS compensation model is slow to reflect changes in best practices, as adding or changing fees is difficult, time-consuming, and expensive. Moreover, if there is fragmentation or inconsistency in how billing codes are applied or implemented across provinces, then this may create a fragmented perspective on the value of digital health technologies/solutions that can support clinical practice and improved patient outcomes, thereby creating variation among the provinces as to how they may value the role of digital health technologies/solutions.

Recommendations include:

1. The FFS model promotes repetition and does not lend itself to innovative health service delivery. Different compensation models should be considered that promote integrated care delivery. Examples could include capitation, salary, or block funding.

2. Should FFS continue to be the dominate compensation model, there needs to be an equivalency of digital to in-office or in-person patient care as the same level of expertise, education and clinical know how goes into the evaluation and diagnosis of patients. For example, the notion that it requires less time to review lab results online versus at an in person visit needs to be addressed.

3. Consideration should be given to formulating a Digital Health Valuation Framework to serve as input into appropriate funding and reimbursement policies (i.e., economic impact, safety and clinical effectiveness, patient experience etc.).

How do rules regarding medical licencing impact the ability of health care providers to deliver digital health care? What steps can be taken to further enable the delivery of digital health care?

- There is an opportunity especially with the increased value and utility of virtual care to ensure that medical licencing is uniformly recognized inter-provincially to align with some of the key pillars of Medicare including portability and accessibility no matter where one needs care in Canada.

- Licensing contracts with standard Terms & Conditions would ensure a timely implementation process for these providers. Clarity on who can sign contractual license agreements for digital technologies would ensure a safe and sound pathway for integration and adoption.

- Medical schools and licensing bodies such as the CMA or Royal College need to incorporate basic requirements for digital proficiency and certification. Otherwise, if not mandated, the adoption and modernization of the health care system will lag.

- Recognition by self-governing medical associations/bodies of legitimate partnerships with industry could open the door to innovations; innovations that may currently be impeded due to inflexibility in the association codes of conduct. The codes or guidance of the codes could be updated to provide examples in which industry can work with Health Care Professionals (HCP's) in a manner that compliantly addresses the gaps in our current healthcare system, without injecting offside inducements.

How do rules regarding the scope of practice for health care providers impact their ability to deliver digital health care to patients? For whom and how can the scope of practice be modified to further enable the delivery of digital health care?

Scope of practice for regulated health professionals are determined by the provinces and the relevant professional colleges. That said, there is an opportunity to assess current scope of practice for some health care professionals that align to various provincial digital health priorities focused on improving patient access, outcomes, and continuity of care. For example, greater integration of pharmacists in the delivery of virtual care may be a benefit to Canadians, especially to educate patients as well as support remote monitoring of various conditions such as diabetes or cardiovascular disease.

In addition, opportunities identified through the pandemic to broaden the scope of practice for Pharmacists (as an example) can create further person-centred care and an easier journey for patients to navigate the health care system. Scope of practice could be evaluated to explore the full benefits of innovation and increasing the ROI and value added. There could be an opportunity to further explore the Nurse Practitioner role as a way to assist with digital opportunities and telehealth.

CONCLUSION

Medtech Canada looks forward to working with the Competition Bureau in shaping the future of digital health care. We believe that these recommendations would strongly contribute to a robust Canadian digital health care sector. Thank you for your consideration of our recommendations. If you have any questions or would like to discuss further, please contact:

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Raj Malik, Vice President, Federal Affairs & Health Systems, Medtech Canada at rmalik@medtechcanada.org or (416) 809-4665.

Additional Resources

Canada Health Infoway

- "A Healthy Dialogue" found that 80% of Canadians are open to sharing their anonymized data to benefit the health system.

https://access2022.ca/section/a-healthy-dialogue

A Healthy Dialogue
Executive Summary.pc

2018-19 Survey of Canadians on Privacy - Office of the Privacy Commissioner of Canada

According to a 2018-2019 national survey conducted on behalf of the Office of the Privacy Commissioner of Canada:

- 92% of survey participants (public) expressed some level of concern about their privacy

- 45% did not feel that businesses generally respect their privacy rights

- 88% of survey participants were at least somewhat concerned about organizations using their online information to make decisions about them

- 74% have not installed or have uninstalled apps because they were concerned about the personal information they were being asked to provide

Information Technology Association of Canada

https://technationcanada.ca/wp-content/uploads/2020/10/ITAC-govt-Cloud-paper-Eng-sept2019-final.pdf

- *"If government does not adopt a cloud environment, it will be increasingly difficult to access or leverage the latest software innovations—and that includes the latest in security services."*

Health Data Hub

In France, the **Health Data Hub[5]** allows easy and unified access, transparent and secure, to health data to improve the quality of care and patient support. The Health Data Hub relies on academic, industrial, national and international partnerships. Articulated around 4 strategic issues, the Health Data Hub's service offerings aim to create a real reinforcement of capacity to innovate to make France a leader in health data analysis.

1. Highlighting the data heritage

2. Making it easier to use data

3. Protect citizens' data

4. Innovating with all stakeholders

MedTech Europe

https://www.medtecheurope.org/resource-library/unlocking-the-full-benefits-of-health-data-recommendations-from-medtech-europe/

160621_mte_position paper_health-data.pdf

Advanced Medical Technology Association

Advanced Principles on Sharing Health data

https://www.advamed.org/member-center/resource-library/advamed-u-s-health-data-privacy-principles/?_ga=2.248629444.2129111159.1624024842-613045982.1624024842

advamed-us-health-data-privacy-principles

International Pharmaceutical & Medical Device Privacy Consortium (IPMPC)

https://docs.wixstatic.com/ugd/932589_9477b774bed744e1a3bf1888fe6f7d4e.pdf