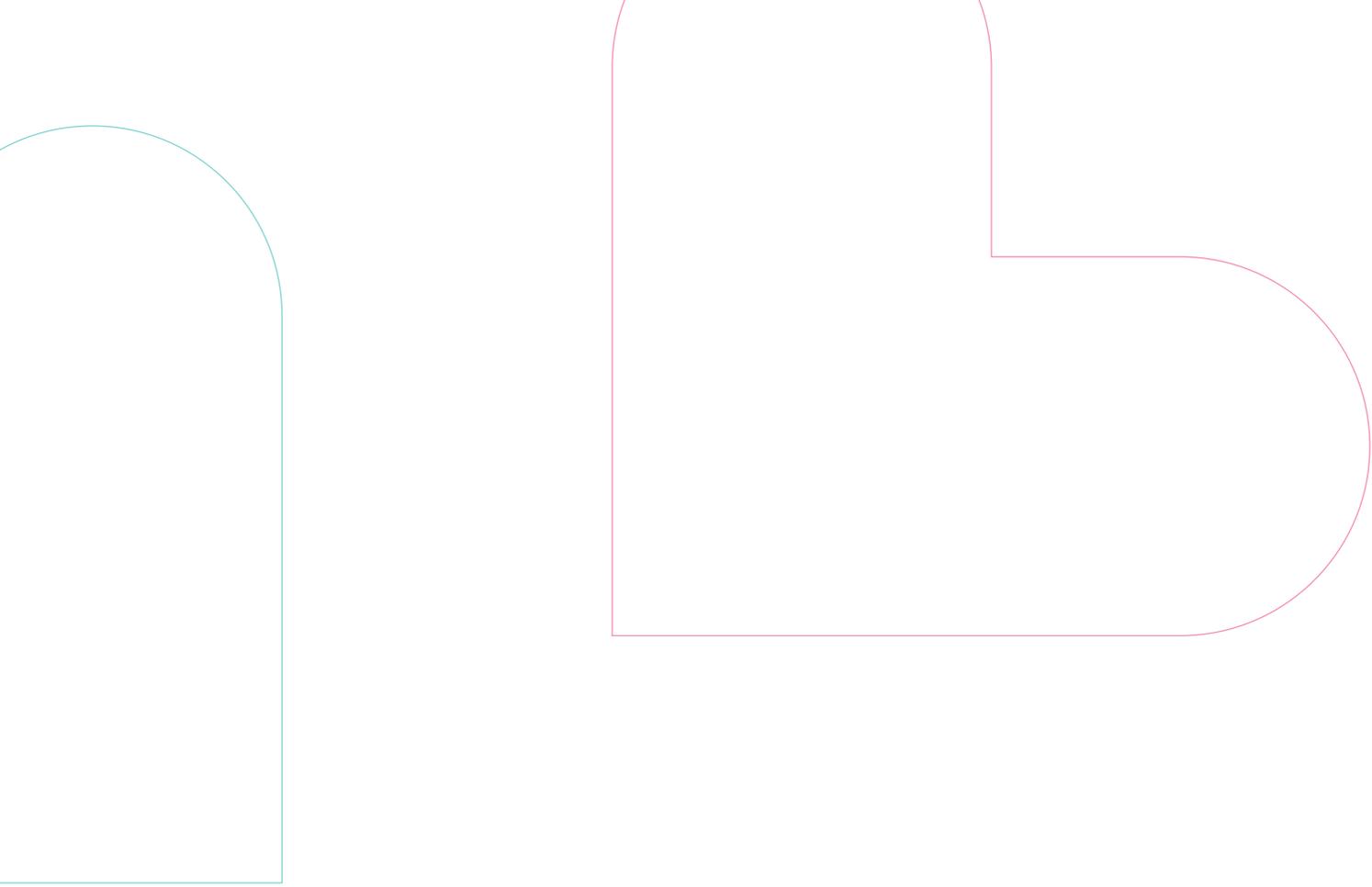


NOVEMBER 2021

IMPLEMENTING ARTIFICIAL INTELLIGENCE IN CANADIAN HEALTHCARE: A KIT FOR GETTING STARTED

Principles and guidance from an expert design lab process
Executive Summary and Report



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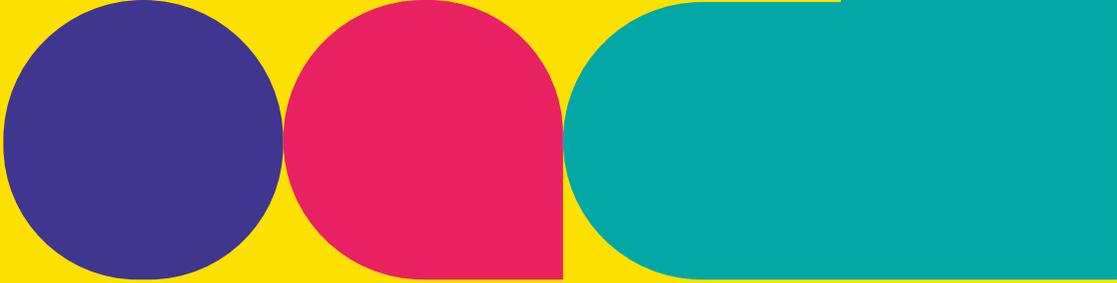
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Executive Summary

Adoption of artificial intelligence (AI) in the Canadian health sector has lagged behind other countries and sectors, despite Canada's position as a world leader in AI technology development. To help speed up greater AI adoption, Healthcare Excellence Canada (HEC), formerly the Canadian Foundation for Healthcare Improvement and the Canadian Patient Safety Institute, partnered with an advisory committee of experts to develop strategies to support health leaders in AI implementation. HEC brought together participants from across Canada to take part in a design lab to answer the following question: **“How can health leaders support the implementation of AI in Canada's health sector to improve care?”**

Throughout the course of the lab, participants identified four high-level guiding principles critical for the success of any AI implementation.

AI innovations are unique and require flexibility to explore and self-learn as they are developed.

AI-based improvement initiatives can be unique in the way that they are designed and implemented. Often, potential AI applications are identified through the exploration of data. Additionally, AI models have the potential to self-learn and improve themselves without human intervention. Both characteristics can challenge the traditional project management approaches and approval processes within healthcare institutions.

Right-sized: Ensure that AI is the right solution for the problem that needs to be solved.

Given the novelty of AI, there is sometimes a rush to use AI as a solution when it might not be the best one for the problem. Health leaders need to prioritize support for AI projects that have the greatest chance of improving care for everyone in Canada.

Co-designed: Patients, families and caregivers, and healthcare providers must be co-design partners in all AI implementation projects.

For health leaders to ensure the buy-in and success of AI projects, they must ensure that patients, families and caregivers, and healthcare providers are involved in the co-design of solutions, kept engaged, educated and informed throughout the life-course of these projects.

Equity-focused: Ensuring the benefits of AI implementation extend to all people in Canada.

Innovations are often built with data that may not address the needs or cultural, linguistic, racial, or gender diversity of the populations being served. Biased datasets will lead to biased tools and datasets can contain hidden biases. Building strategies that encompass intersectionality and engage a broad and diverse group of patients, families, and caregivers is one way to support equitable processes.

To help better understand the specific needs for AI initiatives, design lab participants co-developed a map for the implementation of AI. The map included four main phases:

- A. Setting the Leadership Table
- B. Design & Approvals
- C. Pilot & Implementation
- D. Sustainability & Maintenance

Based on the consensus of the lab participants, the guidance in this report is focused on [Phase A](#) and strategies for engaging and educating patients, families and caregivers, and healthcare providers throughout the implementation journey. The following table provides a high-level overview of that guidance.

Task	Guidance
Identification and scoping of the problem with potential AI solution	<ul style="list-style-type: none"> • There needs to be a better link between problems in healthcare and research/discovery by data scientists. The ideal AI research would link data exploration to the priority challenges identified by patients/families/caregivers and/or direct care providers. • Patients/caregivers and providers should have a clear process to identify problems with potential AI solutions and be engaged in co-design and implementation. • AI won't always be the right solution.
Development of the proof-of-concept	<ul style="list-style-type: none"> • Engagement of patients/families and point-of-care providers is critical to ensure that the solution meets their needs. • Review of literature/stakeholders should be done to ensure that the project isn't reinventing the wheel. • Proof-of-concept must be sufficiently developed to allow health leaders to assess readiness for development and implementation.
Understanding the organizations' readiness and likelihood of success in implementation	<ul style="list-style-type: none"> • Efforts must be made early on to understand data needs, and develop strategies to ensure availability, safety, and legal/regulatory compliance. • Early assessment of readiness, risk, and other components which influence project success, is a way for health leaders to address challenges before implementation begins.
Development of engagement and education strategies for patients, families and caregivers, and healthcare providers	<ul style="list-style-type: none"> • The engagement and education of patients, families and caregivers, as well as healthcare providers who will be impacted by the changes brought about by AI are fundamental for the success of any AI project.

Task	Guidance
<p>Develop sustainability plans, and plans for spread and scale</p>	<ul style="list-style-type: none"> • Considerations of sustainability and spread and scale should be hard-wired into any AI initiative.
<p>Gain final leadership support and resources to move forward with design and implementation of the AI project</p>	<ul style="list-style-type: none"> • Ensure buy-in from senior leadership as well as the necessary clinical leads and managers. • Ensure necessary financing and resources to move into the development phase of the project.

Examples of solutions to put this guidance into action can be found in tables [1](#), [2](#) & [3](#) of this report. Appendices [B-G](#) include tools that can be used to support implementation.

The guidance in this report is designed to support health leaders in developing and implementing AI tools and innovations in their institutions and healthcare settings. It is not meant to be a step-by-step guide for implementation, but instead, it helps to identify some of the barriers and enablers that health leaders should be aware of before starting an AI initiative. It is hoped that it will offer tools and resources to enable greater uptake of AI in Canada and improvements in care for everyone in Canada.

Overview

Artificial intelligence (AI)¹ has been researched since the 1950s and leveraged by various industries over the past 15 years. However, the pace of AI's adoption has not been mirrored within Canada's health sector. This is despite Canada being a world leader in AI technology and efforts by multiple stakeholders to speed adoption. This report is designed to offer guidance to health leaders in the hospital sector (CEOs, CTOs, VPs of Data Science, etc.) to help overcome some of the barriers to adoption.

Since 2019, Healthcare Excellence Canada (HEC), formerly the Canadian Foundation for Healthcare Improvement and the Canadian Patient Safety Institute, has been working with an advisory committee of experts including patients, data scientists, implementers, and policymakers to explore ways in which health leaders can support greater implementation of AI in the health sector. Given HEC's expertise in change management and implementation support for health leaders, this was seen as a key area for guidance in speeding up the adoption of AI. The focus on the hospital sector is a recognition of a greater readiness in this area for AI adoption and implementation. However, the suggestions and recommendations in this report can also offer guidance and insights to those engaged in AI work outside of the hospital sector.

The guidance in this report was co-designed through a design lab process that took place in April and May 2021. Participants included data scientists, AI innovators, AI implementers, patients, families, caregivers, and policymakers.

Supported by an advisory committee of experts, participants worked together to address the following question: **“How can health leaders support the implementation of AI in Canada's health sector to improve care?”**

This report is intended to build on the work that other AI experts and organizations have completed. It aims to offer best practices for the implementation of research-driven improvements and emphasizes how those practices will need to be modified for AI innovations. Priority is given to tools and solutions that may be unique for AI implementation projects. However, proper project management, engagement and sustainability planning are all required to ensure the successful adoption of AI innovations.

It is hoped that this document will enable leaders to build a supportive culture that demystifies AI for staff, patients, families and caregivers, while also encouraging co-creation, innovation and adoption within the Canadian health sector.

1. For the purposes of our discussions, we used the Canadian Institute for Advanced Research's (CIFAR) working definition of Artificial Intelligence from their [Building a Learning Health System for Canadians](#) report (July 2020):

“We define AI to be any current or future machine learning approach to predictive analytics, decision-support systems and/or automated decision-making. Specific examples of today's AI technology that are being applied to health and healthcare include deep learning, reinforcement learning and robotics.”

Design Lab Approach

A design lab is a collaborative, facilitated process meant to shorten the path between problem identification and solution generation. This process puts the people using and applying solutions in the centre of the design. It involves using creative approaches (including adapted Liberating Structures techniques) to explore the issues more widely (divergent thinking) and then focus on potential solutions (convergent thinking). The result is better, more reliable solutions.

The virtual AI in Canadian Healthcare series led by HEC arose from a common interest among key partners in exploring and better articulating a path forward for AI implementation in Canadian healthcare. Partners recognized the many challenges and opportunities, and wanted to hone in on practical guidance for getting started with implementation.

The series brought together health leaders from across Canada to develop guidance that supports the implementation of AI in the health sector. It was a co-design process that recognized the value and insights coming from the perspectives of four groups:

- Policymakers/decision-makers
- Point-of-care implementers (i.e., point-of-care staff and/or managers)
- Patients, families and caregivers
- Data scientists/AI innovators

A range of design thinking facilitation tools and techniques were used over four virtual sessions to develop guidance for healthcare leaders, including:

1. **Key informant interviews:** We conducted interviews with 19 people, including patients and caregivers, data scientists/developers, point-of-care implementers, and policy/decision-makers from across Canada to learn more about the challenges they were facing in implementing AI in the health sector and what they would need for further adoption.
2. **Understanding the system:** Using the user interviews and insights from participants, we identified the current barriers and enablers to AI in the Canadian healthcare environment.
3. **Mapping the journey of the development and implementation of an AI innovation in a hospital setting:** We applied interview insights, data from the system-mapping and participant insights to map the journey of an AI innovation as it proceeds through development and implementation. Once the map was constructed, we identified areas for solution generation.
4. **Development of guidance options:** Multiple guidance options were developed using an “idea on a page” template for each area that was prioritized for solution generation.
5. **Refining the guidance:** Using a mind-mapping exercise, participants spent time building out some of the guiding principles for implementation. Additionally, time was spent validating and reviewing prototype tools that were developed as a result of the ideas generated in an earlier session.

Challenges to AI Implementation in Canada's Health Sector

Despite Canada's role as a pioneer and international leader in AI, adoption of AI in the health sector has lagged behind other countries and other industries. From key informant interviews and a system-mapping exercise that took place during the lab, some key challenges emerged.

Understanding AI

Ensuring an understanding of AI remains a challenge. There is no consensus about what defines AI, and its complexity makes it difficult not only for people to understand its application but also for experts to find ways to communicate with providers, patients and the public. Patients and providers have concerns regarding the safety and quality of AI innovations, as well as potential benefits for their care. Further, it is not always clear when and for what purposes AI should be used in treatment planning and care provision. Policy and decision-makers noted challenges with keeping up with innovations from a regulatory perspective.

Evidence for what AI will deliver

A corollary to the lack of understanding of AI, is the lack of research data to support its use in treatment planning and care provision. As AI is still novel in Canadian healthcare, the evidence base for its use is underdeveloped. Given the evidence-based decision-making processes of both clinicians, and policymakers/funders, it's challenging for AI innovators to attain the buy-in and support necessary to ensure the adoption of these new innovations.

Equity

As with many facets of Canadian healthcare, ensuring equity in AI implementation was identified as a key challenge. There are concerns about bias in the available data, resulting in algorithms or other solutions that may cause harm or improper treatment decisions. This is especially true for groups under-represented in the data or in circumstances where demographic data is not collected (i.e., outcomes for members of different racial or ethnic groups, gender, etc.) Additionally, there are concerns regarding who can access AI innovations. At the moment, AI is implemented mostly in teaching hospitals in large urban settings, with limited application in community hospitals and other rural and remote settings.

Engagement

Another issue that came to the forefront was the lack of engagement and co-design in developing and implementing AI solutions. Often, solutions were created with little input from those who would be using these tools in their clinical processes and those whose care would be impacted by any changes. In some cases, patients were not even aware that AI was being used in treatment decisions. It was noted that this lack of engagement contributed to a lack of understanding and trust in AI innovations.

Data Infrastructure

The necessary data and infrastructure to support AI innovation in the health sector is another barrier that was identified. While there is a lot of data generated in healthcare, it is not always collected or housed in a way that allows the sharing of information between different systems and organizations/institutions, and the quality remains an issue in some areas. Data sharing between and among institutions and jurisdictions was highlighted as a challenge for health leaders. Additionally, there remains issues related to data stewardship and safety, as well as data privacy. Patients that were interviewed noted a willingness to have their data used for AI innovations but highlighted the need for the sharing to be transparent, safe, and used for the benefit of other patients rather than for commercial gain.

Appropriate Human Resources

One of the challenges for healthcare institutions is having staff with the appropriate skills to develop and implement AI initiatives. There is a need for individuals with data engineering expertise to build the necessary infrastructure to make AI work, (i.e., real-time data pipelines that feed into models on the fly and can then circle back with clinical recommendations/guidance/alarms). If internal staff with this skillset are beyond the reach of an institution, it will require leaders to find external partners and expertise to fill this gap.

Creating a Supportive Culture for AI adoption

Given the challenges faced in understanding AI, it is not surprising that health leaders face barriers in ensuring a supportive culture for AI within their institutions. Resistance to change was noted, as were difficulties in gaining funding and leadership support for AI adoption. Participants noted difficulties in ensuring that the right staff were involved and engaged in the development process and building trust between clinicians and data scientists. Finally, the exploratory nature of some AI initiatives can challenge the traditional approval structures within which leaders typically operate.

Regulation

Finally, due to the pace of change in AI and the emerging nature of the research, regulatory, legal and financial structures have struggled to keep up and can serve as barriers to implementation. AI innovators/data scientists noted the need to undertake multiple ethics and regulatory reviews and a lack of transparency around which processes they needed to undertake before using AI in a clinical setting. Additionally, funding for projects was nearly impossible to secure beyond the pilot or research phase, meaning that scale-up of successful innovations remained stalled in most parts of the country.

Guiding Principles for AI Implementation

Throughout the course of the design lab process, several overarching principles emerged from the discussions. These were seen as foundational for ensuring that health leaders were prepared to champion the greater adoption and implementation of AI solutions and initiatives.

AI innovations are unique and require flexibility to explore and self-learn as they are developed.

AI-based improvement initiatives can be unique in the way that they are designed and implemented. Often, potential AI applications are identified through the exploration of data. It is essential that data is accessible for exploration and that the value of AI applications identified through exploration is confirmed and refined with healthcare providers, patients and other stakeholders, before a commitment to pursuing any particular AI-based innovation. Additionally, while adjustments to most innovations need to be human-implemented and deliberate (often made in response to evaluation results), AI models have the potential to self-learn and improve themselves without human intervention. Both of these characteristics of AI-based innovations can challenge the traditional project management approaches and approval processes within healthcare institutions. Health leaders need to be aware of these and other unique aspects of AI-based innovations in order to realize the benefits of AI in learning systems.

Right-sized: Ensure that AI is the right solution for the problem that needs to be solved.

Given the novelty of AI, there is sometimes a rush to use AI as a solution when it might not be the best one for the problem that needs to be solved. Health leaders need to understand and assess the problem and all potential solutions. They also need to prioritize support for AI projects that have the greatest chance of success and improving care for everyone in Canada.

Co-designed: Patients, families and caregivers and healthcare providers must be co-design partners in all AI implementation projects.

AI projects are sometimes developed and implemented without the engagement of the patients, families and caregivers whose care and treatment planning will be impacted by changes brought about by AI innovations. Additionally, clinical staff whose workflow and processes will be affected by these changes are often engaged after much of the design and planning. For health leaders to ensure the buy-in and success of AI projects, they must ensure that patients, families and caregivers, and healthcare providers are involved in the co-design of solutions and kept engaged, educated, and informed throughout the life course of these projects.

Equity-focused: Ensuring the benefits of AI implementation extend to all people in Canada.

Health equity remains a challenge in many parts of Canada's health system, demonstrated quite starkly by the differential outcomes experienced by some communities during the COVID-19 pandemic. The implementation of AI is no different. Innovations are often built with data that may not address the needs or cultural, linguistic, racial, or gender diversity of the populations being served. Biased datasets will lead to biased tools, and datasets can contain hidden biases. For example, if members of subpopulations are less likely to be referred for a necessary medical procedure due to systemic racism in healthcare, AI models built on those data might incorrectly present the sub-population as having less severe illness. Building strategies that are driven by values encompassing intersectionality and multiple identities and which engage a broad and diverse group of patients, families and caregivers, is one way that health leaders can support more equitable processes. Additionally, leaders can collaborate and share with their colleagues in other jurisdictions and settings to ensure that AI innovations don't remain the purview of large teaching hospitals but are accessible for all people in Canada.

Implementation Guidance

Given the pace of change and innovation in the health sector, health leaders have developed skills and practices to support implementation. While these will apply in developing and implementing AI initiatives, certain components are unique to AI and will require leaders to develop new skills or modify existing skills and processes. The following graphic/table outlines some of the differences/considerations that health leaders must be aware of.

AI Initiative	Traditional Healthcare Innovation
<p>Exploratory- many AI initiatives start with an exploration of data before having a clearly defined problem. While this exploration will eventually need to be linked to a problem that needs to be solved and is a priority for providers and patients/families and caregivers, there is a need to create accessible and secure data resources for this exploration to take place. Leaders also need to be aware that buy-in from staff and patients may be more challenging given the novelty of some of these solutions.</p>	<p>Evidence-based- most innovations adopted in healthcare are based on research evidence about potential improvements in care, either from pilot projects or more broad implementation. This approach allows leaders to have solid evidence to share with decision-makers for funding decisions and other necessary approvals. Additionally, clinicians may have a greater willingness to participate in projects where strong evidence exists.</p>
<p>Self-learning- AI models have the potential for continuous learning and improvement as additional data is collected/processed throughout the course of implementation. This updating can happen automatically and doesn't necessarily need outside intervention from coders or data scientists to be changed. This potential for self-learning can lead to improved outcomes in shorter time-frames than with the updating from traditional Plan-Do-Study-Act (PDSA)² or other quality improvement strategies, but will also require appropriate oversight to ensure that self-learning doesn't lead to harmful "model drift"/"model decay."</p>	<p>Evaluation-based - innovations adopted in healthcare are thoroughly evaluated and monitored using quality improvement principles and other strategies. These strategies are often quite rigorous and provide the necessary data and evidence for leaders to make a case for further adoption or end projects when outcomes are not as good as expected. As there is often a lag in collecting and analyzing this evaluation data, there can be delays in adaptation of initiatives where problems arise. However, evaluation and monitoring is a skill set that is often well developed in healthcare institutions.</p>

² The Plan-Do-Study-Act (PDSA) cycle is a scientific method that allows for a test of change with action-oriented learning. <http://www.ihl.org/resources/Pages/HowtoImprove/ScienceofImprovementHowtoImprove.aspx>

AI Initiative

“Black box”– some of the most accurate AI-based innovations function in ways that are not easily explainable or understandable, often being referred to as a “black box.” In some cases, this lack of explainability may be acceptable for stakeholders. For example, surgeons and patients may not need to know the details behind operating room schedule optimization as long as the optimized scheduling works well. In other cases, explainability is paramount. For example, if an AI-based model is being used to determine which treatment a patient receives/does not receive. Working to demystify AI and communicating with stakeholders about its benefits is a skill set that health leaders need to develop to support further AI adoption.³

Evolving processes for regulation, research and funding– given the novel nature of AI and the pace of evolution, processes (approvals, funding, research, etc.) are often not clearly defined. This ambiguity leads to confusion among researchers and potential missed opportunities for collaboration and funding etc. Health leaders will need to adapt their current project management processes to create the necessary flexibility and nimbleness to respond to the evolving nature of AI regulations, research and funding, etc. A process to fully map out these considerations upfront could help to avoid potential blind spots.

Traditional Healthcare Innovation

Visible– standard health innovations can usually be seen and experienced by healthcare providers and patients, families and caregivers. This leads to greater understanding and helps leaders communicate with the appropriate stakeholders. The skills developed to communicate for traditional projects can be built upon and adapted for AI initiatives.

Standard regulatory, research and funding processes– the processes for adopting traditional health innovations are well developed and understood by most health leaders. While they can be onerous and create challenges, there is a general understanding of what is involved. Project management and change processes are often built to reach the milestones and deliverables that are required.

³For guidance on algorithm explainability see Module 6: AI Governance: Structures, Roles and Responsibilities in Canada Health Infoway (2021) [Toolkit for Implementers of Artificial Intelligence in Health Care December 2021 \(Version 1.0\)](#)

To help better understand the specific needs for AI initiatives, design lab participants co-developed a map for the implementation of AI. This map was generated based on a range of organizational and lived experience and provides a visual construction of the key actions deemed necessary to successfully implement an AI project in the health sector (see [Appendix A](#) for the process of the map development and figure 1 for the map).

The map is divided into four main phases:

Setting the Leadership Table

Design & Approvals

Pilot & Implementation

Sustainability & Maintenance

While the map serves as a visual representation of the key steps, it does not show the dynamism in an actual implementation. Many steps can be done in parallel and don't have to be done one after the other. Additionally, as with any initiative in healthcare, there will be starts and stops and barriers that arise during the process that may require the team to take steps back or forward in the process. However, by outlining the full journey, the map allows leaders to understand the full breadth of what is involved in successfully implementing an AI innovation.

The guidance in this report focuses on the first phase of this map and the engagement and education of patients, families and caregivers and healthcare providers throughout the implementation journey. Solutions and guidance are focused on those areas that may be unique for AI implementation. While not covered in this report, the best practices related to project and change management should be integrated into any AI initiative.

Guidance for Implementing Artificial Intelligence Solutions

Phase A

Setting the leadership table



Clarify your problem.
These can be brought forward by patients, their family, clinicians or the senior leadership team



Identify a project lead to coordinate the process for a proposed AI innovation



Preliminary assessment of data sets / data availability and plan to address any gaps



Engage patients, family, providers, and experts to identify and scope out problem for which an AI solution is being proposed



AI assessment completed to determine whether an AI solution is appropriate. If no, then no further action required



Clinician, patients and data scientists collaborate on proof of concept for AI innovation

Complete risk and readiness assessments to understand project feasibility



Co-develop engagement/ education strategy for patients/families and providers



Develop sustainability plan and plans for spread and scale



Leadership approval and support gained (i.e. funding)

Ready for
stage B!

Guidance for Implementing Artificial Intelligence Solutions

Phase B

Design & Approvals



Project manager and development team is appointed



Continue work on data planning including data sharing agreements, privacy impact assessments, etc.



Development team collaborates to bring proof of concept into testable application



Submit ethics board approval request

Apply for regulatory or research approvals that are necessary for pilot and implementation phase



Conduct user testing with patients, families, clinicians, and others who will be impacted by the use of the AI innovation



Create implementation team and identify sites for pilot testing



Develop evaluation strategy for rapid assessment and updating



Update education and engagement strategy for patients, families and impacted staff



Update readiness and risk assessments and complete cost-benefit analysis with updated AI innovation



Finalize all necessary approvals



Secure funding and ongoing leadership support for next phase

Guidance for Implementing Artificial Intelligence Solutions

Phase C

Pilot & Implementation

Identify and meet
technology needs
including calibration
and testing as
applicable



Secure staff time
for training and
implementation
support



Trial run of AI
innovation
(pilot test) including
patients, families and
providers impacted by
the changes

Optimize AI tool
and implementation
protocol as
applicable



Share learnings
from pilot and offer
education and
engagement for new
units or sites



Roll- out to
additional units or
sites



Summative
evaluation of pilot
and implementation
phase

Ready for
stage D!

Guidance for Implementing Artificial Intelligence Solutions

Phase D

Sustainability & Maintenance

Updating of
sustainability plan
and process for
further spread and
scale



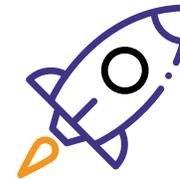
Apply for and
receive necessary
regulatory
approvals



Share findings/
results with broader
community (public
and academic)



Secure long-term
funding for current
and future sites of
implementation



Implement innovation
in additional sites and
markets as applicable

Congratulations!

You are on your way to implementing an AI solution that is effective, sustainable and improves care for patients as well as their families and caregivers.

Setting the Leadership Table

The first phase outlines key steps to help set the stage for AI implementation. Participants noted that, as with the implementation of other innovations in healthcare, many AI initiatives are unsuccessful because the proper planning and scoping does not take place before innovations are developed and rolled out. The following guidance seeks to address the broad categories set forth in this phase.

Identification and scoping of problem with potential AI solution

Guidance:

- Many AI initiatives start with data scientists and AI experts reviewing data sets to understand potential applications. There is a need to better link this process to problems faced in healthcare.
- An ideal implementation would link this data exploration to the priority challenges identified by patients, families and caregivers and/or direct care providers.
- There should be a clear and communicated process for patients, caregivers, families, and providers to identify problems with potential AI solutions. These groups should be involved in scoping out the problem and determining whether an AI solution is the best approach. This must go beyond just providing information and should represent true partnership and co-design.
- Once the problem has been scoped, it is necessary to determine whether AI is the right solution. Not every issue is best served with an AI tool.

Identification and scoping of the AI problem is a critical part of any AI implementation. It allows health leaders to fully lay out the issue to be addressed and then critically appraise what type of solution will work best in their healthcare setting. Such an appraisal should include: considerations of the desired outcomes and objectives, target populations, changes to clinical or administrative workflow, resource requirements and level of effort, and an understanding of the values and beliefs regarding AI in the institution where the solution will be implemented.

Development of the proof-of-concept

Guidance:

- Engagement of patients, families and caregivers is critical to ensure that the solution is understandable, meets their needs, and addresses any concerns they may have about changes in their care.
- Point-of-care providers and their teams must also be engaged as any solution will need to fit with clinical and/or administrative workflow and meet criteria including usability and acceptability.
- A review of the relevant literature and engagement of other stakeholders working in the space should be completed to see if something similar has been developed in order to avoid reinventing the wheel.
- Proof-of-concept must be sufficiently developed to allow health leaders to assess readiness for development and implementation.

Once AI has been identified as the best approach to address the identified problem, the project lead must collaborate with impacted parties to develop the AI tool into a workable solution more fully. While the proof-of-concept may still have some gaps or questions for consideration (i.e., work to acquire necessary data may still be in process), it should be developed enough that patients, families and caregivers, healthcare providers, and senior staff can properly assess both the potential value of the innovation, and its potential for successful implementation.

Understanding the organizations' readiness and likelihood of success in implementation

Guidance:

- Data is a critical component of AI innovations. Efforts must be made early on to understand the data needs and availability, and develop strategies to ensure that data is available, safe, and meets the legal and regulatory requirements for use.
- Early assessment of readiness, risk, and other components that influence project success is a way for health leaders to address challenges before implementation begins.

The health sector is full of examples of projects and changes that have not had the impact or uptake that was anticipated. One of the reasons is the lack of understanding about organizational readiness before a new program, policy or innovation is introduced. Some great ideas are just not ready to be adopted in some locations, and others would be successful with a bit more upfront work. There are a number of internal and external factors that should be reviewed before a project is launched.

Due to the nature of AI projects, there are also a number of legal and regulatory risks and considerations that need to be addressed. These are everything from data sharing agreements, ethics review, informed consent, and regulatory approvals. As many of these are different, depending on which jurisdictions the implementation takes place, health leaders should do a proper risk accounting upfront.

Development of engagement and education strategies for patients, families and caregivers, and healthcare providers

Guidance:

- The engagement and education of patients, families and caregivers, as well as healthcare providers who will be impacted by the changes brought about by AI are fundamental for the success of any AI project.

More detailed guidance about how to engage with patients, families and caregivers, and healthcare providers to ensure adequate education are provided in the next two sections of this report.

Develop sustainability plans, and plans for spread and scale

Guidance:

- Considerations of sustainability and spread and scale should be hard-wired into any AI initiative. While these plans will undergo modifications as the tool is developed and rolled out, early planning is key.

One of the key challenges in AI implementation is moving projects from the pilot or research phase to long-term sustainability. While this is not unique to AI projects in Canada, health leaders can set expectations by requiring developers and implementers to take a long view and plan for scalability and sustainability before any project gets launched.

Gain final leadership support and resources to move forward with design and implementation of the AI project.

Guidance:

- Leadership support is critical for a project's success. Ensure that there is buy-in from not only senior leadership but also the necessary clinical leads and managers.
- Ensure that you have the necessary financing and resources to move into the development phase of the project.

There will be multiple times throughout the design and implementation of any given AI project that leadership support and approvals will be required. The approval at the end of [Phase A](#) will allow the project team to the design and approvals phase of the work.

The following table outlines some of the practical tools that have been developed to support the guidance outlined in [Phase A](#). These tools are meant as samples and can be adapted and modified to meet the specific needs of any organization.

Table 1: Examples of practical tools to help support health leaders in Phase A: Setting the Leadership Table

Guidance	Examples of how to take action
<p>Identification and scoping of the problem with potential AI solution</p> <ul style="list-style-type: none"> • Appraise whether AI is the right solution to the identified problem 	<p>Develop a tool to evaluate the best options to solve the problem</p> <p>Principles:</p> <ul style="list-style-type: none"> • AI may not be the best solution for all problems • Always consider the best practice for a problem • Ensure stakeholder engagement <p>Key components:</p> <ul style="list-style-type: none"> • Situational assessment (current state of problem) • Mapping values and beliefs for AI solutions • Desired outcomes/objective • Consider target populations and equity • Considers alternatives to AI as well • High-level of effort to implement each option • Changes to day-to-day tasks of stakeholder • High-level resources requirements • Option specific (data, etc.) • Human resources • Cost of all of the options <p>A prototype of such a tool is provided in Appendix B</p>
<p>Understanding the organizations' readiness and likelihood of success in implementation</p> <ul style="list-style-type: none"> • Early assessment of readiness, risk, and other components that influence project success is a way for health leaders to address challenges before implementation begins. 	<p>Assessment tool for the critical success factors for AI implementation</p> <p>Principles:</p> <ul style="list-style-type: none"> • Well-being • Respect for autonomy • Privacy and intimacy • Solidarity • Democratic participation • Equity • Diversity inclusion • Prudence • Responsibility • Sustainable Development (taken from the Montreal Declaration for Responsible AI Development)

Guidance

Examples of how to take action

(Continued)

Understanding the organizations' readiness and likelihood of success in implementation

- Early assessment of readiness, risk, and other components that influence project success is a way for health leaders to address challenges before implementation begins.

Key Components:

External factors

- Ecosystem
- Stakeholders
- Government guidelines/restrictions/incentive

Internal factors

- Data
- Computing infrastructure
- Human resources (including data engineering and AI expertise) - either internal staff or external partners/expertise
- Staff engagement with innovations and culture
- Alignment with organizational goals
- Adaptability of innovation
- Training needs and education
- Knowledge translation

A prototype of such a tool is provided in [Appendix C](#).

Tool/checklist to assess organizational risk(s) in AI implementation

Key Components:

Review potential risks in the following areas:

- Data stewardship and privacy
- Ethics/consent
- Regulatory/legal requirements
- Resourcing
- Engagement

Prototype of such a tool is provided in [Appendix D](#).

Engagement and Education of Patients, Families and Caregivers

One of the key principles that became clear in our key informant interviews and throughout the lab process is the importance of engaging patients, families, and caregivers in any AI projects that are developed and implemented. Not only do they need to be partners in co-creation, but there is also a need for targeted education to support patients in understanding the benefits of AI in their care and how things may change. The development of an engagement and education strategy for patients, families and caregivers is a key task in [Phase A: Setting the Leadership Table](#). However, the implementation and updating of this strategy must carry across the entire life-cycle of any AI project.

Participants noted that this engagement strategy should also include a recognition that different patients/families will need to be engaged throughout. Those involved from the very beginning will gain expertise and therefore may cease to represent the 'typical' patient. As such, the perspectives of patients, families and caregivers who are new to the initiative will also be required.

Patient, family and caregiver engagement and partnership is a critical task for health leaders in all aspects of healthcare delivery and planning. Engagement capable environments are those that recruit and prepare and provide support for patients, families, and caregivers members in their roles as advisors and as members of various committees.

It also requires support for patient, family and caregiver engagement structures and initiatives across an organization or community. Further, engagement capable environments support and encourage staff to identify and value the important contributions of patients, families and caregivers. Finally, leadership support and a strategic focus on patient partnership are critical for success.⁴

To enable patients, families, and caregivers to partner in AI development, it is imperative for health leaders to be aware of the level of understanding and acceptability of patients, families and caregivers to the use of AI. As it is a relatively new technology, there is a great deal of trepidation about its use and a lack of understanding about what AI can or cannot do to support improvements in care. You can also use terms such as 'digital health' and make AI relatable to patients, caregivers, and families (i.e., search engines and Siri). This assessment will help leaders develop engagement and education strategies to enable patients, families, and caregivers to be partners in developing and implementing AI projects in their institutions.

⁴Baker R. G; Judd M; Fancott C; Maika C (2016) Creating "Engagement-Capable Environments" in Healthcare. Healthcare Quarterly. 11-34 <https://www.longwoods.com/content/24908/books+/creating-engagement-capable-environments-in-healthcare>

In addition to assessing readiness among patients, families, and caregivers, participants noted that a key role for health leaders is fostering an environment that supports trust, honesty, and transparency about any AI innovations implemented in their institutions. Strategies to foster this type of environment include:

- Empowering patients with access to their own data; this type of access helps patients, families and caregivers to be partners in making care-related decisions.
- Sharing information in a way that it can be understood and appreciated.
- Sharing the benefits and risks of using AI, including short-term and long-term implications.
- Communicating how information is protected and addressing privacy concerns.
- Sharing successes as well as failures with AI development and implementation.
- Establishing and communicating mechanisms for patients, families and caregivers to share concerns about AI projects, and be involved in co-creation.
- Preparing staff to be able to explain the data and processes related to AI.
- Always having an identified staff member who is made available to patients, families, and caregivers should they have any questions about the technology used in their care.

The following table outlines some of the practical tools that have been developed to support the engagement and education of patients, families and caregivers. These tools are meant as samples and can be adapted and modified to meet the specific needs of any organization.

Table 2: Examples of practical tools to help health leaders in the engagement and education of patients, families and caregivers

Examples of how to take action	Principles and key components
<p>Develop a process for engaging patients in AI projects</p>	<p><i>Principles:</i></p> <ul style="list-style-type: none"> • Engagement and co-creation must take place throughout the project. • Engagement should be meaningful and not performative. • Processes must respect the skills and experience of patients, families and caregivers. <p><i>Key Components:</i></p> <ul style="list-style-type: none"> • Clearly articulate what you are asking of patients, families and caregivers. • Frame the engagement in the larger context of why you’re engaging in the first place. • Outline how they will be engaged and what will be expected of their participation. • Provide details about the supports and education they will receive. • Provide details about remuneration (if applicable). • Outline how risks will be mitigated and what processes are in place for patients, families and caregivers to raise concerns and access supports as required. <p>A prototype of such a tool is provided in Appendix E.</p>
<p>Assessment tool to assess patients’ perceptions and understanding of AI to enable engagement and education strategies</p>	<p><i>Key Components:</i></p> <ul style="list-style-type: none"> • Find out what patients, families and caregivers have questions and concerns about. • Understand what patients value in terms of information about AI. • Include diverse perspectives in the process. • Individual organizations can determine how to collect information (staff, focus groups with patients, providers, etc.) • Each organization can determine how to communicate with patients to help address concerns (portals, printouts, chart details, etc.) • Ask patients how they want to be communicated with and at what time during their care journey. • Find and share examples of successful AI projects. <p>A prototype of such a tool is provided in Appendix F.</p>

Engagement and Education of Healthcare Providers

The success or failure of health innovations depends on the engagement and support of the healthcare providers who will be impacted by these changes and AI is no different. There needs to be strategies in place to educate and engage healthcare providers throughout the development and implementation process for any AI project.

Health leaders also have a role in creating an organizational culture that empowers engagement and co-creation and provides supports, including dedicated time and education for healthcare providers to be involved in the development and implementation of AI projects. This involves enabling organizational education strategies and seeking out and advocating for training and mentorship opportunities with partner organizations and institutions. There are many organizations that have, or are in, the process of developing educational offerings for AI, and health leaders can support staff in pursuing this continued education.

The following table outlines some of the practical steps that health leaders can take to support the engagement and education of staff. These are meant as samples and can be adapted and modified to meet the specific needs of any organization.

Table 3: Examples of practical tools to help health leaders in the engagement and education of healthcare providers

Examples of how to take action	Key components
<p>Embed staff that will be using AI tools/innovations in design and planning processes</p>	<ul style="list-style-type: none"> • Include impacted staff in the design of AI tools. • Fit new tools into existing workflow, wherever possible. • Demonstrate how their contributions increase patient safety and quality in the organization. • Pre-testing with staff that are going to use it (e.g., does it work, is it difficult to use, how much do I need to know?) • Participation in design and implementation enables staff to understand and interpret the process, share and educate other colleagues about the tool and what is in the 'black box'.
<p>Competencies for healthcare providers regarding AI</p>	<ul style="list-style-type: none"> • Program/credentialed offering (i.e., CanMEDS approach). • Education/training involving both theoretical and practical applications of AI from various user groups. • Educating future generations of providers (i.e., undergraduate/post-graduate programs). • Continuing education.
<p>Coaching/mentorship program for providers to gain practical skills</p>	<ul style="list-style-type: none"> • Pairing of clinicians/scientists to embed tools in workflow. • Ongoing, long-term mentorship relationship to support initial implementation and future technological evolutions. • Case studies (i.e., videos). • Involvement of various user groups, including patients, families and caregivers. • Organization-based and broader coaching/mentorship network.
<p>Building a network/community of practice to support implementation efforts</p>	<ul style="list-style-type: none"> • AI implementation has been centred in large academic hospitals in urban settings. • A network/community of practice would enable the sharing of insights and experiences with a broader range of institutions. • It would also help to ensure diverse participation and engagement (i.e., wider inclusivity involving community organizations). • A network would enable health leaders to create mentorship opportunities for interested staff that might not be possible within their own organizations.
<p>Education for providers regarding patient partnership and co-design for AI development and implementation</p>	<ul style="list-style-type: none"> • Partnership by design is a process that needs to be embedded in all AI projects. • Health leaders should support staff to learn about engagement principles and strategies to support the work of the organization in creating engagement-capable environments.

Other Considerations

As noted in the [Toolkit for Implementers of Artificial Intelligence in Health Care](#) by Canada Health Infoway, with proper implementation, AI is expected to dramatically improve the quality, safety and efficiency of health care in Canada. For example, in the time of COVID-19, AI solutions have been rapidly developed by three Ontario research teams to better identify, diagnose and treat COVID-19 in their communities⁵ ([full article](#)). As such, this guidance is designed to support health leaders in developing and implementing AI tools and innovations in their institutions and healthcare settings. While it is hoped that this report will help with uptake and implementation, participants noted that there remain challenges to AI adoption outside of health leaders' control. Strategies to engage, educate and communicate with policy and decision-makers at the local, provincial/territorial, and national level will be required to address barriers related to data access and stewardship, sustainable funding, and regulation, to name a few. Health leaders can work with partners to share their learnings about the benefit of AI in the health sector and the need for supportive policy change. [Appendix G](#) provides a tool designed to enable health leaders to begin to plan ways to engage policy and decision-makers in these important conversations.

⁵ Ontario researchers use AI to diagnose and treat covid 19 <https://cifar.ca/cifarnews/2020/12/16/ontario-researchers-use-ai-to-diagnose-and-treat-covid-19/>

Appendix A: Steps to develop the map for the implementation of AI

A key component of the design lab was the development of a multi-layered map of what the ideal state of AI implementation of AI would look like in Canada's health sector. This exercise considered the perspectives and experiences of policymakers/decision-makers, point-of-care implementers (i.e., point-of-care staff) and/or managers, patients, families, caregivers, and data scientists/AI innovators. This approach provided an understanding of the implementation journey, using three AI innovations as examples, and highlighted areas where the development of guidance for health leaders was required. The map offers a visual construction of the key steps in AI implementation and is designed to be used in conjunction with the guidance developed to help health leaders support the further adoption and implementation of AI projects. (see figure 1).

1. Develop scenarios for the implementation of different AI projects. For this lab, we utilized the following scenarios:
 - Scenario 1:** AI for administrative purposes
 - Scenario 2:** AI in diagnostic imaging for treatment planning
 - Scenario 3:** AI in the remote monitoring of patients
2. Work with participants to outline the key phases and steps for an ideal implementation process based on their experiences and understandings.
3. Highlight areas where there are gaps between the ideal and current state of implementation.
4. Celebrate the development of the map and thank all who participated for their insights.
5. Consolidate insights and phases/steps from the maps for the three scenarios into a joint map for AI implementation. Review with the people who provided input.
6. Identify the opportunities to develop implementation guidance.

Appendix B: Decision Matrix: Is Artificial Intelligence a fit?

Decision Matrix: Is Artificial Intelligence a fit?

This decision matrix tool is to be used by organizational leaders when comparing possible investments/ solutions, including AI, to determine if AI is the most appropriate fit. It is encouraged that leaders perform a root-cause analysis prior to the completion of this tool to ensure all solutions considered adequately meet the needs of the objective.

Instructions:

Step 1. Review each of the considerations included in this tool. Modify the considerations to meet the needs of your organization.

Step 2. Using the weighting legend below, associate each category with a numerical weight, indicating the importance of each category to the organization.

Step 3. Using the scoring legend below, assign a score to each consideration for the solution in question.

Step 4. Multiply the score assigned to the weight associated. Enter this value in the appropriate cell.

For example, if the importance of equipment finances was weighted a 5, and the AI solution in question required minimal equipment and therefore scored a 4, the total value entered in the cell would be 20 ($5 \times 4 = 20$).

Step 5. Tally up the cells in each column within a category. These scores can then be compared between solutions.

Step 6. Add together all the total scores from each category to determine a final score for each solution. The option that scores the highest is typically the best fit solution for the organization. Although the option with the highest score may not necessarily be the solution chosen, the relative scores allow for meaningful discussion, leading the team toward consensus.

Weighting Legend

Score	Rating
1	Unimportant
2	Some-what important
3	Important
4	Very important
5	Extremely important

Scoring Legend

Number	Rating
1	Poor
2	Satisfactory
3	Good
4	Very good
5	Excellent

	Consideration	Weight	Solution A Score	Solution B Score	Solution C Score
Cost	Project Management				
	Training				
	Equipment				
	Licensing				
	Sustainability/Maintenance				
	Human resources				
	Total Cost Score:		/150	/150	/150
Implementation	Extent of training required for patients				
	Extent of training required for providers/leaders				
	Extent of training required for leaders				
	Anticipated length of time to implement				
	Total Implementation Score:		/100	/100	/100
Sustainability	Extent of ongoing training				
	Equipment requirements				
	Technology requirements				
	Human resource requirements				
	Sustainable funding				
	Total Sustainability Score:		/125	/125	/125

	Consideration	Weight	Solution A Score	Solution B Score	Solution C Score
Safety/Security	Patient safety				
	Risk of user error				
	Privacy and confidentiality of data				
	Workplace safety				
	Total Safety/Security Score:		/100	/100	/100
Quality	Patient health outcomes				
	Data accuracy				
	Impact on reporting				
	Total Quality Score:		/75	/75	/75
Stakeholder Impact	Ethical considerations				
	Political considerations				
	Interoperability with partners				
	Total Stakeholder Impact Score:		/75	/75	/75
Equity	Accessibility to patients (i.e., wifi)				
	Financial impact to patients				
	Patient literacy requirements				
	Implementable in a low-income delivery organization				
	Language requirements				
	Total Equity Score:		/125	/125	/125

Consideration		Weight	Solution A Score	Solution B Score	Solution C Score
Change Management	Comfort with solution for patients				
	Comfort with solution for providers				
	Comfort with solution for leaders				
	Desire to change				
	Number of departments impacted				
	Required restructuring				
	Total Change Management Score:		/150	/150	/150
		Final Score	/900	/900	/900

Appendix C: Readiness Assessment

The AI Implementation Readiness Assessment tool is intended to provide organizational leadership with a way to understand and review readiness to receive/implement an AI innovation.

How to use the tool:

The project manager for the AI implementation should complete the assessment with input from impacted staff, patient partners, and other key stakeholders.

The first part of the tool asks users to outline some basic parameters of the AI tool being implemented, including aims, problem to be addressed, and target population(s).

This tool provides a table to assess readiness in these key areas:

- Internal Conditions
- External Conditions
- Individuals Involved
- AI Solution

Problem Statement and Rationale: Provide a brief overview of the clinical and/or administrative problem. Explain why the AI solution was selected to address this problem.

Aim Statement: Clearly define the goals of the AI implementation.

Target Population: Briefly describe the target populations that will benefit from the AI implementation project.

Internal conditions

Organizational Culture

Element	Full readiness	Partial readiness	No/little readiness
AI understanding, value and acceptance (trust/acceptance/uptake)	There is a high level of understanding and buy-in of AI at our organization and acceptance of its use in clinical and/or administrative processes.	There is some understanding and buy-in of AI at our organization, and some team members are open to the use of AI for clinical and/or administrative processes.	There is limited understanding and buy-in of AI at our organization and limited acceptance of its use for clinical and/or administrative purposes.
Culture based in innovation and change	Our organization and staff are open to innovation and supportive of change in clinical and/or administrative processes.	Our organization and staff are somewhat open to innovation, and we somewhat support change in clinical and/or administrative processes.	Our organization provides limited support for innovation and can be resistant to change.
Innovation/change experience	Our organization has been involved in the development/implementation of many innovations that have the same level of complexity/change as the AI project we will be implementing.	Our organization has some experience in developing/implementing innovations that have the same level of complexity/change as the AI project we will be implementing.	Our organization has no/limited experience in developing/implementing innovations that have the same level of complexity /change as the AI project we will be implementing.
Project sponsorship	Sponsor(s) have been confirmed, have sufficient authority and/or influence and a record of successful sponsorship, have demonstrated personal commitment, and will dedicate sufficient time and resources to drive and sustain change.	Sponsor(s) with sufficient authority and/or influence, personal commitment and time and a record of successful implementation have been approached but not yet confirmed. OR Sponsor(s) have been confirmed but they have multiple competing priorities.	Sponsor(s) for the project are unclear.

Leadership Alignment

Element	Full readiness	Partial readiness	No/little readiness
Alignment with strategies, goals and priorities	The AI tool/ implementation is unquestionably aligned with the top-level strategy and goals of the organization.	The AI tool/ implementation is aligned with some of the strategies/goals of the organization.	There is no alignment between the tool/ implementation and the goals and strategies of the organization.
Data and computing infrastructure	Our organization has the necessary data and computing capacity to develop/ support the AI tool for implementation.	Our organization has some of the data and computing capacity necessary for implementation, but there are still issues regarding availability and interoperability.	Our organization does not have access to the data or computing capacity that is necessary to support the development/ implementation of the AI tool.
Ongoing maintenance and monitoring	Our organization has the resources and support to update, adapt and maintain the AI tool throughout the implementation process.	Our organization has some ability to update/adapt and maintain, but resources and support are limited.	Our organization does not have the resources to adapt or maintain the tool once implemented.
Education and training	Education on AI and training for this tool has been arranged for new and existing staff; adequate backfill will be provided during training.	Education on AI and training for the tool has been developed, but plans for roll-out, including backfill have not been arranged.	Education on AI and training for the tool has not been arranged.
Funding	Funding for the project has been secured.	Funding for the project is in the process of being secured.	Funding for the project still needs to be secured.
Technology	The technology to support the AI tool development/ implementation is available in our organization .	Some of the technology needed to support the AI tool development/ implementation is available but there are some gaps.	Our organization does not have the technology to support the AI tool development/ implementation.

What are the areas for development?

External Conditions

Are there any external factors that could influence the ability of your organization to develop/implement the AI solution (i.e., competing priorities, health emergencies, legislation, funding/grants, partnerships with other organizations, etc.)?

Individuals Involved

Element	Full readiness	Partial readiness	No/little readiness
Project Team Composition	Our organization has the appropriate staff with the requisite, effectiveness, time, and commitment to execute the development and/or implementation of the AI tool, including staff and/or partners with data engineering expertise.	Our organization has some of the necessary staff with the requisite, effectiveness, time, and commitment, but there are gaps in certain areas.	Our organization has many gaps in terms of the appropriate staff resources to execute the development and/or implementation of the AI tool.
Patient, family and caregiver engagement	There is a plan in place to ensure full co-development and engagement with patients, families and caregivers throughout the development and implementation of the AI tool.	Work is underway to develop a plan for engaging patients, families and caregivers in the development and implementation of the AI tool.	There has been no work done on patient, family and caregiver engagement with the development and implementation of the AI tool.
Healthcare provider engagement	There is a plan in place to ensure full co-development and engagement with impacted healthcare providers throughout the development and implementation of the AI tool.	Work is underway to develop a plan for engaging impacted healthcare providers in the development and implementation of the AI tool.	There has been no work done on how to engage impacted healthcare providers in the development and implementation of the AI tool.

What are the areas for development?

Characteristics of the AI tool

Element	Full readiness	Partial readiness	No/little readiness
Appropriateness (i.e., to the problem, appropriate tool/ model for the data available/setting)	The tool aligns with the clinical/ administrative problem we are trying to solve, and we have the data to support its development.	The tool aligns with the clinical/ administrative needs of our problem, but we require some additional data resources to support its development.	There is no alignment between the tool and our problem, and we do not have the data to support its development.
Complexity (i.e., ease of development/ understanding/ application)	The tool is straightforward to develop and apply and patients and healthcare providers will easily understand its application.	The tool will be straightforward to develop and apply, but there will be some challenges in educating patients and healthcare providers about how it works.	The tool is so complex that development will be challenging, and it will be difficult for providers and patients to understand and use.
Adaptability (i.e., Easy to adapt as requirements/ setting change)	The tool can easily be updated within our organization based on new information from its implementation.	The tool can easily be updated but it will require external support to make any changes.	The tool can not be updated once implemented.
Technological readiness (i.e., has the tool been utilized in another environment and is just being adapted, or is it being developed from scratch)	The technology has been proven through successful deployment in an operational setting and just needs to be adapted for our organization.	The model/ prototype has been developed and tested in a simulated environment and will need to be operationalized and implemented in our organization.	The proof-of-concept has been developed but has not yet been tested in either a simulated or operational environment.

What are the areas for development?

Appendix D: Risk Assessment

AI Implementation – Risk Assessment Tool

The AI Implementation Risk Assessment tool is intended to provide organizational leadership with a summary of the potential risks that need to be considered when implementing AI and an assessment of readiness from a risk perspective.

How to use the tool:

Senior leaders responsible for AI implementation should complete the assessment with input from impacted staff, patient partners, and other key stakeholders. The tool reviews potential risks in these key areas:

- Data stewardship and privacy
- Ethics/consent
- Regulatory/legal requirements
- Resourcing
- Engagement

Problem Statement and Rationale: Provide a brief overview of the clinical and/or administrative problem. Explain why the AI solution was selected to address this problem.

Aim Statement: Clearly define the goals of the AI implementation.

Target Population: Briefly describe the target populations that will benefit from the AI implementation project.

Data Stewardship and Privacy

Question	Response
1. Does the data to support this implementation exist in-house? If yes, go to question 9. If no, go to question 2.	Yes No In progress
2. Have you identified the source of data that you will use? If yes, go to question 6. If no, go to question 3.	Yes No
3. What is your strategy for identifying/accessing the appropriate data to support this innovation?	
4. Is there a risk that you might not be able to access the appropriate data? If yes, go to question 5. If no, go to question 9.	Yes No
5. Can the project proceed if you can't access the appropriate data? What is your plan to mitigate this eventuality?	
6. Do you have a data-sharing agreement with the organization that will be providing the data for this project? If yes, go to question 9. If no, or in progress, go to question 7.	Yes No In progress
7. Do you anticipate any challenges in reaching a data-sharing agreement? If yes, go to question 8. If no, go to question 9.	Yes No In progress
8. What is your plan to mitigate the risk of a data-sharing agreement being delayed or denied?	
9. How will the outputs of the data be shared? Between organizations? With the larger public? With patients?	

Question	Response
10. What are the requirements for data stewardship/data security in your organization?	
11. Can you meet the requirements of data stewardship /data security for your organization and/or the organization with whom you are sharing data? If yes, go to question 13. If no, go to question 12.	Yes No
12. What strategies can you undertake to bring your organization/project into compliance with data stewardship requirements?	
13. What is the process/protocol if there is a breach of data?	
14. Does your organization require a privacy impact assessment for new projects/innovations? If yes, go to question 15. If no, go to next section of the assessment tool.	Yes No
15. Have you completed the privacy impact assessment for this project? If yes, go to next section of the assessment tool. If no, or in progress go to question 16.	Yes No In progress
16. Are there any risks that the privacy impact assessment might delay or prevent the project from proceeding? If yes, go to question 17. If no, go to the next section of the assessment tool.,	Yes No
17. What are your strategies to mitigate this risk?	
18. What strategies do you have in place for controlling bias and ensuring representativeness in the data that will be used and the outputs produced?	

Ethics

Question	Response
1. Will ethics board approval be required for this project? If yes proceed to question 2. If no, proceed to question 6.	Yes No
2. Will ethics board approval be required at multiple sites/ organizations for this project? If yes, proceed to question 3. If no, proceed to question 3.	Yes No
3. Have you completed the ethics board review for this project? If yes, proceed to question 6. If no, or in progress, proceed to question 4.	Yes No In progress
4. Do you anticipate any risks in getting ethics board approval for this project, at this site or at the other sites (if applicable)? If yes, proceed to question 5. If no, proceed to question 6.	Yes No
5. What strategies do you have in place to mitigate the risks of ethics approval not being granted?	
6. Do you have a process in place to ensure informed consent for participation in this initiative? If yes, proceed to the next section of the assessment tool. If no, or in progress, proceed to question 7.	Yes No In progress
7. Do you anticipate any risks in getting a consent process in place for this project? If yes, proceed to question 8. If no, proceed to the next section of the assessment tool.	Yes No
8. What strategies do you have in place to mitigate the risks of getting a consent process in place for this initiative?	

Regulatory / Legal Requirements Approvals

Question	Response
1. Does this project/innovation require research or grant approval before being implemented in your hospital/organization? If yes, proceed to question 2. If no, proceed to question 5	Yes No
2. Has research/grant approval been obtained for this project/innovation? If yes, proceed to question 5. If no, or in progress, proceed to question 3.	Yes No In progress
3. Are there any risks that research/grant approval will delay this project/innovation and/or that regulatory approval may be denied? If yes, go to question 4, If no, proceed to question 5.	Yes No
4. What are your plans to mitigate the risks associated with research/grant approval?	
5. Does this project/innovation require regulatory approval before being implemented in your hospital/organization? If yes, proceed to question 6. If no, proceed to question 9.	Yes No
6. Has regulatory approval been obtained for this project/innovation? If yes, proceed to question 9. If no, or in progress, proceed to question 7.	Yes No In progress
7. Are there any risks that regulatory approval will delay this project/innovation and/or that regulatory approval may be denied? If yes, go to question 8. If no proceed to question 9.	Yes No
8. What are your plans to mitigate the risks associated with regulatory approval?	
9. Are there any additional legal or regulatory requirements that you need to be aware of?	
10. What are your plans to address these requirements?	

Resourcing

Question	Response
1. Has the funding for the project/innovation been secured? If yes, proceed to question 4. If no proceed to question 2.	Yes No
2. Is there a risk that funding won't be secured? If yes, proceed to question 4. If no, proceed to question 3.	Yes No
3. How do you plan to mitigate the risk that funding won't be secured?	
4. Is your funding from the private sector- if yes what are the protocols you have established to ensure independence and avoidance of bias?	
5. What is the long-term strategy regarding funding- have you thought about sustainability?	
6. Do you have the appropriate staff to support the implementation of the project/innovation? (i.e., data scientists/engineers, clinicians, educators, patient partnership specialists, ethicists, evaluators etc.) If yes, proceed to question 9. If no, proceed to question 7.	Yes No
7. Do you have a plan in place to attract and retain the appropriate staff for the project/innovation? If yes, proceed to question 9. If no, proceed to question 8.	Yes No
8. How do you plan to mitigate the risk of not having appropriate/sufficient staff resources to support the implementation of this project/innovation?	
9. Do you have a plan to train and educate the appropriate staff? If yes, proceed to the next section of the assessment. If no, proceed to question 10.	Yes No
10. What is your plan to develop and implement an education and training plan for appropriate staff?	

Engagement

Question	Response
<p>1. Do you have an engagement strategy to partner/co-create with patients, families and caregivers in the development and implementation of this project/innovation. If yes, proceed to question 3. If no, proceed to question 2.</p>	<p>Yes No</p>
<p>2. If no plan is in place, how will you ensure that patient, family and caregiver input is incorporated in the development and implementation of this project?</p>	
<p>3. Do you have an engagement strategy to partner/co-create with healthcare providers in the development and implementation of this project/innovation? If yes, proceed to question 5. If no, please proceed to question 4.</p>	<p>Yes No</p>
<p>4. If no plan is in place, how will you ensure that healthcare provider input is incorporated in the development and implementation of this project?</p>	
<p>5. What is your strategy for engaging/reporting with senior staff and Board members regarding the project development and implementation?</p>	
<p>6. How are you going to engage your public and stakeholders with the results of the development and implementation of the project/innovation?</p>	

Appendix E: Patient Engagement Planning Tool

Engagement Planning Tool

The Engagement Planning tool is intended to provide leaders with the understanding of the different components required in engagement. This tool is not exhaustive of all the different components but will guide the purposeful thinking around how to engage with patients, caregivers, and families.

How to use the tool:

Health leaders trying to engage ought to fill out the template prior to each engagement event, including, but not limited to, informal interviews, focus groups, and surveys. This will allow leaders to think about the what, where, why, when, and how of engagement to ensure it is meaningful and done respectfully.

Engagement	
Circle:	Patient OR Caregiver OR Families OR Other _____
Describe the level of diversity (consider rural, racialized, minority groups, level of digital and health literacy)	
Purpose of Engagement	
Method of Engagement	
Level of Decision Making/ Complexity	
Experience Required	
Time Commitment	

Engagement

Preparation Required	
Level of AI knowledge prior to engagement <i>(Do not make assumptions, ask patients directly)</i>	
Level of AI experience prior to engagement <i>(Do not make assumptions, ask patients directly)</i>	
Is AI education required prior to engagement? If yes, how will that be fulfilled?	
Communication (Who, What, When, Why, How) Ensure that all communication is at an appropriate level and free of jargon.	Pre-event: During event: Post-event/follow-ups:
Risks & Mitigation	
What are the identified fears related to the use of AI? How will you address those fears?	
Recognition (i.e., monetary) (based on # of hours, complexity, and risk)	
Do people require any support to fully participate? (ie. Accessible documents)	
What mental health supports have you put in place or identified to ensure safety for the people?	

Appendix F: Patient Engagement - AI Patient Interview Guide

This guide is meant to help health leaders or the interviewer, think of what you might try to learn from patients, and suggests how. The interviewer can be anyone on your team. We encourage you to empower patient leaders to lead the interviews. The interview guide is not a script, but more of a primer. **You are encouraged to add your own question that are specific to your context and Artificial Intelligence (AI) project. It is also recommended that you only ask 3-4 main questions.**

Note: This guide is specifically for patient engagement. A separate interview guide will need to be created for caregivers, point-of-care implementers, and decision-makers.

Your goal should be to help your patient share the **essence** of their experience - stories of real things that happened and their real impact. Getting people to share meaningful stories and insights is tough, unusual, and requires you to follow a few ground rules:

- **Explain the purpose of these conversations in the first place, prior to starting the interview.** Ensure that there is sufficient time for the patient to ask questions or raise concerns.
- **You cannot treat patients as if they are a means to an end.** They are more than just the information and stories that they share. Ensure that you have adequately thought through reimbursement, communication, and support. See the Patient Engagement Planning tool to ensure you think through some of the major buckets.
- **Interviewees are only experts in their own experience.** Asking hypothetical questions about current or future events, or asking for opinions about broad topics, doesn't help them share what's really valuable: **their own lived experiences.**
- You may face the challenge that patients will not always be aware of the AI technology being used for their care. **Ask about their experience using relatable, everyday technology, such as Amazon, Siri, or other AI.** They also may not have a deep understanding of what AI is. In those cases, focus on the person's feelings, perceptions and reactions to the technology and remember to probe.
- **Ask why, a lot.** People rarely, if ever, mean to misrepresent, but they accidentally do so by glossing over key facts or details they may not realize are important. Asking why if something seems peculiar or even just mildly interesting will help you and the interviewee **understand motivations and causes**, which are powerful. Try to get to the core values and beliefs.
- **Learn to live with silence and hold space for awkwardness.** If they're struggling with words or reacting emotionally, the best thing you can do is give them space and acknowledge their feelings, rather than trying to shut down the conversation and move on.
- **Go deep rather than broad.** Since an interviewee is only an expert in their own experience, and everyone's experiences are different, we don't rely on any one interviewee to speak on behalf of any other people, group or organization. We don't need to compare their answers side-by-side with other interviewees
- Prior to beginning the interview, **let the patient know of the supports in place** should they require it. This includes financial and mental health supports.
- Prior to beginning the interview, **let the patient know exactly how this information will be used**, how it connects to the bigger picture, and how you will keep them updated.

- **Consider using the term ‘digital health’ instead of Artificial Intelligence.** From a patient perspective, AI may not mean anything to them. You can focus the interview on AI-related technologies without specifically mentioning AI.
- **Ensure you have a clear definition of Artificial Intelligence** shared with the patient that is appropriate for their level of AI knowledge, and that it lacks any jargon.
- If required, **build in education on AI as part of the interview process.** This could be a simple 5 to 10-minute basic explanation of AI prior to starting.

Interview Questions (select 3-5)

- How comfortable are you with AI? (Or digital health OR relatable technology such as Siri?)
- What has your experience been with this technology?
- What do you see as the benefits of using this technology in care?
- What are you worried about when AI is used in your care?
- How would you like to see digital health/AI applied to your care?
- From your experience, what do you think is the most important system change necessary for AI to be better integrated in the health sector?
- From your experience, do you think there are any ideas or beliefs that need to be overcome in order for AI to become a larger part of improving care?
- How has your level of comfort with the use of AI for your care changed?
- What do you wish AI developers would consider when creating AI?
- What do you wish decision-makers would consider when supporting/funding AI projects?
- What do you wish front-line staff/providers would consider when using AI for your care?
- How can health leaders make patients and caregivers more comfortable with the use of AI in their care?

Appendix G: Policymaker Engagement Planning Tool

The Policymaker Engagement Planning Tool is intended to set the stage by providing policymakers with an understanding of the key elements of the proposed AI solution for informed decision-making. You can use this tool once the relationship is established with the policymaker(s) and there is agreement and interest in further discussions on the proposed AI solution. This tool is not exhaustive of all the different components but will guide the purposeful thinking around how to engage with patients.

How to use the tool:

Anyone trying to engage policymakers ought to fill out the template for each event, including but not limited to focus groups, committee meetings, surveys. This will allow you to think about the what, where, why, when, and how of engagement to ensure it is concise, meaningful and done respectfully.

Engagement	
Purpose of Engagement	
Method of Engagement	
Level of Decision Making	
Time/Cost Commitment for the Policy Maker	
Is the timing good?	
Is there a gap/real need?	
What are the benefits?	

Engagement

What is the anticipated key impact (i.e., effectiveness, efficiency, equity)?	
How safe is it?	
Who will be impacted?	
How much effort is required?	
How much will it cost?	
Who are the other players involved (i.e., staff/clinician, patient/family/caregiver, community)?	
Is there a better solution?	
Who else is using it?	
Can we coordinate across jurisdictions?	
How it aligns with your priorities	



Appendix H: Additional Resources

Key Canadian Institutions for Artificial Intelligence

[Canadian Institute for Advanced Research, Pan-Canadian AI Strategy](#)

[Mila – Quebec Artificial Intelligence Institute](#)

[Vector Institute for Artificial Intelligence](#)

[Alberta Machine Intelligence Institute](#)

Healthcare Excellence Canada (formerly, Canadian Foundation for Healthcare Improvement and Canadian Patient Safety Institute)

Implementing Artificial Intelligence in Healthcare: Lessons Learned from Innovators and Early Adopters

[Webinar Recording](#)

[Webinar Summary](#)

Stakeholders' Perspectives: How Artificial Intelligence Can and Should Be Used in Healthcare

[Webinar Recording](#)

[Webinar Summary](#)

Recommended Readings

Canada Health Infoway (2021) [Toolkit for Implementers of Artificial Intelligence in Health Care December 2021 \(Version 1.0\)](#)

Drysdale, E., Dolatabadi, E., Chivers, C., Liu, V., Saria, S., Sendak, M., Wiens, J., Brudno, M., Hoyt, A., Mazwi, M., Mamdani, M., Singh, D., Allen, V., McGregor, C., Ross, H., Szeto, A., Anand Verma, A., Wang, B., Paprica, A., & Goldenberg, A. (2020). (rep.). [Implementing AI in healthcare.](#)

Evans, T., Naylor, D., Strome, E., Bernstein, A., Dodge, D., Durand, A., Goldenberg, A., Goebel, R., Jacobs, J., Le Bouthillier, A., McDonald, T., McGrail, K., Murphy, G., Paprica, A., Piovesan, C., Strong, M., & Tamblyn, R. (2020). (rep.). [Building a Learning Health System for Canadians: Report of the Artificial Intelligence for Health Task Force.](#)

McCradden, M. D., Sarker, T., & Paprica, P. A. (2020). Conditionally positive: A qualitative study of public perceptions about using health data for artificial intelligence research. *BMJ Open*, 10(10). <https://doi.org/10.1136/bmjopen-2020-039798>

NHS Health Education England (2018). (rep.). [The Topol Review - Preparing the healthcare workforce to deliver the digital future: Interim Report - A Call for Evidence.](#)

Registered Nurses' Association of Ontario – AMS Healthcare (2020). (rep.). [Nursing & Compassionate Care in the Age of Artificial Intelligence: Engaging the Emerging Future.](#)

Reznick, R. K., Harris, K., Horsley, T., & Hassani, M. S. (2020). (rep.). [Task Force Report on Artificial Intelligence and Emerging Digital Technologies](#).

Topol, E. J. (2019). Deep medicine: How artificial intelligence can make healthcare human again. Basic Books.

Wiens, J., Saria, S., Sendak, M., Ghassemi, M., Liu, V. X., Doshi-Velez, F., Jung, K., Heller, K., Kale, D., Saeed, M., Ossorio, P. N., Thadaneys-Israeli, S., & Goldenberg, A. (2019). Do no harm: A roadmap for responsible machine learning for health care. *Nature Medicine*, 25(9), 1337–1340. <https://doi.org/10.1038/s41591-019-0548-6>

Education & Training Opportunities

[The Michener Institute of Education at UHN](#) (i.e., courses, certifications, etc.)

- [Artificial Intelligence in Health Care Certificate Program](#)
- [Artificial Intelligence Fundamentals](#)
- [Special Topics in the Digital Revolution: The Road to Artificial Intelligence in Health Care 101](#)