Canada's Drug and Health Technology Agency

CDA-AMC Health Technology Review

Implementation Review for Artificial Intelligence-Enabled Medical Devices: Main Report

August 2024

Implementation Review

Abbreviations

AI	artificial intelligence
API	Application Programming Interface
CDA-AMC	Canada's Drug Agency – L'Agence des médicaments du Canada
DTAC	Digital Technology Assessment Criteria
DHIEX	digital health information exchange
DHT	digital health technology
HTERP	Health Technology Expert Review Panel
HTA	Health Technology Assessment
IT	Information Technology
MFA	Multi-Factor Authentication
ML	machine learning
MLMD	machine learning(-enabled) medical device
NHS	National Health Service
OWASP	Open Web Application Security Project
PHI	personal health information
PIPEDA	Personal Information Protection and Electronic Documents Act
SaMD	Software as a Medical Device
SME	small and medium-sized enterprises
WHO	World Health Organization

Key Messages

What is the Issue?

- Artificial intelligence (AI) uses algorithms or models to perform tasks and mimic human behaviours such as learning, making decisions, and making predictions. Globally, we are seeing a widespread increase in the interest, development, and use of AI-enabled medical devices. Comprehensive evaluation within health technology assessment (HTA) can ensure that digital health technologies, including AI-enabled medical devices, are adequately equipped to balance benefits and harms, while being interoperable and equitably accessible to people living in Canada.
- In the UK, a checklist called Digital Technology Assessment Criteria (DTAC) is used as an add-on component to HTAs to capture additional considerations for the implementation of digital health technologies. The 5 core areas of DTAC include clinical safety, data protection, technical security, interoperability, and usability and accessibility. In Canada, we currently do not have a tool equivalent to DTAC that can be used as an add-on to traditional HTA.
- An implementation review is needed to assist health systems in Canada in preparing for the uptake of digital health and AI-enabled medical devices, as these technologies pose new challenges, by assessing whether the safeguards and assessment criteria captured by DTAC and other AI-related resources are in place.

What Did We Do?

- We conducted an implementation review, using a phased approach, to determine if DTAC can be applied to the health care context within Canada to inform the implementation of digital health technologies and to identify any additional implementation considerations specific to the use of AI-enabled medical devices in Canada. We integrated ethics and equity considerations across both phases of the review.
- In phase 1, we applied DTAC to the health care context in Canada by determining whether we have equivalent or similar measures, strategies, and policies in place to implement digital health technologies safely.

- In phase 2, an information specialist searched for literature to identify implementation guidance specific to AI and relevant to Canada to supplement DTAC. One reviewer screened publications for inclusion based on predefined criteria, incorporated relevant information into tables, and narratively summarized the findings.
- We leveraged patient engagement activities conducted in a concurrent Canada's Drug Agency review of a specific AI-enabled medical device in stroke detection to learn from a patient contributor with lived experience of a hemorrhagic stroke. We learned about her experience, perspectives, priorities, and thoughts about using AI in clinical decision-making.

What Did We Find?

- With some caveats, we found that many of DTAC's assessment criteria have equivalent or similar guidance for the health care context in Canada. Some exceptions derive from the differences in Canada's current governance and health care structure (e.g., the level of governance for Canada's privacy laws depends on the type of data and jurisdiction and, unlike the UK, Canada does not have electronic health records managed at the federal level). Further investigation is required to understand if certain policies in Canada provide sufficient coverage to fulfill DTAC's criteria (e.g., clinical safety).
- We identified several considerations for implementing AI-enabled medical devices, with many having underlying ethical and equity implications. Much of the identified guidance emphasizes implementation considerations that apply to the AI system's entire lifecycle, including the most prevalent consideration: ensuring AI-enabled medical devices are monitored, maintained, and sustainable. Examples of additional considerations include AI data governance and data protection; transparency and explainability (e.g., AI models must be explainable for all users); and inclusiveness, equity, and minimizing bias (e.g., ensuring data used to train AI is representative of the intended population).
- The patient contributor highlighted several considerations relevant for this review, such as data protection and privacy (e.g., informing the patient about using AI technologies as part of care provided) and accessibility and equity (e.g., equitable access).

What Does This Mean?

- We have identified key considerations for AI-enabled medical devices that health care decision-makers may consider for the safe and successful implementation of AI in health care in Canada.
- This implementation review for all AI-enabled medical devices is to be used alongside reviews of specific AI technologies, including the concurrent review of RapidAI for Stroke Detection, and will serve as a foundational report to be tailored for each AI topic and updated with the latest developments in the regulation and other aspects of management of AI in the context of Canada.

Context and Policy Issues

What Are AI-Enabled Medical Devices?

Digital health technologies (DHTs), including AI-enabled medical devices, are advancing rapidly and generating much hope and hype.[1] Artificial Intelligence (AI) uses algorithms or models to perform tasks and mimic human behaviours such as learning, making decisions, and making predictions.[2] When a medical device incorporates AI algorithms and machine learning (ML) models to enhance its functionality and performance, it is often described as an AI-enabled medical device or MLMD.[2,3] An example of an AI-enabled medical device is the software platform RapidAI,[4] which was assessed alongside this review (found on the project website). RapidAI provides tools for medical imaging by using AI to facilitate viewing, processing, and analysis of CT images.[4] The overarching goal of RapidAI is to help clinicians assess patients with suspected medical conditions and determine the appropriate treatment.[4] While DHTs promise to improve various outcomes (e.g., better access to health care), evaluating and implementing them presents new and unique challenges. AI likely poses all the challenges (e.g., data considerations, interoperability issues) characteristic of other classes of DHTs and additional ones (e.g., algorithmic fairness and biases, black-box or continuous-learning nature),[5-7] serving as a useful test case for addressing the many new and unique challenges posed by DHTs.

How Are AI-Enabled Medical Devices Regulated in Canada?

In Canada, medical devices are regulated by the Medical Devices Regulations, which are established under the authority of the Food and Drugs Act.[8,9] The Regulations utilize a risk-based approach to regulating products within their scope, with devices classified into 1 of 4 classes (i.e., Class I represents the lowest risk and Class IV the highest).[10] Software has become an increasingly important part of many products integrated widely into digital platforms, including those used for medical purposes.[10,11] In 2019, Health Canada provided guidance documents to clarify how Software as a Medical Device (SaMD) fits into Health Canada's regulatory framework for medical devices, including examples of software using AI.[10,12] SaMD is defined as software intended to be used for 1 or more medical purposes that perform these purposes without being part of a hardware medical device.[10,12]

All health care organizations, including regulatory bodies and HTA agencies, in Canada and internationally face similar challenges associated with DHTs, including AI-enabled medical devices, that go beyond each organization's or jurisdiction's purview. As such, there has been a strong interest in working together and aligning approaches across organizations and jurisdictions,[13] and important work has been aligned with Canada, the UK, and the US in the regulatory setting.[14,15]

Why Is It Important to Do This Review?

Globally, we are seeing an increase in medical devices relying upon software incorporating AI.[3] With the inherent nature of AI being a disruptive technology in health care, its comprehensive assessment within health technology assessment (HTA) is essential to ensure that DHTs are adequately equipped to balance benefits and harms, while being interoperable and equitably accessible for people living in Canada. To this end, CDA-AMC recognized the importance and timeliness of assessing AI-enabled medical devices and included an activity in its 2024-25 Annual Business Plan to support the implementation of AI by several means, including the assessment of an AI-driven technology in radiology using a digital health assessment framework.[16] This review addressed that objective, identifying and describing implementation considerations specific to the use of AI-enabled medical devices in Canada, alongside a review of a specific AI technology called RapidAI for stroke detection (found on the project website).

CDA-AMC has recently established information-sharing and collaborative relationships with various organizations, including an international HTA partnership of HTA bodies.[17] From this partnership, CDA-AMC learned of the Scottish Health Technology Group's evidence framework, which outlines an approach to DHT assessment.[18] This includes an HTA framework[19] and Digital Technology Assessment Criteria (DTAC)[20] as an add-on component. The Scottish group's approach to add on DTAC is consistent with the National Institute for Health and Care Excellence's approach (i.e., mandates DTAC for use in the National Health Service [NHS]). This review of implementation considerations applied DTAC[20] to the health care setting in Canada. The accompanying review of RapidAI for Stroke Detection (found on the project website) applied the Scottish Health Technology Group's HTA framework,[19] leveraging existing work to ensure alignment and harmonization across organizations and to gain efficiency and sustainability and planning to share our experiences with the framework and the criteria with the international partners.

DTAC is a checklist that captures the additional considerations for the implementation of DHTs not captured by traditional HTA that need to be completed and approved as minimum baseline standards for use in the UK setting.[20] For example, it includes 5 core areas to establish whether the product is clinically safe to use from risk management perspectives (i.e., under "clinical safety"); collects, stores, and uses data compliantly (i.e., under "data protection"); meets industry best practice security standards (i.e., under "technical security"); exchanges data with other systems well (i.e., under "interoperability"); and follows best practice and meets user needs (i.e., under "usability and accessibility").[20] As of August 2024, Canada does not have a DTAC equivalent for health care systems to use at the point of procurement or as part of an ongoing monitoring process for DHTs, including AI-enabled medical devices. While its questions are generally specific to the UK setting, we expected DTAC could be applied to the health care context within Canada to inform the implementation of DHTs.

Objectives

This report aims to assist health systems in Canada in preparing for the uptake of AI-enabled medical devices by assessing whether appropriate safeguards and assessment criteria are in place. The key objectives of this implementation review are to identify and describe implementation considerations specific to the use of AI-enabled medical devices in Canada.

The target audience of this work is large and includes regulators, government officials, health care decision-makers, clinicians, health care professionals, DHT developers, and researchers, among others.

Research Question

1. What are the implementation considerations for the use of AI-enabled medical devices in Canada?

Methods

Study Design

We conducted an implementation review using a 2-phase approach:

i. we applied DTAC to the health care context in Canada by determining whether we have equivalent or similar measures, strategies, and policies in place to implement DHTs in Canada safely (phase I).

ii. we conducted a literature review to identify implementation toolkits, guidance, and recommendations specific to AI and relevant to Canada to supplement DTAC, in case there are any additional considerations important for AI-enabled medical devices use in Canada (phase II).

We integrated patient input and ethics and equity considerations across both phases of the implementation review.

This report is not a systematic review and did not involve a critical appraisal of the literature. It is not intended to provide recommendations for or against the use of AI in health care. Thus, conclusions or recommendations about the value of or place in therapy for AI are outside of this report's scope.

Phase 1. Apply DTAC

For this review, we focused on applying all assessment criteria (i.e., Sections C and D) of DTAC to the health care context in Canada. Section C focuses on DTAC's core assessment criteria, which includes technical questions about clinical safety, data protection, technical security, and interoperability criteria. Section D focuses on key usability and accessibility principles.

For each component of Section C and D of DTAC, one researcher reviewed each question within and:

- determined what the question is asking and who is responsible for addressing it in the context of the UK;
- investigated who is responsible for overseeing the element identified by the question in the context of Canada (e.g., federal government, provincial/territorial government, international organization);
- investigated what measures, strategies, and policies are in place in Canada to address the question if they are regulated or mandated in some capacity (e.g., by Health Canada) and whether they are equivalent or similar to the UK;

One reviewer obtained publicly accessible documents from government websites (e.g., the NHS in the UK, Government of Canada) and organizational websites (e.g., International Organization for Standardization). One reviewer extracted and populated these data into tables in Microsoft Word and progressed to Phase 2.

Phase 2. Conduct Literature Review

Literature Search Methods

An information specialist conducted a focused internet search using keywords describing AI in health care and artificially intelligent medical devices, by browsing and searching sources listed in relevant sections of Grey Matters: A Practical Tool For Searching

Health-Related Grey Literature.[21] Sections included websites of Canadian and major international health technology agencies, regulatory agencies, and international health organizations to identify information on the implementation considerations for AI in health care. Searching was completed on May 21, 2024. The information specialist limited the search to English-language documents.

Screening and Guidance Selection

One reviewer screened the literature search results in Microsoft Word and reviewed the full text of all potentially relevant publications. Table 1 presents the selection criteria.

Table 1: Selection Criteria

Criteria	Description
Concept	Implementation considerations for the use of AI-enabled medical devices [a]
Context	Canada and comparable health systems to Canada[b]
Types of Sources	Implementation toolkits, guidance, and recommendations (e.g., guidance from reputable health organizations or professional associations)
Publication Date	No date limits
Language	English

AI = artificial intelligence.

[a] We define AI-enabled medical devices as those used for medical purposes to have a direct involvement in and direct impact on patient care to achieve specific health outcomes for those patients, aligned with Health Canada's approach to defining Software as a Medical Device[22] and NICE's Evidence Standards Framework for Digital Health Technologies and Tier C technologies.[23]

[b] Countries that qualified as having comparable health systems to Canada for this review included (listed in alphabetical order): Australia, France, Germany, Netherlands, and UK, which are Organisation for Economic Co-operation and Development (OECD) members and have a mix of public and private health care.[24]

Exclusion Criteria

One reviewer excluded publications that did not meet the selection criteria outlined in Table 1. If a guidance document included outdated evidence (e.g., describes a law that no longer applies), we only included the current and relevant information for this review.

Data Extraction

We used a pragmatic approach to extract and synthesize the data. One reviewer extracted and populated all relevant data into tables in Microsoft Word, including bibliographic details, such as organization name, year of publication, country, target audience (e.g., regulators, DHT developers), and principal components addressed (e.g., clinical safety, data privacy, interoperability).

Analysis, Synthesis, And Reporting of Findings

During phase 1, the reviewer first populated Table 2 in the Supporting Information document (found on the project website; refer to *Main Findings*) with details about what each assessment question is asking, who is responsible in the context of the UK and Canada, and any equivalent measures, strategies, and policies that are in place in Canada. During phase 2, the reviewer conducted a descriptive analysis to supplement the data table from Phase 1 (i.e., Table 2 in Supporting Information document [refer to *Main Findings*]) by adding additional implementation consideration themes identified for using AI-enabled medical devices in Canada next to the corresponding sections (i.e., grouping similar considerations together, determining theme names based on these groupings). Table 3 in the Supporting Information document (refer to *Main Findings*) provides detailed examples of these additional implementation considerations identified for AI-enabled medical devices. The reviewer produced a narrative summary of the results presented in the Supporting Information document (refer to *Main Findings*). Finally, the reviewer provided general conclusions about whether Canada has DTAC's assessment considerations already in place by our various jurisdictions in Canada.

Ethics and Equity Considerations

The integration of ethics and equity considerations was driven by an analysis of key items with ethics and equity implications arising in DTAC, augmented by key Ethics of AI tools and frameworks (e.g. UNESCO Recommendation on the Ethics of AI;[25] WHO Guidance: Ethics and Governance of AI for Health),[26] as well as the EUnetHTA Core Model 3.0 Ethics Domain[27] and the Equity Checklist for HTA.[28]

We used prompts and guiding principles from these sources to help identify and reflect on ethics and equity considerations in the implementation of AI and DHTs relevant to patients, providers, and health systems. With the assistance of a reviewer with ethics expertise, we synthesized the findings of these prompts and descriptive analyses into analytic categories representing the key ethical and equity considerations related to AI and the implementation of DHTs more broadly.

Patient and Clinician Engagement

Invitation to Participate and Consent

Patient and clinician engagement is an important component of our projects, as it allows us to consider their experiences when writing our report. We leveraged the engagement activities conducted for the RapidAI review (found on the project website) to incorporate input from patients and clinicians into this project.

For the RapidAI review, we disseminated a patient engagement request for individuals with lived experience of a hemorrhagic stroke through several large patient advocacy groups. We also sent an engagement request to several clinics that specialize in AI and use RapidAI, seeking a clinician to participate in a 1:1 engagement. Interested individuals – 1 patient and 1 clinician – responded to our outreach requests, and a Patient Engagement Officer conducted introductory discussions by email or Zoom. During these initial discussions, the Patient Engagement Officer described CDA-AMC and gave an overview of the purpose and scope of the project and the nature of the engagement. Both interested parties were invited to participate, and the interested patient agreed. The clinician declined due to time constraints.

The Patient Engagement Officer obtained informed consent from the patient contributor to participate in a discussion with CDA-AMC project team members and for a recording and summary of the discussion to be shared with the broader project team for their review. The patient contributor was offered a gift card as a gesture of thanks for her time and expertise and was offered the opportunity to be thanked by name in the report or to remain anonymous.

Engagement Activities

We invited the patient contributor to participate in an interview facilitated by the Patient Engagement Officer. Three members of the project team also attended. The purpose of attending the dialogue is for the project team members to hear directly from an individual with lived experience of a hemorrhagic stroke and ask questions relating to what they are reading in the literature, including AI use in health care. This offered insights to the project team members and allowed for a more nuanced understanding of the literature.

With the patient contributor's consent, we recorded the dialogue for note-taking purposes, and so that other members of the project team could review and learn from the conversation. We structured the interview into 2 parts: (i) the patient contributor's lived experience with a stroke and (ii) AI in interpreting image results. Patient involvement was guided by the Guidance for Reporting Involvement of Patients and the Public (version 2) Short Form reporting checklist,[29] which is outlined in Table 4 of the Supporting Information document (found on the project website; refer to *Patient Engagement*).

The Patient Engagement Officer subsequently drafted a summary of the conversation and sent it to the patient contributor for review and approval. The summary was used as a prompt for the authors of this report as they were drafting the report and was not published. To inform this review, we used the summary to extract any discussion points or themes related to AI implementation considerations.

External Review

Peer Review

Before the review phase began, 1 clinical expert with expertise in stroke assessment, 1 clinical expert with expertise in AI radiology, and 1 ethics expert with expertise in AI consulted for the RapidAI review (found on the project website) reviewed the project plan. The same experts will review this draft version of the report, and their feedback will be incorporated into the final version of the report.

Feedback Opportunity

This draft version of the report will be posted on the CDA-AMC's website. This allows for interested parties the opportunity to provide feedback on the draft report. All feedback will be considered, and, where appropriate, revisions will be made to the draft report and reflected in the final version.

Summary of Findings

Summary of Included Guidance

For phase 1 of this review, we used DTAC as our reference document and applied it to the health care context in Canada. We identified most of the relevant information to contextualize each assessment question in DTAC from the UK setting to Canada from search engine results of government websites (e.g., provincial, territorial, and federal) and websites of international organizations (e.g., International Organization for Standardization).

For phase 2 of this review, our literature search results included 13 relevant guidance documents that described implementation considerations for AI-enabled medical devices. Among these documents, we focused our data extraction, analysis, and synthesis from the general health guidance documents from Canada (i.e., directly applicable to health care context in Canada, not specialty-specific). We also used the Ethics and Governance of AI for Health report from the WHO and the other identified international guidance as contextual examples.

Guidance from Canada

We identified 8 relevant guidance documents from Canada.

Canada Health Infoway published a comprehensive toolkit for implementers of AI in health care.[30] This toolkit provides an overview of the issues related to implementing and using AI solutions in health care. It offers strategic and operational guidance for designing responsible AI projects and governance programs. The guidance includes thorough checklists for identifying and addressing bias in AI systems, AI vendor assessment, and data testing and monitoring.[30] For example, the AI vendor assessment checklist could be used as a guide when evaluating vendors for any AI-related medical devices in the health care context. The checklist asks several questions under the following categories: commitment to responsible innovation, value alignment, inclusivity, nature of technology, risk management, data quality testing, data access, data sharing, transparency and explainability, human oversight, accountability, and knowledge transfer.[30] Canada Health Infoway also published an additional digital health solutions guidance document regarding privacy and security for vendors, health care organizations, and patients.[31] This guideline contains a small subsection about health care AI, and its content largely overlaps with Canada Health Infoway's Toolkit for Implementers of AI.[31]

Health Canada, the UK Medicines and Healthcare products Regulatory Agency, and the US Food and Drug Administration jointly published 10 guiding principles that can inform the development of good ML practices promoting safe, effective, and high-quality AI- and MLMDs.[15] Health Canada has since released draft pre-market guidance for an ML system of an ML-enabled medical device.[32] Health Canada's pre-market guidance targets manufacturers submitting a new or amendment for Class II, III, or IV MLMDs under the regulations.[32] Health Canada also expects applications for an MLMD to include information about how the manufacturer has adopted good ML practice[15] within the organization and implanted them through the product lifecycle.[32] For example, transparency requirements should consider those involved in patient health care across the medical device's lifecycle (e.g., patients, users, health care providers, and regulators).[32]

The Vector Institute, an Ontario-based AI research institute, produced a Health AI Implementation Toolkit[33] to highlight common deployment barriers for those looking to implement innovative health AI research in a clinical context. This guidance includes a health AI implementation checklist under 4 primary considerations: do you have a mature, validated AI model? What is your technical

integration strategy? What is your change management strategy? Do you have a data governance and sustainability plan? This guidance primarily targets individuals (e.g., researchers, clinicians, health professionals) who have developed a robust, mature health AI model or application and are looking to deploy their solution in a clinical environment.[33]

In 2022, the Canadian Law and HTA Working Group published Legal Guidance for HTA bodies.[34] This publication is intended to support Canadian HTA bodies in incorporating legal analysis into their evaluations. Its primary target audience is non-lawyers working within HTA bodies. For example, they mention AI poses an increased risk of privacy breaches and acknowledge the existing legislation attempts to balance the patient's right to privacy with the needs of health care workers, administrators, and policy makers to use and disclose the information to provide treatment, conduct research, perform billing, and deliver effective health care. This guidance provides trigger questions for HTA bodies to consider around such topics. Additionally, we identified other specialty-specific guidance from reputable associations (e.g., the Registered Nurses' Association of Ontario for clinical practice in a digital health environment and the Canadian Association of Radiologists for ethical and legal issues related to AI in radiology).[35,36]

International Guidance

We identified 5 international guidance documents aimed at health systems comparable to Canada,[24] including Australia, France, the UK, and the WHO.

The WHO published a report that endorses key ethical principles for the use of AI for health.[26] The WHO[37] also developed a framework that provides an overview of considerations used in evaluating clinical evidence regarding AI-SaMD, aiming to help formulate a consensus for guiding validation, evidence generation, and reporting across the total product life-cycle within a global health context. Given the nature of this guidance, we focused on extracting information related to implementation considerations (e.g., deployment, post-deployment monitoring and surveillance) rather than clinical evaluation.[37]

The UK's Medicines and Healthcare products Regulatory Agency produced guidance to ensure that medical device regulation is fit for purpose for software, including AI.[38] Moreover, the UK has further regulatory guidance on the regulation of AI as an medical device[39] and NICE's evidence standards framework for DHTs for the HTA setting now includes evidence requirements for AI and data-driven technologies with adaptive algorithms.[23] The Australian government regulates AI as an medical device when it is used for diagnosis, prevention, monitoring, prediction, prognosis, treatment, or alleviation of disease, injury or disability.[40] They also have evidence requirements for AI software throughout the product lifecycle and include robust post-market monitoring practices to ensure continued device performance and model accuracy.[40] Haute Autorité de Santé in France has a guide for submitting a medical device and health technology for HTA.[41] They provide a 7-page table for applicants to complete when the medical device has at least 1 ML process.[41]

We provided details regarding the publications included in the Supporting Information document (found on the project website; refer to *Characteristics of Included Guidance*). We described additional details about the relevant AI considerations in the subsequent section and Table 3 of the Supporting Information document (refer to *Main Findings*).[30] We also provided a list of potential references of interest that did not meet our eligibility criteria in the Supporting Information document (refer to *References of Potential Interest*), which includes publications focusing on knowledge user perspectives and examples of preliminary frameworks or guidance as additional resources that may be useful to others.

Implementation Considerations

Implementation considerations identified from DTAC and guidance from Canada and international sources were organized by the 5 core areas of DTAC: clinical safety, data protection, technical security, interoperability, and usability and accessibility.

Clinical Safety (Section C1 of DTAC)

Applying DTAC's Section C1 to the Health Care Context in Canada

The clinical safety section of DTAC provides considerations to establish that the DHT product is clinically safe to use beyond the typical clinical benefits and harms considerations in HTA from risk management perspectives (e.g., clinical risk management activities for the development and maintenance of health information technology [IT] systems).[20] Where we found an equivalent

measure, strategy, or policy, clinical safety considerations described in DTAC are federally governed in both the UK (i.e., NHS, Medicines and Healthcare products Regulatory Agency) and Canada (i.e., Health Canada).

Specifically, for the UK, DTAC asks whether Clinical Risk Management activities undertaken for the DHT product comply with DCB0129, a standard for organizations responsible for health IT development and maintenance. DCB0129 outlines the clinical risk management standards for manufacturers of health IT systems. In Canada, a similar international standard to DCB0129 is ISO 1491, which applies to manufacturers of medical devices worldwide.[42] For medical devices in Canada, manufacturers of Class II, III, and IV devices must obtain a medical device license (i.e., a Medical Device's Active License) before selling a medical device in Canada.[43] The application for a medical device license is completed through Health Canada.[44] Class I medical devices do not require a license but are monitored through the establishment licensing process.[43] Health Canada has medical devices regulations (SOR/98-282) outlining safety and effectiveness requirements,[9] SaMD Guidance, including risk classification of medical devices, and guidance for incident reporting.[32,43,45-47] The NHS provides a clinical risk management system template that outlines the processes to ensure that all health care IT used to support care within the organization is developed, implemented, and used safely. We did not identify an equivalent clinical risk management system template for the context in Canada. We did identify a landing page on Health Canada's website devoted to compliance and enforcement of medical devices (e.g., forms, guidance, policies, and laws).[48] Additional investigation is required to determine if the forms, guidance, policies, and laws that Health Canada provides on their website provide sufficient coverage to fulfill DTAC's criteria for clinical safety.

Additional Considerations for AI-Enabled Medical Devices

Maintenance, monitoring, and sustainability throughout the AI product lifecycle

The WHO's Ethics and Governance of AI for Health guidance highlights the importance of promoting human well-being, human safety, and the public interest in AI technologies.[26] WHO emphasizes that AI technologies should satisfy regulatory requirements of safety, accuracy, and efficacy before deployment, and measures should be in place to ensure quality control and quality improvement (i.e., monitoring, maintenance, and sustainability).[26]

We identified additional guidance that provides AI considerations for establishing clinical safety before deployment and as a part of maintenance and monitoring after deployment. The fundamental reason for regularly monitoring and maintaining AI products is to ensure their relevance, accuracy, efficacy, and safety.[33] Thus, AI considerations about monitoring and maintenance have been included under this clinical safety section unless they were explicitly linked to data protection, technical security, interoperability, or usability and accessibility. This concept also coincides with the idea of iterative implementation, which is described in the literature as a way to overcome AI implementation barriers in primary health care in Canada.[49] These considerations are presented together (i.e., lifecycle approach) to showcase specific examples from the identified evidence.

- Performance and validation: Health Canada's draft guidance reiterates the need for manufacturers of MLMDs to provide performance or bench testing or software verification and validation information (e.g., descriptions of the chosen performance metrics, acceptance criteria and operating point or threshold with clinical and risk-based justifications; evidence to demonstrate that the ML system performs as intended and meets expected performance requirements when integrated as part of the medical device system or software). Health Canada states manufacturers should also provide the appropriate clinical evidence, including clinical validation studies, to support their device's safe and effective clinical use.[32] The Vector Institute[33] provides further considerations to ensure the AI model validation process is comprehensive and rigorous and the model is robust and generalized well to new and unseen data. They state this can improve outcomes while maximizing patient safety and privacy.[33] They also state AI systems should incorporate feedback and continuously improve based on user needs and technological advancements to remain relevant and beneficial in the long term.[33] Performance monitoring is a component of the sustainability strategy for evaluating the AI tool.[33] It involves regularly monitoring the system's performance and impact on patient outcomes to identify any issues that need to be addressed and demonstrate the system's value to its users.[33,35] When applicable, emphasis should be placed on the performance of the Human-plus-AI team rather than the model's performance in isolation.[15,35]

- Risk assessment and management: The identified guidance emphasizes providing evidence of risk management to address risk of harms (e.g., by addressing questions such as "If the system does not operate as intended, could it negatively impact

patients' standard of care?" and "Could the output from the AI system result in denying services for a patient?" and monitoring performance degradation such as data drift).[15,30,32,40]

- Data quality testing: The Vector Institute suggests implementing "processes to regularly check, clean, and improve the data quality to ensure its accuracy and consistency" (e.g., by addressing questions such as "Does the vendor have documented processes to test data for completeness, representativeness, and accuracy?" and "Has an assessment been done to see if the source of data is suitable for the intended purpose?").[30,33]

Table 3 in Supporting Information document provides additional examples (found on the project website; refer to *Main Findings*).

During the interview with the patient contributor, she discussed clinical safety. Specifically, the patient contributor hoped AI could result in a faster and more accurate diagnosis. She hoped this might help clinicians initiate the most appropriate treatment sooner, which could reduce the damage caused by stroke (i.e., her lived experience with a medical condition) and improve outcomes (e.g., mortality). The patient contributor posited that, while ensuring the accuracy of the AI technology was a concern, she was curious whether AI could accurately identify issues earlier than a clinician or prevent human error.

Data Protection (Section C2 of DTAC)

Applying DTAC's Section C2 to the Health Care Context in Canada

The data protection section of DTAC provides considerations to establish that the DHT product collects, stores, and uses data compliantly (e.g., ensuring assessment and mitigation strategies and a Data Protection Officer are in place).[20] In the UK, data protection laws of personal information and health information are federally regulated. In Canada, privacy legislation is governed at the federal level and at the provincial and territorial level, depending on the data type and jurisdiction. Through the Office of Privacy Commissioner of Canada, PIPEDA (Personal Information Protection and Electronic Documents Act, S.C. 2000, c 5) privacy legislation generally applies to private-sector organizations that collect, use, and disclose personal health information (PHI) in the course of a commercial activity.[50] There is also guidance on how PIPEDA applies to processing personal data across borders.[51] Alberta, British Columbia, and Quebec have their own private-sector privacy laws that have been deemed substantially similar to PIPEDA.[30,52] Ontario, New Brunswick, Nova Scotia and Newfoundland and Labrador have also adopted "substantially similar legislation" regarding the collection, use, and disclosure of PHI.[50] Collection, use, and disclosure of PHI by a physician is governed by that jurisdiction's health privacy legislation if one exists. Freedom of Information and Protection of Privacy and Health Information Acts are additional health privacy laws in Canada, which are governed at the provincial and territorial level.[30] In the UK, some businesses require registering with the Information Commissioner and paying a data protection fee. In Canada, all businesses that handle personal information are subject to privacy laws (e.g., PIPEDA), but there does not appear to be a registration or data protection fee requirement.[50] Businesses may complete a PIPEDA's voluntary self-assessment tool to evaluate and improve their personal information management systems and practices.[53]

It is also noted that the Government of Canada has tabled Bill C-27, Digital Charter Implementation Act, 2022.[54,55] This Act aims to strengthen Canada's private sector privacy law, create new rules for responsible AI development and deployment, and continue advancing the implementation of Canada's Digital Charter.[55] Bill C-27 would repeal Part 1 of the PIPEDA and enact: *Consumer Privacy Protection Act, the Personal Information and Data Protection Tribunal Act, and the AI and Data* Act.[55] The Office of the Privacy Commissioner of Canada's submission on Bill C-27 states that it follows the former Bill C-11, the Digital Charter Implementation Act, 2020, which also proposed amendments to PIPEDA and died on the Order Paper when Parliament was dissolved on August 15, 2021, in advance of the 2021 federal election.[56] Thus, until Bill C-27 receives Royal Assent, PIPEDA remains Canada's current federal privacy law.

DTAC states Data Protection Officers are required in the UK depending on the type of organization and core activities.[20] For example, a Data Protection Officer is needed if an organization's core activities involve processing health data.[20] For Canada, the federal and provincial personal information protection acts all suggest designating a privacy representative.[53,57,58] [59] The UK government has a Data Security and Protection Toolkit that all organizations must use if they have access to NHS patient data. Since the provincial and territorial governments in Canada govern the management of PHI, there is no centralized federal toolkit for data security and protection of patient data. DTAC also identifies Data Protection Impact Assessment, which helps organizations assess and demonstrate compliance with data protection obligations.[20] In the UK, guidance for this assessment is provided by the

Information Commissioner at the federal level. In Canada, it is more nuanced, given guidance for personal information would be at the federal level and guidance for health information would be at the provincial and territorial level, and Data Protection Impact Assessments are mandated in some jurisdictions (e.g., British Columbia, Quebec) but not others (e.g., Alberta).

Because of the nuances of Canadian privacy laws, mobilizing high-quality, diverse datasets of PHI from across Canada for AI training can be challenging.[30] Despite this, it appears that Canada has equivalent policies to address DTAC's considerations for data protection that reflect our laws and the structure of the health care systems.

Additional Considerations for AI-Enabled Medical Devices

AI data governance and data protection

A critical part of deploying an AI application is having a robust data governance strategy.[33] The Vector Institute,[33] Canada Health Infoway,[31] and Health Canada[15] suggest establishing comprehensive organizational policies and procedures for AI data governance to ensure AI's responsible use and deployment, such as data quality, privacy, security, access, sharing, lifecycle management, and regulatory compliance. Appropriate data governance should enable access to the right data for the right people at the right time.[31,33]

Several ethical considerations relate to AI data governance, training, and operationalization, including consent, de-identification, privacy law compliance, and data transmission security.[30] The Canadian Association of Radiologists also emphasizes the ownership of electronic medical records and the secondary use of de-identified medical data is a complex issue that will likely depend on the type of use.[36] They mention that tools and policies are required to facilitate and standardize the anonymization of medical images, which is likely relevant for other specialties as well.[36] Moreover, they highlight emerging legislation advocates for robust de-identification methodologies and cautions against the risk of re-identification.[30]

Canada Health Infoway suggests that AI system implementors create a code of ethics and principles, provide ethics training, and establish an ethics board or subcommittee.[30] Further considerations included protecting human autonomy (i.e., maintaining human control of health care systems and medical decisions) and allowing individuals to opt out of being included in the data used to train or run the AI system.[30] The Canadian Association of Radiologists states "respect for data privacy requires balancing the principle of beneficence and justice (to improve medical care for others via secondary use of an individual's data) versus the principle of respect for autonomy (as regards the concept of free and ongoing informed consent)."[36] Individual data participants can request access and correction to their personal information under Canadian privacy laws. These rights can be difficult to implement where data are co-mingled in large databases for AI algorithm training (i.e., technically challenging to segment data). To this end, the Canadian Association of Radiologists describe that in order to facilitate the development of AI applications in health care, a transition from "informed consent" for specific data uses to "broad consent," "opt-out consent," and/or "presumed consent" to more general data uses is required.[36] Using examples from other countries, Canadian Association of Radiologists describes what each consent model might look like. For example, the European Union's General Data Protection Regulation allows patients to give general "consent to certain areas of scientific research, when in keeping with recognized ethical standards" (i.e., broad consent). They mention the data custodian and the general parameters of potential data use are identified and agreed to, but the exact projects and users of the data are not known. They presented the example of "opt-out" consent (e.g., allowing certain items to be excluded) as an option that will likely be difficult to feasibly implement as it would be cumbersome and logistically challenging. Canadian Association of Radiologists provide a further recommendation "to advocate for general adoption of revised forms of consent (such as ''broad consent'') for appropriately safeguarded secondary use of data for AI in Canadian health care."[36] Importantly, the Canadian Association of Radiologists also recommends advocating for programs to educate the public and increase awareness of the benefits of sharing personal health data that is fully anonymized as well as harm reduction strategies.[36] Thus, the use of AI in health care has prompted data considerations of how models data governance and informed consent (including modified, dynamic, and broad consent, or waivers of consent) can evolve in an attempt to balance considerations of privacy and autonomy, the purported benefits of the use of AI technologies, and public interest.[26]

Multi-disciplinary, data governance team throughout the product life cycle

The identified guidance emphasizes the importance of a multidisciplinary data governance team that is leveraged throughout the lifecycle of the AI product. The team can be enhanced by including members from diverse areas such as privacy, security, information technology, legal, clinical, ethics, industry, science, and senior management.[30,33] This concept also coincides with

participatory co-design, which the literature describes as a way to overcome AI implementation barriers in primary health care in Canada.[49]

Monitoring, maintenance, and sustainability

Certain considerations must be made to ensure proper data protection, such as conducting regular audits to ensure ongoing compliance with all relevant regulations, developing a security control profile to monitor and mitigate the identified risks to privacy and security, and maintaining a process for assessing risks of re-identification.[31,33]

There are, however, situations where some patients may be less concerned about privacy and data protection considerations and believe that these may be superseded by access to care. Specifically, the patient contributor suggested that, in a crisis, she felt that most people would not be thinking of privacy and data sharing; instead, she would be focused on diagnosis, treatment, and survival. The patient contributor suggested that there might be a divide regarding privacy concerns, with some individuals potentially being more protective of their privacy and wanting more testing and validating of newer technologies before embracing them, while others might be more accustomed to sharing their data and interacting with newer technologies. In addition, the patient contributor expressed curiosity about whether patients will be informed that their clinicians used AI in their diagnosis. She did not know whether the technology was in use at the time of her stroke. Moreover, she briefly shared concerns about the safety of information and storage reliability.

Technical Security (Section C3 of DTAC)

Applying DTAC's Section C2 to the Health Care Context in Canada

The technical security section of DTAC provides considerations to establish that the DHT meets industry best practice security standards (e.g., ensuring testing and measures against cyber threats and proper requirements are in place).[20] In the UK, the related considerations for technical security are federally governed through the National Cyber Security Centre. The technical security considerations where we identified an equivalent measure, strategy, or policy in Canada were federally governed through the Innovation, Science and Economic Development Canada, Communications Security Establishment Canada, or Health Canada.

For the UK, DTAC asks for a Cyber Essentials certificate. CyberSecure Canada from Innovation, Science and Economic Development Canada is a federal cyber certification program that aims to raise the cyber security baseline among small and medium-sized enterprises (SMEs) in Canada, increase consumer confidence in the digital economy, promote international standardization, and better position SMEs to compete globally.[60] To be eligible for certification, the organization must implement the security controls in the National Standard CAN/CIOSC 104:2021 Baseline cyber security controls for SMEs.[61] Moreover, the Canadian Centre for Cyber Security (part of Communications Security Establishment Canada) published updated cyber security guidance for SMEs.[62]

DTAC also asks for a summary report of an external penetration test of the product that included Open Web Application Security Project (OWASP) top 10 vulnerabilities from within the previous 12-month period. The OWASP Foundation is a not-for-profit organization with educational resources, guidelines, and open-source tools to help improve the security of SMEs' software. They provide guidance on the OWASP top 10 vulnerabilities[63] and penetration testing methodologies applicable to both the UK and Canada.[64] For additional direction, Health Canada published a guidance document outlining pre-market requirements for medical device cyber security, which mentions structured penetration testing.[65] The Canadian Centre for Cyber Security guides the top measures to enhance cyber security for SMEs[66] (ITSAP.10.035[67]). Compared with guidance from Canada, the UK's National Cyber Security Centre provides more details on producing clean and maintainable code.[68]

DTAC asks to confirm whether all privileged accounts have appropriate Multi-Factor Authentication (MFA). In Canada, we have guidance on MFA for organizations and individuals,[69] and strong user identification (e.g., MFA) is enforced as a top measure to enhance cyber security for SMEs (i.e., recommended but not mandated).[66] DTAC also requests that logging and reporting requirements be clearly defined.[20] The Canadian Centre for Cyber Security provides information about network security logging and monitoring (ITSAP.80.085), including a checklist of network security logging and monitoring best practices (i.e., recommended not mandated).[70] It is unclear if Canada has recommended or mandated guidance on load testing. The details about load testing within

the DTAC guidance are sparse, limiting our ability to find equivalent measures. Overall, it appears that we have technical security measures equivalent to DTAC in the health care context in Canada.

Additional Considerations for AI-Enabled Medical Devices

Monitoring, maintenance, and sustainability

The Vector Institute emphasizes that measures to secure data are defined (e.g., encryption methods, access controls, firewalls) and, to ensure data security, regular audits should be conducted (i.e., a component of the sustainability strategy of the AI tool).[33]

Interoperability (Section C4 of DTAC)

Applying DTAC's Section C4 to the Health Care Context in Canada

The interoperability section of DTAC establishes how well the product exchanges data with other systems.[20] In the UK, the related considerations for interoperability are federally governed through the NHS and Government Digital Services. In Canada, we identified similar measures, strategies, and policies related to interoperability criteria at the federal (e.g. Treasury Board of Canada Secretariat) and provincial and territorial levels (e.g., Ontario Health).

DTAC includes questions about Application Programme Interfaces (APIs) and whether the AI product exposes any API or integration channels for other consumers. APIs provide an efficient and controlled way to make data accessible to other systems remotely.[71,72] Still, direct system-to-system access enabled through APIs increases the risk and impact of a security breach.[71,72] The Government of Canada provides API Guidance[73] and API security best practices[74] that describe industry standards for secure interoperability (e.g., OAuth 2.0,[75] among others). We also identified the digital health information exchange (DHIEX), a regulatory framework allowing Ontario Health to define and implement the health information standards and requirements for interoperability specifications.[76] It is unclear if other provinces or territories have similar frameworks. In the UK, an NHS number is used to identify patient record data, which does not apply to Canada's current health care structure.[77] Relatedly, the Minister of Health introduced Bill C-72 in June 2024, *An Act respecting the interoperability of health information technology and to prohibit data blocking by health information technology vendors,* also coined the *Connected Care for Canadians Act*.[78,79] Bill-72 is intended to enable a more connected health system by ensuring that health information technology that is licensed, sold, or supplied as a service by a vendor is interoperable and to prohibit data blocking by the vendor.[78,79] Bill-72 seeks to establish a framework that allows for the safe and secure exchange of health data, enabling patients better access to, and more control over, their personal health information.[78] DTAC includes the assessment question, "Is your product a wearable or device, or does it integrate with them? If yes, provide evidence of how it complies with ISO/IEEE 11073 Personal Health Data (PHD) Standards." The International Organization for Standardization is an industry-standard that applies in Canada.[80] Moreover, Canada Health Infoway has been responsible for licensing, defining, and maintaining pan-Canadian standards that promote interoperability.[81] Overall, Canada appears to have similar API guidance for interoperability considerations.

Additional Considerations for AI-Enabled Medical Devices

Technical infrastructure and integration

We identified guidance highlighting the importance of having a technical integration strategy and defining integration points as applicable.[33] The Vector Institute describes an integration point as where an ML solution interfaces with existing health care infrastructure.[33] The guidance emphasizes it is essential to have a proper integration point with the clinical workflow and systems for health care deployment of AI solutions because it ensures that these systems "effectively augment medical professionals' decision-making, enhancing efficiency, and improving patient outcomes without disrupting existing processes that need to be preserved."[33] For example, the guidance advises asking the following question: "How does AI product fit into the current clinical workflow and IT systems?"[33]

Monitoring, maintenance, and sustainability

Health Canada's draft guidance for MLMDs reiterates the need for manufacturers to provide performance or bench testing or software verification and validation information (e.g., evidence to support inter-compatibility with all supported input and output devices).[32] The following are a few examples of interoperability considerations identified by the Vector Institute as part of a

sustainability strategy for an AI tool: (i) the AI system should fit seamlessly into the existing clinical workflows to minimize disruption to the current system (to reduce resistance and improve the likelihood of long-term adoption); and (ii) AI applications should be user-friendly following best practices for user-centered design, should integrate smoothly with existing systems to encourage widespread adoption, and should be easy to use and understand for end users (e.g., clinicians, medical staff, patients).[33] The Vector Institute also suggested that designing for the simplest model possible with the fewest features can improve model interoperability.[33]

Usability and Accessibility (Section D1 of DTAC)

Applying DTAC's Section D1 to the Health Care Context in Canada

The usability and accessibility section of DTAC provides considerations to ensure the DHT product has followed best practices and meets user needs. In the UK and Canada, the related considerations for usability (e.g. simplicity and reliability of service) and accessibility (e.g., engaging with users and understanding their needs, ensuring everyone can use the service, use and contribute to open standards) are federally governed. This core area of DTAC draws on the UK's NHS Service Standard.[82] The Government of Canada's Treasury Board of Canada Secretariat published Digital Standards[83] that generally complement the Points described in the NHS standard. These Digital Standards intend to improve government services in the digital age and are targeted for government practice (i.e., not directed to industry or consumer products specifically).[83] However, the content, headings, and descriptions provided in these standards largely overlap with the NHS Service Standards. For example, DTAC emphasizes the need to understand users and their needs in the context of health and social care by asking, "Do you engage users in the development of the product?"[20] This question aligns with NHS Service Standard Point 1[82] and the Government of Canada's Digital Standards, Design with Users.[83] There are some instances where the language between the UK Service Standard and Canada's Digital Standards do not fully overlap (e.g., choose the right technology, D1.9; operate a reliable service, D1.11). However, this seemed to be covered by the information presented in the interoperability section of DTAC and by specific AI considerations from the identified guidance (e.g., technical infrastructure and integration, monitoring, maintenance, and sustainability). The Government of Canada Digital Standards are the closest equivalent identified for the health care context in Canada, and it is unclear if there are other service standards in place for industry/consumer products.

DTAC also describes the need for the service to be usable by everyone and comply with Web Content Accessibility Guidelines used in the UK and Canada. It is noted that the Treasury Board of Canada Secretariat is currently reviewing the Standard on Web Accessibility. As a part of a commitment to an accessible and barrier-free Canada, it is presently recommended that organizations adopt the Harmonized European Standard (EN 301 549) and adhere to the guidance available in the Guideline on Making Information Technology Usable by All.[84] Therefore, this DTAC section seems to have counterparts in Canada's health care context.

Additional Considerations for AI-Enabled Medical Devices

Transparency, explainability, and intelligibility

The WHO's Ethics and Governance of AI for Health guidance[26] highlights the importance of ensuring transparency, explainability, and intelligibility. WHO states transparency requires sufficient information to be published or documented when designing and deploying an AI technology that considers the individuals involved in patient health care across the product's lifecycle (e.g., patients, health care providers, users, regulators).[26,30] Canada Health Infoway emphasizes the value of explainable AI in health care as enhancing trust (e.g., "providing explanations to patients will help foster trust and reassure them about the AI system's safety and equity"); compliance (e.g., "regulations are now moving towards requiring explanations be provided when AI systems decide or support decision-making. Knowing how to effectively explain AI decisions to a variety of stakeholder [user] groups will help mitigate the risks of non-compliance."); and enhanced service delivery (e.g., "providing explanations to patients helps ensure that AI-supported care delivery is patient-centric").[30] Further, Canada Health Infoway[30] provides an extensive list of considerations regarding:

- best practices for transparency and explainability policies and procedures (e.g., "establish a process of stakeholder [user] engagement to assess what would constitute a meaningful explanation", "identify within your organization those that will be accountable to manage and oversee explainability requirements");

- questions for AI vendor assessment (e.g., “What mechanisms does the vendor propose to make the system more transparent and explainable? For example, disclosing what training data was used, which variables contributed most to a specific outcome, and what data quality tests were conducted to ensure that the system performs as intended.”); and
- transparency and explainability-related questions organizations can ask when assessing the potential risks of an AI system (e.g., “Is the system’s technique compatible with the required level of explainability [e.g., consider that using deep learning techniques may yield lower levels of explainability]?”).[30]

Inclusiveness, equity, and bias

The WHO’s Ethics and Governance of AI for Health guidance[26] highlights the importance of inclusiveness, equity, and mitigating bias. Bias threatens inclusiveness and equity because it represents a departure, often arbitrary, from fair and equitable treatment and outcomes.[26] WHO states “inclusiveness requires that AI used in health care is designed to encourage the widest possible appropriate, equitable use and access, irrespective of age, gender, income, ability or other characteristics.”[26] Strategies must be in place to identify and reduce bias in AI technologies. For example, if health-related AI systems, are trained using non-representative data (e.g., exclude equity-deserving populations), this could reinforce or worsen existing discriminatory treatment within the health care system.[85] We identified guidance that showcase some examples of necessary risk management for bias:

- Ensure clinical study participants and data sets represent the intended patient population.[15,33] For example, “data collection protocols should ensure that the relevant characteristics of the intended patient population (for example, in terms of age, gender, sex, race, and ethnicity), use, and measurement inputs are sufficiently represented in a sample of adequate size in the clinical study and training and test datasets so that results can be reasonably generalized to the population of interest.”[15] The Vector Institute states this helps ensure the “model can generalize well to new and unseen data, improving predictive accuracy.”[33] AI developers should ensure that AI data, especially training data, do not include sampling bias and are accurate, complete, and diverse.[26] This also helps assess usability and identify circumstances where the model may underperform.[15]
- According to Health Canada’s draft guidance, manufacturers should apply sex and gender-based analysis and consider the unique anatomical, physiological, and identity characteristics of patients over the MLMD's lifecycle (i.e., design, risk management, data selection and management, development and training, testing and evaluation, clinical validation, transparency, and post-market performance monitoring).[32] “This includes considering sex and gender, racial and ethnic minorities, elderly and pediatric populations, and pregnant people and collecting and analyzing disaggregated data on sub-populations in clinical studies, training data, and test data, as appropriate.”[32]
- The WHO also states ”the effects of use of AI technologies must be monitored and evaluated, including the disproportionate impact on specific groups of people when they mirror or exacerbate existing forms of bias and discrimination” (i.e., re-iterates monitoring, maintenance, and sustainability considerations).[26]

We acknowledge that algorithmic bias can be considered a clinical safety or usability consideration. For this review, we aligned bias considerations with usability as discussed in the Government of Canada's Digital Standards,[83] described in the usability and accessibility section. Nevertheless, we recognize the importance of mitigating algorithmic biases for the overall clinical safety of patients. Moreover, Canada Health Infoway includes a thorough checklist for identifying and addressing bias in AI systems to promote responsible and ethical AI development and use.[30] The checklist provides several questions at each stage of the lifecycle, including ideation and feasibility, design and development, validation, and deployment and monitoring. For example, the following questions are considerations during deployment and monitoring: “define triggers that will automatically alert those responsible for oversight and monitoring of the AI system should the AI system begin to behave unexpectedly; if automatic triggers are not possible, define how often the AI system should undergo re-validation to ensure it remains free from bias and robust; document acceptable use criteria for the AI system to ensure the system is only deployed in an appropriate context; consider algorithmic auditing by third parties to ensure that your AI system remains free from bias; if indicators of unwanted bias are found in the system, immediately retrain or re-develop the system”.[30]

An element of equity also involves equitable access to technologies. The patient contributor discussed the topic of equitable access to AI technologies through expressed concern about the accessibility of RapidAI (i.e., the AI-enabled medical device used as an

example) outside of major stroke centres. She wondered whether all major hospitals could benefit from this technology to assist in quickly triaging (and potentially transferring) patients. She also had concerns about access to services in rural and remote community hospitals. This example aligns with Section D1.4 of DTAC: "make sure everyone can use the service".[20]

Responsibility and accountability

The WHO[26] states responsibility can be assured by the application of "human warranty." This implies evaluation by patients and clinicians in developing and deploying AI technologies. WHO states there should be accountability when something does go wrong in an application of an AI technology.[26] The Canadian Association of Radiologists also asserts guidelines are required before deploying AI tools in hospitals to reduce the potential harm and liability for malpractice in case of medical error which includes AI.[36]

User buy-in and organizational readiness

With the disruptive nature of AI, a change management strategy for implementors of AI-enabled medical devices is important for the success of its deployment. The Vector Institute[33] described the importance of a change management strategy and dedicated an entire section on how to effect change. The Vector Institute emphasizes the need to have buy-in from:

- clinical users (e.g., patients, clinicians, organizations);
- informatics team (e.g., a multi-disciplinary team of in the areas of data science and analytics, IT infrastructure, data management, application development, information security, clinical informatics, and quality assurance); and
- senior leadership from multiple departments.[33]

A change management strategy touches on many of the AI considerations already discussed (e.g., risk assessment, regulatory compliance, ethics, and compliance) but is described at the organizational level with additional considerations, including clinical champions, shared vision, budget allocation, and return on investment.[33] They provide example risk assessment questions regarding organizational readiness (e.g., "Will the AI system affect current employee roles and responsibilities? Will it lead to workforce redundancies? Will employees need new training? Are existing policies adequate to cover the safe and effective operationalization of the system?").[33]

Monitoring, maintenance, and sustainability

To strengthen the regulation of AI in or as medical devices, the Canadian Law & HTA Working Group suggests an increased pre-market review and continuous post-approval surveillance are needed.[85] We identified considerations for monitoring AI systems to ensure they perform as intended, including monitoring for bias and human accountability, especially after deployment. This broadly extends from DTAC's Section D1.7 consideration: iterate and improve frequently. For instance:

- Examples of questions from Canada Health Infoway for bias and non-discrimination assessment during deployment and monitoring: "Define triggers that will automatically alert those responsible for oversight and monitoring of the AI system should the AI system begin to behave unexpectedly; if automatic triggers are not possible, define how often the AI system should undergo re-validation to ensure it remains free from bias and robust; document acceptable use criteria for the AI system to ensure the system is only deployed in an appropriate context; consider algorithmic auditing by third parties to ensure that your AI system remains free from bias; if indicators of unwanted bias are found in the system, immediately retrain, or re-develop the system."[30]
- An example of a question from Canada Health Infoway for AI vendor assessment: "What human oversight mechanisms does the vendor have in place (e.g., are there measures in place that would enable a human to intervene in, override, or reverse system outputs effectively?")[30]

Limitations

For phase 1 of this review, we mainly relied on publicly available information from government websites. For phase 2 of this review, we limited our eligibility criteria to Canada and a select number of comparable health systems to Canada (i.e., Australia, France,

Germany, Netherlands, and UK). We acknowledge that other countries may offer unique considerations for AI in health care, including countries with different health systems to Canada, and that we would have missed such considerations in this review. For both phases of the review, 1 reviewer conducted all data extraction and synthesis, and there is a possibility that relevant information or guidance was missed. We identified guidance with a lot of relevant content, and this report aimed to showcase the breadth of implementation considerations for AI-enabled medical devices. Therefore, not all considerations are described in this report. Instead, we have extensively referenced the identified guidance to allow our readers to refer to them in more detail, as needed. Moreover, this report is not a systematic review and does not involve a critical appraisal of the literature. Thus, conclusions or recommendations about the value of or place in therapy for AI are outside this report's scope.

We leveraged patient engagement from the concurrent RapidAI review (found on the project website). Though we had intended to engage with 3 individuals (i.e., 2 patients and a clinician), we had limited response to our outreach during the RapidAI review and engaged 1 patient contributor in the end. Our approach also required individuals to have access to reliable technology, phone, and internet access to view our recruitment initiatives and participate as contributors, which could have excluded some voices. It is worth considering whether people without reliable access to communication technologies would also face unique challenges or considerations around access to or use of DHTs that may not be captured in this review. Moreover, we cannot presume the opinions of 1 patient contributor engaged in the review of a specific AI technology reflects other patients' perspectives on all AI technologies in health care, and we cannot provide clinician perspectives without their participation. Therefore, while this implementation review covers all AI-enabled medical devices, to be applicable to reviews of specific AI technologies beyond RapidAI, it will likely require some tailoring.

Conclusions and Implications for Decision- or Policy-Making

Application of DTAC To the Health Care Context in Canada

We conducted an implementation review using a phased approach. In the first phase, we sought to determine if and how DTAC applies to the health care context within Canada by exploring whether we have equivalent or similar measures, strategies, and policies to implement DHTs safely. Focusing on all assessment criteria of DTAC, we provide a high-level summary according to each of the 5 core areas of DTAC, including clinical safety, data protection, technical security, interoperability, and usability and accessibility. Taken together, DTAC generally applies to the health context in Canada with equivalent or similar guidance in place with some important caveats, which are summarized below.

For clinical safety, Canada appears to have similar medical device regulations, conformity declaration policies, and certain risk management activities. However, there may be differences in what the UK requires compared with Canada, such as documentation. For example, the NHS provides templates for "clinical risk management system," which we did not identify on Health Canada's website. Additional investigation is required to determine if the forms, guidance, policies, and laws that Health Canada provides on their website provide sufficient coverage to fulfill DTAC's clinical safety criteria.

When considering the data protection domain, the UK's personal and health information data protection laws are federally governed. Canada has many privacy laws in place, and the level of governance depends on the data type and jurisdiction. For example, personal information is governed at the federal level, and health information is governed at the provincial or territorial level. In addition, the Government of Canada has tabled Bill C-27, Digital Charter Implementation Act, 2022, which would update or replace current laws.[54,55] Though Canada's data protection laws are nuanced, it appears that the country has equivalent laws to address DTAC's considerations for data protection.

For technical security, it appears that DTAC has equivalents in the health care context in Canada. Specifically, we identified guidance and policies that correspond well with the DTAC assessment criteria for this domain (e.g., CyberSecure Canada for a cyber security certificate and guidance on MFA for organizations). We did not identify policies about load testing, but this may be because there was little context on this within the DTAC guidance, limiting our ability to look for equivalents.

Canada appears to have similar API guidance for interoperability considerations as the UK and complies with international standards, including ISO/IEEE11073 Personal Health Data Standards and OAuth 2.0. Compared to the UK, interoperability regarding electronic

health records is more complex in Canada, given that Canada's current health care structure does not have electronic health records managed at the federal level.[77]

For usability and accessibility strategies, DTAC drew primarily from the UK's NHS Service Standard,[82] and Canada published Digital Standards[83] that generally complement the Points described in the NHS standard. There are some instances where the language between the UK and Canada standards do not fully overlap, but this seemed to be covered by the information presented in the interoperability section of DTAC and by specific AI considerations from the identified guidance. DTAC describes the need for compliance with Web Content Accessibility Guidelines, which are used in both the UK and Canada. Therefore, this section of DTAC also has equivalents in the health care context in Canada.

Ethics and Equity Considerations

Considering the overall purpose of DTAC, many ethics and equity considerations for DHTs are already embedded into the assessment criteria. The ethical considerations for DHTs are mainly found in the data protection domain, which relates to data privacy, management, and ownership concepts (i.e., Domains C2.3, C2.5, C2.5.1 of DTAC). The WHO guidance also reflect similar ethical considerations.[18,86] The equity considerations for DHTs are mainly found under the usability and accessibility domain, which primarily relates to the involvement of relevant users (e.g., patients, caregivers, providers) in technology design, and whether their needs are incorporated into elements of technology design (i.e., Domains D1.1, D1.1.1, and D1.2 of DTAC). For example, DTAC asks to consider whether a diverse range of users were engaged, and if not, who may not have been included and whether that has implications for how the subsequent questions may be answered (e.g., are there aspects of the user journey that may not have been considered?). Similar equity considerations are reflected in the Scottish Health Technology Group's HTA framework.[18]

WHO's Ethics and Governance of AI for Health document's 6 fundamental ethical principles for AI use for health align with certain DTAC criteria but offer more specific considerations for AI technologies versus broader considerations for DHTs. WHO's fundamental ethical principle 1 (protect human autonomy) largely falls under DTAC's data protection domain. This can be investigated by looking at human control over the technology, including full informed consent to all aspects of the technology and its application and elements of how personal data are used and managed to protect privacy. Data governance in Canada also requires considering and respecting First Nations, Inuit, and Métis data sovereignty principles (e.g., the First Nations principles of OCAP®,[87] Manitoba Métis principles of OCAS,[88] and Inuit Qaujimajatuqangit[89]), which have implications for guiding the respectful governance of data collected with, from, or about Indigenous peoples. WHO's principle 2 (promote human well-being, human safety, and the public interest) largely falls under DTAC's clinical safety domain and invites us to consider both impacts on individuals and groups or communities. Principles 3-6 (ensure transparency, explainability and intelligibility; foster responsibility and accountability; ensure inclusiveness and equity; and promote responsible and sustainable AI) relate to DTAC's usability and accessibility domain. As emphasized in the Scottish Health Technology Group's HTA framework[18] and DTAC,[20] WHO's principle 4 reflects the importance of including patients and providers (and their values) in the technology design and considering who or what is accountable for the AI algorithm's decisions in its design and application.

Summary of Identified AI Considerations

In the second phase, our review aimed to identify implementation toolkits, guidance, and recommendations specific to AI and relevant to Canada to supplement DTAC in case there are any important additional considerations for AI-enabled medical device use in Canada. We identified guidance from Canada and international guidance from the WHO, Australia, France, and the UK. We found many additional considerations for AI-enabled medical device use in Canada, which we describe under the most relevant of the 5 core areas identified by DTAC. The AI consideration themes include monitoring, maintenance, and sustainability; AI data governance and data protection; multi-disciplinary data governance team throughout the product lifecycle; technical infrastructure and integration; transparency, explainability, and intelligibility; inclusiveness, equity, and bias; responsibility and accountability; and user buy-in and organizational readiness. Each of these AI considerations serves its own purpose and is described in the findings section to explain how they can be considered for AI-enabled medical device implementation.

The most recurring AI considerations discussed across all DTAC core assessment criteria were monitoring, maintenance, and sustainability across the lifecycle of the AI product, highlighting its importance. We believe this theme extends beyond DTAC's Section D1.7 consideration to "Iterate and improve frequently", as it has implications for all 5 core areas of DTAC, especially clinical

safety. This coincides with the concept of iterative implementation, which is described in the literature as a way to overcome AI implementation barriers in primary health care in Canada.[49] A key AI data governance consideration is protecting human autonomy (i.e., maintaining human control of health care systems and medical decisions) and allowing individuals to opt out of being included in the data used to train or run the AI system.[30] Transparency, explainability, and intelligibility is a consideration that is specific to AI systems and requires close consideration. AI models must be interpretable and explainable for all knowledge users to understand their decision-making process.[33] A known concern for AI-enabled medical devices is algorithmic bias, and the identified evidence highlighted some ways to conduct risk management strategies for bias, such as ensuring AI data are representative of the intended population and are therefore accurate, complete and diverse.[15,26] Another key AI consideration was responsibility and accountability, which are needed if something goes wrong when applying AI technology (i.e., "human warranty").[26]

Future Developments

Expectedly, guidance for AI-enabled medical devices will continue to evolve as more AI-enabled medical devices develop and more health care organizations consider and deploy these products. A recent perspective paper from the New England Journal of Medicine AI discussed a new role some health systems have created, the Chief Health AI Officer, to provide specialized leadership.[90] This role could include developing a comprehensive AI strategy aligned with the organization's goals, identifying high-impact use cases, ensuring effective implementation, and ensuring responsible AI application and compliance with evolving regulations.[90] Given the number of implementation considerations for AI-enabled medical devices, the role of Chief Health AI Officer may be a practical decision for health care organizations. Also, the STANDING Together collaboration has developed international consensus-based recommendations to highlight and mitigate potential harms caused by bias in data and algorithms to ensure the future of AI-enabled health care is inclusive and equitable.[91] They provide recommendations intended to address inequitable AI health technology performance across the lifecycle. Specifically, they list recommendations for documenting and using health datasets.[91] The extended scientific paper on these recommendations, including detailed explanatory text giving context and rationale for each item, is still in development.[91] In addition, we also noted some emerging regulations in privacy law (e.g., Bill C-27, *Digital Charter Implementation Act*, 2022;[54,55] *Connected Care for Canadians Act*, 2024[78,79]), and there are also emerging regulations in AI, such as the right to contest decisions made by AI systems.[30] This idea was reinforced by the patient contributor engaged during the RapidAI review (found on the project website) who asked whether patients will be informed that AI is involved in making their diagnosis. These examples exemplify the ever-changing landscape and perhaps the need for future frameworks to be published as living documents to allow for adaptions as new guidance becomes available.

Implications for Clinical Practice and Policy-Making

In this review, we identified key implementation considerations for AI-enabled medical devices and whether those have been addressed in Canada. With some exceptions, we found that many of the safeguards and assessment criteria captured by DTAC in the UK setting have equivalent or similar measures, strategies, or policies in place within the health care context in Canada. Senior health care decision-makers can use this information to ensure that AI technologies of interest meet the minimum baseline standards set out by DTAC and inform next steps for safe and successful implementation of AI-enabled medical devices in Canada.

This implementation review for all AI-enabled medical devices is to be used alongside reviews of specific AI technologies, including the concurrent review of RapidAI for Stroke Detection (found on the project website), and will serve as a foundational report to be tailored for each AI topic and updated with the latest developments in the regulation and other aspects of management of AI in the context of Canada.

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Questions or requests for information about this report can be directed to **Requests@CADTH.ca**