IMPLEMENTING HEALTH INNOVATION:
TRANSLATING ITS COMPLEXITY FOR HEALTH INNOVATORS IN ONTARIO

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Project Summary

Canada is a leader in creating innovative health technologies. However, many seemingly great innovations fail to penetrate the Ontario health care system. Current processes and pathways for implementation in Ontario are complex and there is no widely accepted, consistent approach. The lack of clarity and transparency for implementing innovative health technologies in Ontario creates a system that is difficult to understand and navigate. This poses a major challenge for health innovators who lack knowledge about the structure and function of the system and pathways for commercialization. The Ontario health care system requires a framework to support health innovators navigate the innovation ecosystem in order to improve decision-making among health innovators, engagement among stakeholders, and sharing and accessing information and services. To address this problem, a translational thought strategy was taken to leverage the knowledge of experts in health care, industry, government and academia to develop a solution to help guide health innovators through the health innovation implementation process in Ontario. As a result of this work, we provide a comprehensive overview of the current processes and pathways of the health innovation ecosystem and provide a potential solution to help guide and support health innovators through the health innovation implementation process in Ontario.

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Background

Innovative health technologies have the ability to provide extraordinary benefits to patients and the health care providers who care for them. New technologies may provide value and a meaningful benefit beyond the current state of health care (Ontario Bioscience Innovation Organization, 2013). Technological advancements play a vital role in health care research and innovation. With a large number of hospitals and research institutes, Ontario is a “hub” for health research and innovation. Toronto alone generated more than $840 million in research revenue and had over 1000 home grown companies in the health science sector in 2016 (TOHealth!, 2016). Yet, health innovators experience major challenges mobilizing research knowledge and resulting innovative health technologies into the Ontario health care system. This is partly due to no clearly defined framework for navigating the implementation process and stakeholders having important but poorly understood roles in the health innovation ecosystem. Innovation requires openness and risk taking, and its adoption must be monitored and evaluated to ensure it meets both fiscal demands and health outcomes (Ontario’s Chamber of Commerce, 2016). and this further contributes to the gap in access and navigation of pathways and processes for implementation.

The structure of the health care system in Ontario is complex. The complexity of the system is in part due to fragmented organizational structures and processes, and to a lack of communication among stakeholders (health care professionals, academia, industry and government). As a result, the health care system can be difficult to for innovators to understand and to navigate their way through, posing numerous issues related to commercialization and reimbursement in Ontario. With no clearly defined innovation processes or pathways, many potentially important technologies fail to penetrate the health care system and their adoption and diffusion are unsuccessful.

Moreover, the Ontario health care system operates under a single payer model where services not products – such as devices and technologies – are reimbursed by the government. This reimbursement process does not facilitate health care innovation, and a recommendation by the Ontario Ministry of Health to fund certain innovative technologies does not guarantee that a product will be reimbursed or adopted. The Ontario government also has two conflicting priorities that make it difficult for health innovators to implement an innovation locally: 1) the province aims to develop a culture of innovation that supports home-grown talent and acts as a catalyst to accelerate health technology commercialization efforts in Ontario (Office of the Chief Health Innovation Strategist, 2017); but 2) the province must remain agnostic to the type of innovation that is adopted and mandates that the ‘best’ innovation be chosen to solve a given health need, regardless of vendor. With misaligned priorities and no formal process to determine which innovation to adopt further hinders commercialization efforts among health innovators.

The Ontario health care system is characterized by an environment where either local companies fail to scale their businesses according to the population or market, successful companies leave the province, or innovators only supply their products to jurisdictions outside of Ontario (Ontario’s Chamber of Commerce, 2016). In such a system that is difficult to navigate, it is also challenging to access venture capital, relevant professional talent, and/or the Ontario market (specifically, the public health care system) (Ontario’s Chamber of Commerce, 2016). As Ontarians, we miss opportunities to access innovative health care options (e.g., sleep apnea device developed by BresoTEC) that would otherwise address health challenges and promote improvements in the health and well-being of our communities.

The Ontario health care system needs an innovation ecosystem where pathways to commercialization are linear, and where innovation is smoothly adopted into the system (Ontario's Chamber of Commerce, 2016). To decrease the gap between research and implementation of innovative health technologies, communication, transparency and collaborative partnerships between relevant stakeholders, and areas of the health system and health innovators must be solidified. In doing so, pathways to adoption can be optimized and innovative health technologies will become easier to implement and sustain.

In summary, from a systems perspective, there is a lack of clarity and transparency for the current processes and pathways in Ontario for the implementation of innovative health technologies. Health innovators are left to navigate this complex system with little-to-no knowledge or guidance from the system or stakeholders involved. As a result, health innovators fail to scale their businesses here motivating them to leave Ontario or to implement in other jurisdictions.

Need

Based on observations and the literature, there is a clear need to help guide and support health innovators through the technology implementation process within the Ontario health care system to promote the successful adoption of innovative health technologies into clinical practice.

Problem Statement

The current processes and pathways to implementation in Ontario are complex and lack transparency. There is no widely accepted, consistent approach to innovation implementation within the Ontario health care system.

Capstone Project

This Capstone project served as a platform to identify, propose and execute a meaningful translational research endeavour that would offer tangible benefits relevant to health innovators and other community partners. This project sought to understand a complex health systems issue by exploring how industry, academia and hospitals function both independently and interdependently to implement innovative health technologies within Ontario's Government regulated health care system. Using the translational thinking framework, our team leveraged the expertise and insights of a diverse stakeholder base through a creative, iterative, and open-ended design process. Our team used both traditional and design thinking methods to arrive at our conclusions. The ensuing report describes the problem space examined by our team, the approach we took to explore this space, as well as our findings and recommendations.

Methods

To explore this problem space, our team applied the Translational Thinking Framework (Figure 1), adapted for the health sciences from "design thinking" methodology (Brown, 2008). Design thinking is a solution-based and user centric approach that aims to tackle complex problems that are unknown or ill-defined (Brown, 2008). Translational Thinking incorporates creativity, brainstorming and divergent and convergent thinking through experiential learning. The process is iterative and employs abductive reasoning to facilitate a deep understanding for the problem and its context before a solution can be proposed. The section below describes the steps taken by our team to achieve our project goal.

Discovery Phase

With an interest in innovative technologies and digital health, motivational behaviour and health care, our team sought to learn more about the health innovation and commercialization space.

Exploratory Research

To explore and define the parameters of our project, our team spent time scoping, planning and defining our problem space. To do this, we took an exploratory research approach (Hanington & Martin, 2012) to gain a solid knowledge base for the health science sector and health innovation space. From our exploration, we garnered a deep understanding for the environmental contexts, challenges, needs, and desirable outcomes of this space. We spent 6 months in the discovery phase exploring the health technology and innovation landscape and identifying problems to address within the scope of our capstone project. The direction of our project took many turns before we narrowed scope to focus on the barriers and challenges of health innovation implementation within the Ontario health care system. Through our exploratory research, we sought to understand how industry, academia and hospitals function both independently and interdependently to implement innovative health technologies within Ontario's Government regulated health care system.

Literature Review and Environmental Scan

To achieve a deeper understanding for the health care system, we conducted a literature review by doing a scoping search through the University of Toronto library databases and consulted a librarian to help guide our search. We also conducted an environmental scan to identify current trends in health innovation, and the specific actions and processes among stakeholders in this space. A broad exploration provided a high-level overview of the landscape and the activities that take place. Our discoveries led us in many complimentary and opposing directions; however we collected relevant information about the activities, environments, interactions, and users that both hinder and drive innovation in the health care sector.

Snowball Sampling through Networking and Stakeholder Engagement

As part of our field work, we explored the interrelated components of the health innovation space and the interactions between them, we capitalized on networking and stakeholder engagements to understand individual and organizational behaviour, preferences, and stakeholder need. To collect this information from stakeholders, we used a snowball sampling approach. Snowball sampling (Biernacki & Waldorf, 1981) is a nonprobability sampling technique where primary data sources (i.e., stakeholders) nominate other potential primary data sources (i.e., additional stakeholders in a professional network) to be used in research. Snowball sampling is based on referrals from initial participants to generate additional participants to generate a sample group.

To target stakeholders and initiate a snowball sampling technique, we attended networking events, workshops, and other speaking engagements to build our sample and collect qualitative information to inform our understanding of health innovation specific to Ontario. We learned that while Ontario is a leader in research and innovation, it is extremely challenging to commercialize innovative health technologies locally, in our own health system. Our team applied this important problem against our findings from the literature review and environmental scan to further develop our research question and advance our project.

Cognitive Mapping

To make sense of the problem space, our team used cognitive mapping to visualize the information we collected into a network of ideas and associations from our literature review,

environmental scan, and networking and stakeholder engagements. Cognitive mapping (Hanington & Martin, 2012) allowed us to organize the mass of complex information in a visual form. Using this technique, we identified several relationships between the barriers and facilitators of innovation implementation in Ontario, allowing us to more fully explore and reflect upon the problem space, and to define our problem and need for this project.

Once our interests and project scope were well-defined, attracting key opinion leaders to form an advisory committee was integral to the success of our project. We sought leaders with expertise in medicine, health technology, business and innovation. Our advisory committee and TRP facilitator provided immense support and guidance that helped us organize our project objectives and to execute specific strategies to achieve them.

Definition Phase

We narrowed our project scope to focus on why innovative health technologies fail to penetrate the Ontario health care system. From abstraction and reflection of information collected in the discovery phase, our team identified our problem and focus as: ***the current pathways to the implementation of innovation in Ontario are complex and lack transparency, and there is no widely accepted, consistent approach to innovation implementation within the Ontario health care system.***

To investigate this problem further and to refine our objectives, we used the snowball sampling technique again to engage stakeholders from the health technology industry, academic and community hospitals, procurement organizations, research institutes, and government (Table 1). Using a semi-structured interview approach that included both targeted and exploratory questioning, we collected insightful information from stakeholders. These engagements provided professional and personal accounts about how health technologies move from idea generation to commercialization. These accounts provided us with a rich understanding required to address this unmet need among health innovators, as they must navigate complex pathways with little knowledge or guidance from the system or stakeholders.

The key to successfully completing this phase of our project was to map our problem within the Want-Need-Problem solution framework (Figure 2), and to identify and explore the most prominent pathways for innovation implementation. To visualize the problem within the Want-Need-Problem framework, we plotted the information we collected from the discovery phase and synthesized it into a specific problem space. We then compared the current state of the issue to the desired state. The current state of health innovation implementation in Ontario is defined as being poorly understood and executed. Many ideas and technologies developed for health fail to commercialize in Ontario. In a desired state, the health system (and stakeholders that operate within it) use clearly defined mechanisms to remove barriers that stifle innovation. It also includes the development of a framework for innovation in the health care system to support health innovators through the implementation process for the successful adoption and diffusion of health technologies. In doing so, health innovators can engage stakeholders sooner and better align their innovative health technologies with the needs and priorities of the health care system. From our findings, we determined that there is a need to develop a source of support to help guide health innovators through implementation pathways in order to facilitate more accurate decision-making and understanding of the health care system and implementation process.

Validation and Iteration Phase

To validate our defined need and brainstorm potential solutions, we pursued a co-design approach with experts in health care, industry, government and academia (Table 1). Through

this collaborative process, we leveraged the creativity, expertise and dynamic perspectives of these stakeholders through a series of brainstorming and workshopping sessions to validate our need and solution.

Engaging with various stakeholders in this problem space allowed us to validate our chosen problem and identified need. Once again, we capitalized on snowball sampling to connect with stakeholders in government, industry, research organizations, and health care. We used a semi-structured interviewing approach to ask targeted questions and collect professional insights about the health innovation implementation space to validate our need. These methods provided us with more clarity for the current structure and function of the innovation implementation processes and how these stakeholders operate and function within it.

From our engagements with various health systems and innovation stakeholders, we developed a process map prototype to illustrate the most prominent innovation implementation pathways in Ontario and how stakeholders navigate and operate within them (discussed in Results section below). Our prototype underwent several iterations as we sought continuous feedback from stakeholders to validate and refine our working model.

Ideation Phase

Our team used design thinking techniques (i.e., brainstorming and prototyping) to devise solutions that would help address our identified problem. Based on the work done during the validation phase, we determined that ***the Ontario health care system requires a framework to support innovation implementation through a well-defined system and more transparent pathways and processes to improve decision-making among health innovators, engagement among stakeholders, and sharing and accessing of information and services within the innovation ecosystem.*** The first step toward this goal was to develop a resource for health innovators to highlight the various pathways and stages of the implementation process, key considerations, and resources required for innovation implementation in Ontario. This resource is an attempt to better equip health innovators with the information they need to navigate the health innovation ecosystem, and to make innovative health technologies easier to implement into clinical practice.

During this phase, we ideated on useful ways to disseminate this knowledge. Based on our conversations with various health innovation stakeholders and discussions as a team, we concluded that web-based resource with an interactive map component would act as a valuable tool to support health innovators. An active website provides health innovators and community stakeholders a snapshot of the innovation implementation landscape in Ontario, and acts as a resource to guide decision making and navigation through the Ontario health care system.

To execute this knowledge dissemination plan, we partnered with members of the MaRS Studio Y Fellowship program that were exploring the same problem space. After several meetings, we solidified a collaborative partnership. The decision to partner with the Studio Y Fellows provided an opportunity to leverage diverse and complementary skills sets. With similar outcome goals, a collaborative effort would add more value than competing projects. The convergence of teams allowed us to offer ideas, share dynamic perspectives, and optimize a set of robust skills as a group. From this collaborative partnership, we were able to integrate new information and processes within our current work which led to the construction of a website for health innovators as our final deliverable. As a newly formed team, we prototyped the design, format and function of the website and continued to design pathways for innovation implementation. A User Experience (UX) designer was contracted to create the website for our group. Through our collaborative partnership with the Studio Y fellows and the UX designer, we turned our static

content into a format that could be displayed and navigated on our website by health innovators and community partners. The website [no longer in service] was accessed here: www.hiio.ca (Health Innovation Implementation Ontario).

Evaluation Phase

As part of our final deliverable, our team is currently validating the HIIO resource. To validate the resource for its accuracy and usefulness we are collecting expert feedback using a Delphi technique. This evaluation is currently underway. Details of the Delphi technique and methods are discussed in Appendix C and Figure 3.

Results

Our work throughout this Capstone project resulted in important findings for the current processes and pathways for health innovation implementation in Ontario.

Structure of the Ontario Health Care System

Understanding the structure of the Ontario health care system (Health Care Tomorrow, 2015) is an important consideration when identifying the target market and payer and navigating the health care system (Figure 4). The Ministry of Health and Long-Term Care (MOHLTC) is the governing body of the Ontario health care system. The MOHLTC oversees the Ontario Local Health Integration Networks (LHINs), the regional bodies responsible for overseeing the administration of health care services, and Ontario Health Insurance Plan (OHIP), the government run health insurance plan for the province of Ontario. The Ontario LHINs are responsible for the regional planning, integration and distribution of provincial funds for public health care services. OHIP is responsible for reimbursing physicians for their health services.

Health Innovation Implementation in Ontario (HIIO)

To display the current processes and pathways for innovation implementation in Ontario, we plotted the phases of the commercialization life cycle for innovative health technologies and digital health solutions (Figures 5) by designing a website and interactive process map for innovation implementation in Ontario. This resource was developed through co-design with the MaRS Studio Y Fellows and inspired by the navigation guide produced by the National Health Services (NHS, 2016).

The Health Innovation Implementation Ontario (HIIO) resource illustrates the process and pathways for commercialization of innovative health technologies in Ontario. This process is segmented into 7 distinct phases and sub-phases (Figure 5) and summarized below:

1. Ideation
2. Product Development
3. Regulation (Health Canada approval)
4. Evidence Generation
5. Health Technology Assessment (HTA)
   - 5.1. HTA: Non-government
   - 5.2. HTA: Government
   - 5.3. No HTA
6. Payer
   - 6.1. Hospital Procurement
   - 6.2. Government Reimbursement
   - 6.3. Alternative Payer
7. Diffusion

For a more detailed description of the HIIO process map phases and results of our work, please go to www.hiio.ca (password is HIIO2018!).

Phases 1-3 of the HIIO process map have clearly defined work flows, and our team determined that health innovators and community stakeholders have the most difficulty navigating the system following Health Canada approval (Phase 3: Regulation). Regulatory approval is an extensive process, but its requirements and procedures are clearly defined. The real barriers and challenges from idea generation to implementation lie between phases 4-7 of the innovation implementation process.

Phase 1: Ideation

An innovator must define the purpose of a product and its tangible and intangible benefits for users and decision makers within a health care context. Conduct a market analysis for existing and competing products and perform a SWOT analysis to inform the health care and economic potential of your innovative idea. The payer of your product should also be identified here.

Phase 2: Product Development

Once an idea has been conceptualized into a potential product (or proof of concept), an innovator must design, develop and prototype the product using an iterative process. Market analysis and user engagement will inform the competitiveness and usefulness of the product. It is important to develop your product using a reimbursement model and to determine the costs associated with your product early. These are important decision-making factors to a payer when considering the purchase your product. It is also important to remember that Ontario is a single payer system.

Phase 3: Regulation

Health Canada regulates medical devices based on risk class (Class I: low risk, II, III, IV: highest risk). To obtain regulatory approval, evidence to support the safety, effectiveness and quality of a device/technology must be obtained before it can be authorized for sale in Canada.

Digital Health Solutions

Health Canada is adapting its regulatory approach to include the review of digital health solutions to keep pace with innovation and advances in the medical device and digital health technology sector. The newly formed Digital Health Review Division will review current and future medical devices using a digital health technology. For more information, see the Notice: Health Canada's Approach to Digital Health Technologies.

Phase 4: Evidence Generation

Once Health Canada approval is received; additional evidence generation may be required. The payer in Ontario (whether via procurement or government) needs specific evidence to have confidence in the innovation's ability to fulfil a given health need. Evidence should demonstrate clinical effectiveness for various patient populations, feasibility and system readiness, appropriate outcome data, stakeholder demand and cost effectiveness. A summary of this evidence is often required for a Health Technology Assessment (described in Phase 5).

There are several channels in which evidence can be generated in Ontario. For example, the innovator can collaborate with hospitals, healthcare providers or research institutions to conduct a pilot study. This is also an important way to engage stakeholders who will be using the product and to secure buy-in early in the process. Another channel is to conduct a trail in another jurisdiction (e.g., the US or Europe) to generate evidence for its clinical utility, and/or the innovator can go straight to market and sell the product of interested buyers from international

markets. Adoption by international customers, like the US or Europe, can be a much quicker process than in Ontario to scale and diffuse a technology. Once the product is utilized internationally, data produced for its effectiveness can be used to support the product in the Ontario market.

Traditional evidence generation is carried out through clinical trials funded by government. An innovator can partner with the government, or strategically apply for available funding opportunities. This channel provides a source of funding to produce more evidence in support of an innovative product. However, clinical trials are lengthy and expensive, and many small-to-medium sized enterprises and/or start-ups do not have the required capital or resource intensive support to carry out a trial. Partnering with a contract research organization (CRO) may also be a viable option. CROs specialize in evidence generation and assist health innovators through this process.

Phase 5: Health Technology Assessment (HTA)

A health technology assessment (HTA) is the gold standard for the systematic evaluation of properties, effects, and/or impacts of health technologies. It is a multidisciplinary process that evaluates the social, economic, organizational and ethical issues of a health intervention or health technology. The main purpose of conducting an assessment is to inform policy decisions. In Canada, an HTA can be performed at the provincial, regional, hospital or national level (Table 2). An HTA may also be performed by government or non-government entities (i.e., private companies may perform their own HTAs). Alternatively, some health technologies do not require an HTA. Health innovators must be informed on the criteria used to assess health technology so they can adequately prepare evidence and business case to support their product.

Phase 5.1: Health Technology Assessment (HTA) – Non-Government

Non-governing entities can conduct an HTA for a product. A multidisciplinary team of experts use rigorous, high quality research methods to evaluate the effectiveness and efficacy a product. An HTA may be performed at the national, regional and hospital level (Table 2). Local entities at the regional and hospital level typically conduct HTAs to support decision making for the acquisition, implementation, maintenance, and disinvestment of health care technologies (Martin, Polisena, Dendukuri, Rhainds, & Sampietro-Colom, 2016).

Phase 5.2: Health Technology Assessment (HTA) – Government

A disruptive health innovation may undergo a HTA by Health Quality Ontario (HQO) and the Ontario Health Technology Advisory Committee (OHTAC). Products evaluated by these governing bodies undergo a rigorous HTA process and set of assessment criteria. HQO is mandated to make evidence-based recommendations to the MOHLTC on which health care services and devices should be publicly funded in Ontario. HQO conducts an HTA for a product and OHTAC reviews it before making their final recommendation back to HQO. Following a recommendation by OHTAC, HQO makes their final recommendation to the MOHLTC about whether to fund a service or product. A product or service may receive a positive or negative recommendation, or a government endorsement (see Figure 6 for more details).

OHTAC HTA criteria:

- Potential to improve health outcomes relative to existing alternatives
- Number of patients likely to use the health service/ intervention
- Potential to reduce harm relative to existing alternatives
- Patients accessing health services or interventions outside the province or country
- Implementation feasibility/system readiness
- Stakeholder demand

- Potential unmet need
- Equity impact
- Potential cost-effectiveness
- Potential savings to the health care system

Phase 5.3: No Health Technology Assessment

Most innovative health products do not require an HTA. Instead, innovators and device/technology manufacturers supply information about the utility and value of a product. During the Development (Phase 2), Regulation (Phase 3) and/or Evidence Generation (Phase 4) phases, a product may already have enough compelling evidence to go straight to market.

Phase 6: Payer

A decision to fund an innovative health product in Ontario is determined by the payer (the health care system).

There are various ways in which an innovative health technology may be funded:

- Hospital procurement
- Government reimbursement
- Alternative payer(s)

The health care system demands that health innovators provide the required evidence needed to convince a payer to invest in their product. If there is a lack of evidence to support a product and it fails to gain adoption, a health innovator must circle back for more testing and/or re-development of the product.

Decisions to reimburse an innovative health product in Canada are highly de-centralized. In Canada, provinces are responsible for managing their own health services. Reimbursement decisions are highly dependent on our constrained health care budget as a single payer system and the priorities of our public healthcare system. The vast majority of reimbursement decisions for market-approved products are made at the hospital level, which typically receive global funding for providing services (Husereau, Arshoff, Bhimani, & Allen, 2015).

Phase 6.1: Payer – Hospital Procurement

In Ontario, individual hospitals or buying groups have the autonomy to purchase a health product or implement a service from their own budget. Hospitals have three buckets in their funding budget: 1) global budget (GB), 2) health-based allocation model (HBAM), and 3) quality-based procedures (QBPs). Every year, the MOHLTC releases fixed funding to the Ontario LHINs to distribute across hospitals. The LHINs make strategic decisions to fund new products or programs. The LHINs are also responsible for administering regional funding and make decisions about whether to procure a product or program. A health care product must undergo an intensive procurement process with individual healthcare institutions or hospital buying groups before the product can be purchased and adopted by a hospital or a group of hospitals.

In Ontario, hospitals or shared service organizations (SSOs) can decide to purchase a product or implement a service from their own budget (London Health Sciences Centre, 2012). Every year, the MOHLTC will release funds to the LHINs for distribution among hospitals. The LHINs then decide whether to carve out a new program or fund a new technology. Since the LHIN is responsible for administering regional funding, they can decide whether they want to procure a technology or not.

The GB of a hospital makes up 30% of its entire budget. The GB is irrelevant to the population, hospital servers, or procedures done at the hospital. This component of the budget is fixed and covers operating expenses only. The HBAM (Ontario Hospital Association, 2012) makes up 40% of the hospital's budget. HBAM compares hospitals against each other under their local LHIN, and the LHIN then estimates expected health care expenses based on demographics and clinical data from competing hospitals. This component of the budget is based on evaluations of hospitals that treat more resource intensive patients and those who do not. The final component of a hospital's budget is QBP, and accounts for 30% of the budget. QBP considers the types of procedures and surgeries across hospitals and reimburses according to the type and quantity of procedures performed at each. QBP also mandates the number of procedures to be administered at each hospital in a year (London Health Sciences Centre, 2012). Understanding how the hospital budget works will help a health innovator determine how hospitals operate financially to reallocate resources to fund their product.

Changes in OHIP billing code may be required to accommodate the adoption of an innovative health product. Changes to OHIP billing codes can be lobbied for separately from the government reimbursement process. However, a change on OHIP billing code takes 7 years, on average. Bypassing the government reimbursement process can often be advantageous to a health innovator, as this pathway is labour and time intensive and requires large capital to proceed through the lengthy and expensive reimbursement process.

Buying Groups:
Procurement by Shared Service Organizations (SSOs) and Group Purchasing Organizations (GPOs) follow standardized procurement policies and processes to increase efficiency, financial control, quality and value for money.

- **SSOs:** Not-for-profit corporations providing integrated supply chain management services to member and customer hospitals regionally.
- **GPOs:** Not-for-profit national strategic sourcing organizations working on behalf of hundreds of healthcare organizations across Canada

Both SSOs and GPOs manage and reduce supply costs by leveraging better pricing from suppliers through aggregated volume purchasing.

Broader Public Sector (BPS) Procurement Directive: BPS mandates legal parameters for procurement. The BPS sets requirements and standard processes to guide designated BPS organizations on how to provide goods and services to Ontarians. The BPS mandates that procurement must be fair, competitive and transparent. The BPS also mandates the rules under which devices or technologies can be procured by hospitals or SSOs. Depending on the cost of the solution, a request for quote (RFQ) or a request for a proposal (RFP) are required. An RFQ can be private, while an RFP is public. There are set grading criteria, with a strong weight on cost-effectiveness. A simplified version of these guidelines is depicted in Figure 8.

Value-Based Procurement (VBP): VBP is a procurement methodology that can be employed while still following the BPS directive. Innovative procurement practices are increasingly tailored towards VBP which involves making investment decisions based on the overall value to the organization or system, rather than focusing narrowly on costs of a specific product or service.

Phase 6.2: Payer – Government Reimbursement

For an innovative product to be reimbursed by the Ontario Government, the product must undergo an HTA (Phase 5.2) by HQO before a recommendation is made to the MOHLTC to

either reimburse or not reimburse a product (Figure 6). A health innovator must be aware that a positive recommendation made to the MOHLTC does not mean that their product will be reimbursed and/or adopted by the Ontario health care system. This is because the government supports a solution to a particular need and does not support a specific vendor. These decisions are vendor agnostic. Adoption of a solution that is vendor dependent (i.e. only one vendor available) is not as relied upon. Furthermore, government reimbursement programs do not mean that the hospital will adopt the program. This process is lengthy and typically take at least 2 years. However, 81% of approved technology from the HTA gets funded.

Decisions to reimburse a product are largely influenced by government funding priorities, strategic political objectives announced by provincial ministers of health or local administrators, and by physician/laboratory fee schedules.

Phase 6.3: Payer – Alternative Payer

Many health innovators choose to bypass the long and expensive implementation process to publicly reimburse their innovative health product. Instead, an innovative health product may be commercialized using an alternative payer, which include:

- **Private Health Care Organizations:** Private health care organizations (e.g., private clinics) may be interested in purchasing an innovative health care product if the priorities of the private health care organization and user aligns with the benefit and value of the product.
- **Allied Health Care Professionals:** Many services and products used by allied health care professionals are not publicly reimbursed and require private funds to care for patients. In this case, the demand for an innovative health care product may be high if the priorities of allied health care professionals and their clients align with their need and value of the product.
- **Direct to Consumer:** Many Ontarians and health care providers are willing to pay for an innovative health product if it meets an unmet health need important to them.
- **International markets:** Adapting the business model of a product for international markets prior to entering the Ontario and Canadian market may help with commercialization and adoption efforts.
- **Hospital/Charitable foundations:** If an innovative health product solves an unmet need for specialized conditions, diseases, or diagnosis and treatment of health care problems, it is worthwhile to lobby hospital or charitable foundations.
- **Private Donor:** Securing a private donor to fund your innovative health product will increase your chances of implementing within a hospital where both the priorities of the donor and hospital align.
- **Venture Capital (VC) Investment:** Attracting VC investments will help to support commercialization of innovative health technologies that demonstrate the ability to dramatically increase health care productivity by reducing health care costs and improving patient health.

Phase 7: Diffusion

Scaling and diffusion can be achieved following a decision to fund an innovative health product. Innovations scale most rapidly and effectively when the diffusion strategy is devised and implemented from the initial Ideation phase and carried throughout the innovation implementation process. For innovations to be widely adopted in the Ontario health care system, they also need to be feasible and viable to implement.

Case studies

The following case examples were assessed against the HIIO process map to demonstrate the challenges and barriers faced by health innovators and to also highlight the problems with the current pathways to commercialize an innovative health technology in the Ontario health care system. With more transparent, clearly defined processes and pathways, many of these outcomes and decisions could have been strategized differently to support the commercialization efforts health innovators.

Case Study 1: 7D Surgical

7D Surgical is an Ontario-based company that developed machine-vision image guided surgery to perform fast, cost-effective radiation free spinal navigation. The procedure takes less than 20 seconds compared to traditional systems that can take up to 30 mins. It is a highly specialized health technology. This company has successfully made it through to Phase 7 using an alternative payer model.

Phase	Description	Barriers/Facilitators
1. Idea generation	Developed at Sunnybrook	Academic and entrepreneurial (co-owners) so they can have grant $ but they also have business acumen
2. Product development	Hospital partnerships Developed product at Ryerson to own 100% of IP	Early adopters in hospitals so had a lot of data and trials Autonomy over decisions and technology
3. Regulatory	HC, FDA approval	Marketable in Canada and the United States
4. Evidence generation	CFI grant at Sunnybrook	Access to grant, foundation and donor money
5. Health Technology Assessment	No HTA	Business model has been to side step government process and go to US
6. Payer	Bypassed the government implementation pathway International markets; Individual hospital	Lack of resources for slow approval process Purchasing depends on funding announcements (RFPs)
7. Diffusion	International markets; Individual hospital	Only 1 machine in Ontario (Sunnybrook hospital) because of CFI grant agreement; The US has larger operating and capital budgets; less time to market in US; densely populated in US so there is a larger market demand

Case Study 2: BresoTEC

BresoTEC is an Ontario based company with an innovative health technology that provides effective and simple technologies for the management of sleep apnea and related health conditions. This company is stuck in Phase 5: HTA.

Phase	Description	Outcome
1. Idea generation	proof of concept early	-
2. Product development	-	
3. Regulatory	HC approval	Generated enough evidence for device to apply for continued support via MaRS EXCITE

4.	**Evidence generation**	MaRS EXCITE program + RCT; demo project in collaboration with MOHLTC	Generated positive outcome to support technology and build an evidentiary bundle for the value of the technology
5.	**Health Technology Assessment**	HTA	Halted at level of government
6.	**Payer**	No government reimbursement Reliant on hospital RFPs	Not marketable in Ontario for reimbursement Solution did not meet exact specifications and need of hospital; has not sold a single device in Ontario
7.	**Diffusion**	US does not have same restrictions; Has not penetrated the Ontario health care system	Not enough commitment from clinicians and stakeholders to push innovation; lack of incentive alignment for tech and health care system

Case Study 3: da Vinci Surgery – Robotic-Assisted Surgery

The da Vinci System is powered by robotic technology that allows the surgeon's hand movements to be translated into smaller, precise movements of tiny instruments inside the patient's body. This technology has successfully made it through to Phase 7 via international markets. It has been implemented in some Canadian provinces, but not in Ontario. This is a result of differing provincial perspectives and evaluation outcomes using a government HTA process. (MOHLTC has decided not to publicly fund robotic prostatectomy).

Phase		Description	Outcome
1.	**Idea generation**	N/A	-
2.	**Product development**	Developed in US	-
3.	**Regulatory**	FDA, HC approval	FDA approval received in 2000
4.	**Evidence generation**	Evidence generated for multiple types of laparoscopic surgery	-
5.	**Health Technology Assessment**	HTA performed by Ontario government	Only examined use of machines for prostatectomy – not for any other use cases
6.	**Payer**	Recommendation by government against public funding for da Vinci	Recommendation against public funding for da Vinci; cost-benefit not supported by OHTAC and HQO.
		Individual hospitals; US and international market	Disproportionate procurement between Canada (Ontario) and international markets
7.	**Diffusion**	Individual hospitals; Canada, US and international markets	More than 4,100 da Vinci surgical systems are installed around the world, 2,703 of them in the United States, and 31 in Canada

Discussion

Our team gained a comprehensive understanding in the current processes and practices for how industry, academia and hospitals function both independently and interdependently for the implementation of innovative health technologies within Ontario's Government regulated health care system. From our findings, we learned that the Ontario health care system is complex and difficult to navigate. From a systems perspective, there is a of lack clarity and transparency for the current processes and pathways in Ontario for the adoption of innovative health technologies, and this negatively impacts a health innovator's willingness and ability to successfully implement their product within the Ontario health care system. Health innovators are left to navigate this complex system with little-to-no knowledge or guidance from the system or stakeholders involved. The inability to navigate the system, coupled with the lack of access to services and support, push health innovators to implement their innovation elsewhere, or not at all. The discussion below describes the barriers affecting successful adoption, key considerations for navigating the current system, methods and mechanisms to support adoption, and future recommendations as well as main takeaways from our project.

Barriers to Health Innovation Adoption

Below is a list of the organizational, behavioral, technical and socio-political barriers we found to hinder successful adoption of health innovations in Ontario:

Organizational

- Current procurement structure: cheapest upfront cost of a product is procured. Newer strategies emerging but downstream benefits are currently not considered.
- Government process: time and labour intensive. A positive recommendation does not equal acceptance or funding and is not guaranteed to lead to hospital-wide adoption; typically required to undergo procurement process.
- Incremental innovations: if a product is only incrementally better and not disruptive, it is difficult to get adopted.
- Small-to-medium-sized enterprises / start-ups: very difficult for small companies to penetrate the system due to lack of capital and organizational influence.
- Government funds service not the technology itself.
- Government does not support specific vendors, and if only one vendor available this might be detriment to funding.
- Decision makers often do not have science backgrounds, making the assessment and understanding of a products value and the impact on the health care system.
- Ownership of intellectual property varies at different institutions. Stringent institutional policies can be a barrier to innovation.

Technical

- Start-ups and SMEs die and cannot sustain themselves throughout the lengthy and expensive commercialization process.
- Not enough funding for SMEs at the middle stages of product development / commercialization.
- Institutional requirements for grants and funding mean that small businesses/health innovators do not have access to many funding opportunities on their own.
- Government HTAs only evaluate one application of a technology. Limited scope of assessment means it could be missing other important applications.

- High cost of innovative solution/product (manufacturing costs, supply and maintenance costs).

Behavioural
- Risk adverse health system and decision makers.
- Lack of understanding for implementation pathways.
- Clinical champions to support innovation and early adoption.
- Patient demand and need misaligned with product or political agendas.
- Lack of understanding for the health care system.
- Lack of buy in from physicians if no OHIP billing code in place.
- Lack of support from institutional leadership.

Financial
- Operating under a fixed health care budget slows innovation because there are no funds left to invest in innovative health technologies.
- If innovation does not benefit bottom line of a hospital there is less incentive for adoption.

Key Considerations for Navigating the Current Health System

To navigate the current health care system in Ontario, health innovators must change their approach to function within the system's current constraints. We compiled a list of key considerations for health innovators to help them better navigate the system:

- **Determine whether your innovative health solution meets an unmet need** for patients, providers, or systems.
- **Validate your technology out of your current context/environment.** Get your product into the hands of your target users and hospitals who will use it.
- **Identify a clinical champion and/or patient advocates.** Leverage support from hospital organizations, clinical champions and patient advocates to drive the demand and adoption of your innovative health product.
- **Clearly define the value proposition of your innovative health technology.** A well-defined value proposition must demonstrate a real solution for an unmet health or systems need. A clear value proposition will attract stakeholders to your product.
- **Devise a business model that aligns with health priorities.** Having a business model that caters to the constraints of the health care system will ensure success in the future. Different business models will be needed regionally. A good business model will align your product to the Ontario health care priorities.
- **Identify your payer.** Knowing who will pay for your product is essential to the successful adoption and diffusion of your product. This is likely the most important consideration for a health innovator; know who will pay for the innovation and how funds will be secured to do so. Examples of payers: patients, individual hospitals, SSOs, and government.
- **Determine whether your health technology is a disruptive or non-disruptive (incremental) innovation.** Innovation is categorized by its impact as either disruptive or non-disruptive/incremental. Disruptive innovations typically do not have competitors in the market or very few exist. If the innovation is disruptive there will be a new market for it. If the innovation is non-disruptive or incremental, it usually aims to improve an existing product, process or service. Incremental innovations are harder to adopt. They need to cost less than what is currently on the market to beat out competitors in procurement RFPs. If an incremental innovation has downstream benefits but does not align with a hospital's financial goals, the product is not likely to penetrate the market. Incremental technologies typically travel through the hospital procurement pathway while disruptive technologies undergo the

government pathway. This is because disruptive technologies will need new billing codes as well as infrastructure to support its use.

Methods and Mechanisms to Support Adoption

There are several ways to strategically plan for the adoption of your innovative health product:

1. **Clinical Champions:** Securing a clinical champion can act as a separate pathway to support an innovative health product. Find influential physicians and leading medical experts who are willing to act as clinical champions to support the clinical utility and economic benefit of your product. Clinical champions can help achieve adoption by lobbying government or hospital boards, and on-boarding colleagues.
2. **Engage early adopter hospitals:** There are two types of hospitals: early adopters (usually in the GTA) vs. late adopters (community hospitals). Engage and target early adopter hospitals to help with scaling and diffusion of your product.
3. **Hospital and clinical pilots:** Engage users and experts in the product development phase (Phase 2) to achieve downstream adoption. Partnering with hospitals and clinics to conduct pilot studies have many benefits. Involving users and experts early in the process may lead to more buy-in later. Engaging users and experts through co-design helps identify whether your product meets an unmet need and user demand. Pilot testing helps generate evidence required for government reimbursement, hospital procurement, or alternative payers.
4. **Partnership with large health care organizations:** Partnering with a large health care organization increases your chance of implementing an innovative health product. Large health care organizations have the infrastructure as well as the human, financial, and intellectual resources to support a product through the innovation implementation process. Start-ups or small-medium size enterprises (SMEs) typically do not have the capital or resources to undergo a lengthy and expensive implementation process. A strategic partnership will increase the chances of successful adoption.
5. **Strategic procurement:** Developing your product under an existing procurement model and planning your pricing and procurement strategy early in the product development phase will align your product with hospital funding mechanisms. It is also important to determine where your product will meet the greatest need in regions and hospitals in Ontario in order to target specific organizations and buying groups. Creating a strong business case that aligns with procurement requirements and health care priorities will make it easier to implement locally before wider spread scale in other regions.
6. **International markets:** Changing your business model to penetrate international markets prior to entering Canadian markets may help with commercialization and adoption efforts. The process of implementation in Ontario is long and expensive. The United States operates within a private health care model, has many payers and is more densely populated to test your product and generate revenue following commercialization.
7. **Targeted funding programs and opportunities:** Specific programs and funding opportunities exist in Ontario and Canada that support health innovators to develop and test an innovative health product to increase the chance of diffusion through scaling and adoption. These include programs like MaRS EXCITE and MaRS Procurement by-Co-Design, Ryerson DMZ, the Ontario Centres of Excellence's (OCE) Health Technology Fund and REACH program.
8. **Hospital and charitable foundations:** If your innovative health product solves an unmet need for specialized conditions, diseases, or diagnosis and treatment of health care problems, it is worthwhile to lobby hospital or charitable foundations. Funds from these organizations may help purchase new innovations as well as provide the required infrastructure to house new innovations. Many innovators in Ontario have seen success accessing charitable foundations.

Future Recommendations

In its current state, the health system is complex and difficult to navigate. To retain innovative companies and health technologies in Ontario, there is a need for more clearly defined processes and pathways to support health innovators navigate the innovation ecosystem and health care system. To achieve this, our provincial health care system must conduct a systems wide evaluation of all public innovation and commercialization services to consolidate and streamline them. Consolidating resources into a centralized shared innovation office has the ability to cut unnecessary costs and increase efficiencies across systems and stakeholders. A consolidated innovation office has the ability to streamline the structure and operations to support innovation implementation by assigning clear roles and responsibilities among organizations and stakeholders. With clearly defined process and pathways, health innovators are better able to navigate the health system. In addition, health innovators will have access to the key programs, services, and stakeholders they require at each stage of the commercialization process. For example, Israel has one government body that oversees all aspects of innovation and the processes and pathways for navigating the health system are more clearly defined. Furthermore, increasing transparency of the government reimbursement process would help support the advancement of innovation implementation by understanding the decision-making hierarchies and practices of the Ontario government. Considering that the BPS mandates procurement to be fair, competitive and transparent, the government should follow suit. Funding dollars should also be re- distributed and allocated to support funding for start-ups and SMEs, independent of academia/research institutions. Currently, many start-ups and SMEs cannot support the advancement of their innovative health technology without an academic affiliation or investment from venture capital. Funding opportunities should be re-evaluated to support innovative companies that create here to sustain their economic growth and development.

Until our government performs a province wide evaluation for the innovation implementation process, we must work within the constraints of our complex health system in order to equip health innovators with the knowledge and understanding they need to successfully navigate Ontario's innovation landscape and health care system. We believe that creating a Health Innovation Strategist role is one solution to reduce the current problems and challenges faced by health innovators through this process. Services offered by Health Innovation Strategist would include robust consultations, health and economic assessments for innovative health technologies, and strategic planning for implementation early in the ideation and product development phases, and at all levels of the innovation implementation process.

To drive Ontario's economic value and improve our health care, it is essential to retain and attract talent and innovative health technologies here. Health innovators must understand how to navigate the system to do this. A Health Innovation Strategist would exercise the skills and expertise required to guide health innovators through the implementation processes and pathways by facilitating more accurate decision-making and deeper understanding of the innovation landscape and health care system.

To promote successful adoption, innovative health technologies must undergo rigorous assessments to determine whether it is a viable product that meets both the health and economic needs of our province. Health innovators also require a strategic plan to navigate the system for successful adoption of their innovative health technology within Ontario. A Health Innovation Strategist has a solid overall understanding of the system, access to strong relationships and networks, and an ability to problem solve in the face of adversity and complex systems. Through robust consultation and assessment of an innovative health technology, a

Health Innovation Strategist can develop a strategic plan that aligns an innovation's value and success based on the understanding of the health care system and health-based economy. Providing a service like this in the early stages of product development and at all levels of the innovation implementation process will allow health innovators to better navigate the complex innovation implementation process and to market their product for successful adoption. In addition, a Health Innovation Strategist can review the technology and fit within the system to make market projections about the short, medium, and long-term needs. These projections will allow a health innovator to choose a pathway that is accessible and easy to navigate. Through the support of a Health Innovation Strategist, health innovators become better equipped with the knowledge they need to make informed decisions from both a clinical and business planning perspective.

To support the adoption of innovative health technologies in Ontario, we must look towards new models that help health innovators navigate the complex innovation landscape within our current health care system. However, this is beyond government, industry or current health systems infrastructure. One solution is to seek both public and private partnerships of the Ontario government and health industry to provide a portion of subsidies to fund the role of Health Innovation Strategists as a paid for consultation service to health innovators. Until there are more transparent processes and pathways for innovation implementation in the health care system, health innovators require guidance and support to navigate and maneuver the system for successful adoption of their innovative health technology. A private-public partnership can help Health Innovation Strategists operate between entities and across organizations within health science sector to promote and support innovation within our province. This provides an opportunity to promote business-government relationships within and outside of Ontario, giving health innovators better access to the innovation pipeline in Ontario. This solution would result in huge short- and long-term cost savings of both time and money. In turn, these efforts will help to accelerate economic growth for the Ontario health innovation sector, as well improve the delivery of health care to patients due to an increase of new innovations penetrating the market.

In conclusion, the current innovation implementation process requires a more streamlined approach and there needs to be mechanisms and supports in place to help health innovators successfully penetrate the market. To successfully implement an innovative health technology within the Ontario health care system, health innovators must:

1. **Understand the current processes and pathways for innovation implementation to promote successful navigation through the health care system.**

2. **Assess their innovative health technology in order to determine whether it is viable to fund in Ontario or through an alternative payer.**

3. **Strategize an implementation plan that aligns with Ontario's economic and political health care priorities.**

References

1. Biernacki, P., & Waldorf, D. (1981). Snowball sampling: Problems and techniques of chain referral sampling. *Sociological methods & research, 10*(2), 141-163.
2. Brown, T. (2008). Design thinking. *Harv Bus Rev, 86*(6), 84-92, 141.
3. Dalkey, N. C. (1969). *The Delphi method: An experimental study of group opinion*. Retrieved from

4. Hanington, B., & Martin, B. (2012). *Universal Methods of Design: 100 Ways to Research Complex Problems, Develop Innovative Ideas, and Design Effective Solutions*. Rockport, MA: Rockport Publishers.
5. Health Care Tomorrow. (2015). *Understanding the health care system*. Retrieved from
6. Husereau, D., Arshoff, L., Bhimani, S., & Allen, N. (2015). *Medical device and diagnostic pricing and reimbursement in Canada*. Retrieved from Edmonton, AB:
7. Jones, J., & Hunter, D. (1995). Consensus methods for medical and health services research. *Br Med J, 311*. doi:10.1136/bmj.311.7001.376
8. Lofmark, A., & Martensson, G. (2017). Validation of the tool assessment of clinical education (AssCE): A study using Delphi method and clinical experts. *Nurse Educ Today, 50*, 82-86. doi:10.1016/j.nedt.2016.12.009
9. Löfmark, A., & Mårtensson, G. (2017). Validation of the tool assessment of clinical education (AssCE): A study using Delphi method and clinical experts. *Nurse Educ Today, 50*, 82-86.
10. London Health Sciences Centre. (2012). *Ministry of Health and Long-Term Care: Patient Based Funding*. Retrieved from London Health Sciences Centre: http://www.lhsc.on.ca/About_Us/LHSC/Corporate_Information/Board_of_Directors/Meetings/201204ptbsdfund.pdf
11. Ludwig, B. (1997). Predicting the future: Have you considered using the Delphi methodology. *Journal of Extension, 25*(5), 1-4.
12. Martin, J., Polisena, J., Dendukuri, N., Rhainds, M., & Sampietro-Colom, L. (2016). Local health technology assessment in Canada: Current state and next steps. *Int J Technol Assess Health Care, 32*(3), 175-180. doi:10.1017/s0266462316000210
13. NHS. (2016). *Office for life sciences: a how-to guide: A guide for navigating the innovation pathway in England*. Retrieved from
14. Office of the Chief Health Innovation Strategist. (2017, 2017-12-12). Office of the Chief Health Innovation Strategist. Retrieved from http://www.health.gov.on.ca/en/pro/programs/ochis/
15. Ontario Bioscience Innovation Organization. (2013). *Realizing the promise of healthcare innovation in Ontario: Increasing value for the patient, health system, and economy*. Retrieved from
16. Ontario Hospital Association. (2012). *Health-based allocatin model (HBAM): What you need to know*. Retrieved from https://www.thegce.ca/EDUCATION/Documents/2.HBAM-What%20You%20Need%20To%20Know.pdf
17. Ontario's Chamber of Commerce. (2016). *Transformation through value and innovation: Revitalizing health care in Ontario* Retrieved from http://www.occ.ca/wp-content/uploads/HTI_March15.pdf
18. Polit, D. F., & Beck, C. T. (2004). *Nursing research: Principles and methods*: Lippincott Williams & Wilkins.
19. Rayens, M. K., & Hahn, E. J. (2000). Building consensus using the policy Delphi Method. *Pol Polit nurs Prac, 1*. doi:10.1177/152715440000100409
20. Robinson, P., Oades, L., & Caputi, P. (2015). Conceptualising and measuring mental fitness: A Delphi study. *International Journal of Wellbeing, 5*(1).
21. Schulz, V., Kozell, K., Biondo, P., Stiles, C., Tonkin, K., & Hagen, N. (2009). The malignant wound assessment tool: a validation study using a Delphi approach. *Palliative medicine, 23*(3), 266-273.
22. TOHealth! (2016). *Toronto region human health and sciences: Cluster action plan summary*. Retrieved from http://www.tohealth.ca/wp-content/uploads/TOH_ClusterPlan_2016_Summary.pdf
23. Vandelanotte, C., Dwyer, T., Van Itallie, A., Hanley, C., & Mummery, W. K. (2010). The development of an internet-based outpatient cardiac rehabilitation intervention: a Delphi study. *BMC cardiovascular disorders, 10*(1), 27.

Appendices

1. **Appendix A: Figures**
2. **Appendix B: Tables**
3. **Appendix C: Evaluation Phase – Delphi Technique**

Appendix A: Figures

Figure 1. Translational Thinking Framework
(Retrieved from: https://trp.utoronto.ca/translational-thinking/)

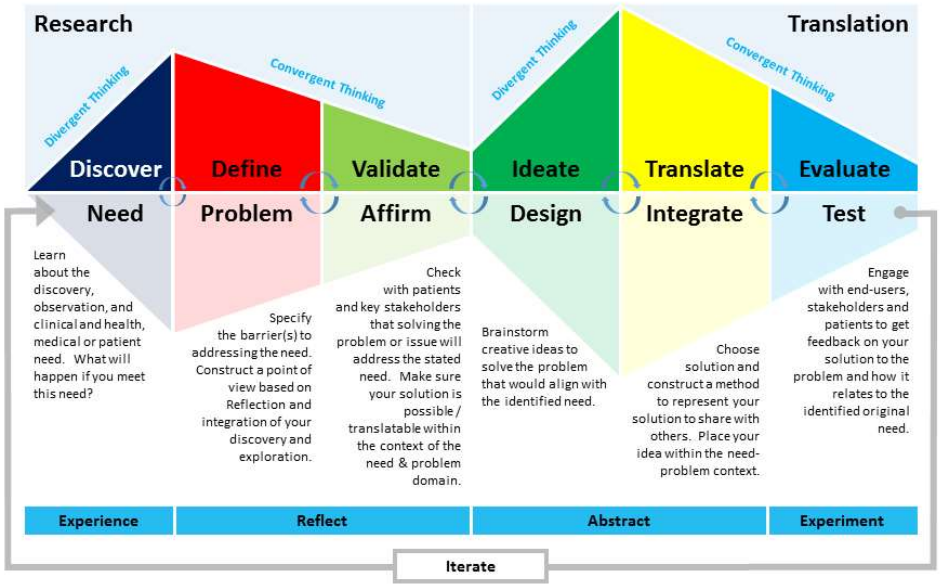


Figure 2. Want-Need-Problem Solution Framework

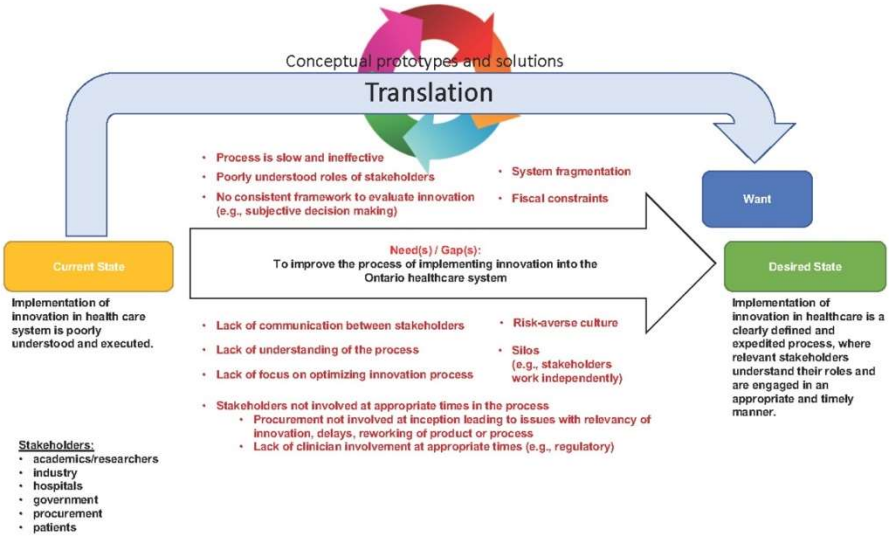


Figure 3. Study method summary using a Delphi Model

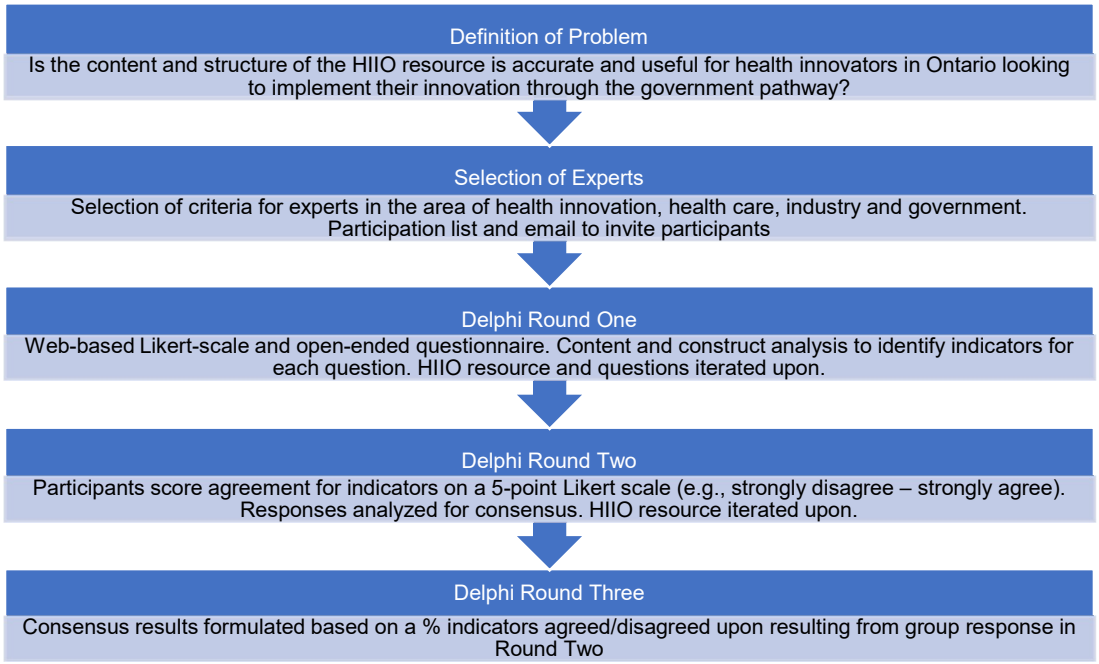


Figure 4. Structure of the Ontario Health Care System
(adapted from Understanding the Ontario Health Care System report, 2015)

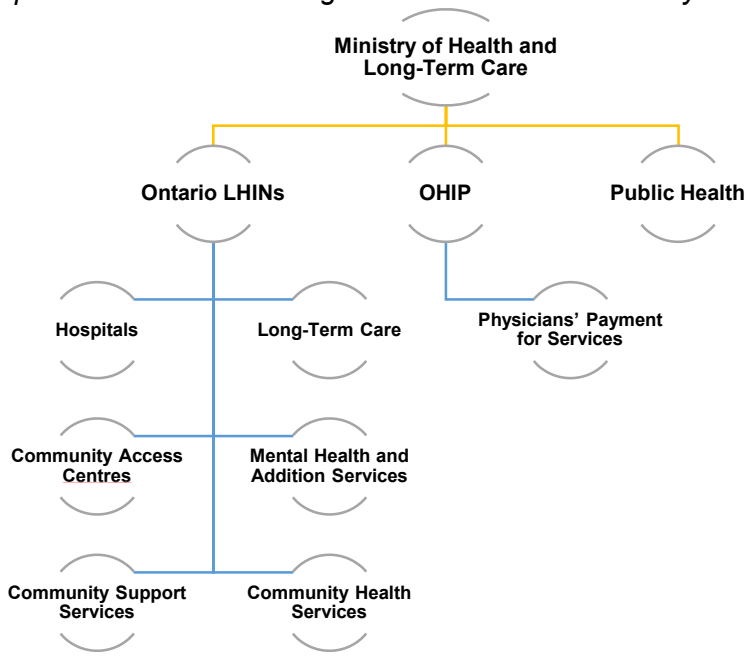


Figure 5. Process map for health technologies and digital health solutions in the Ontario health innovation ecosystem

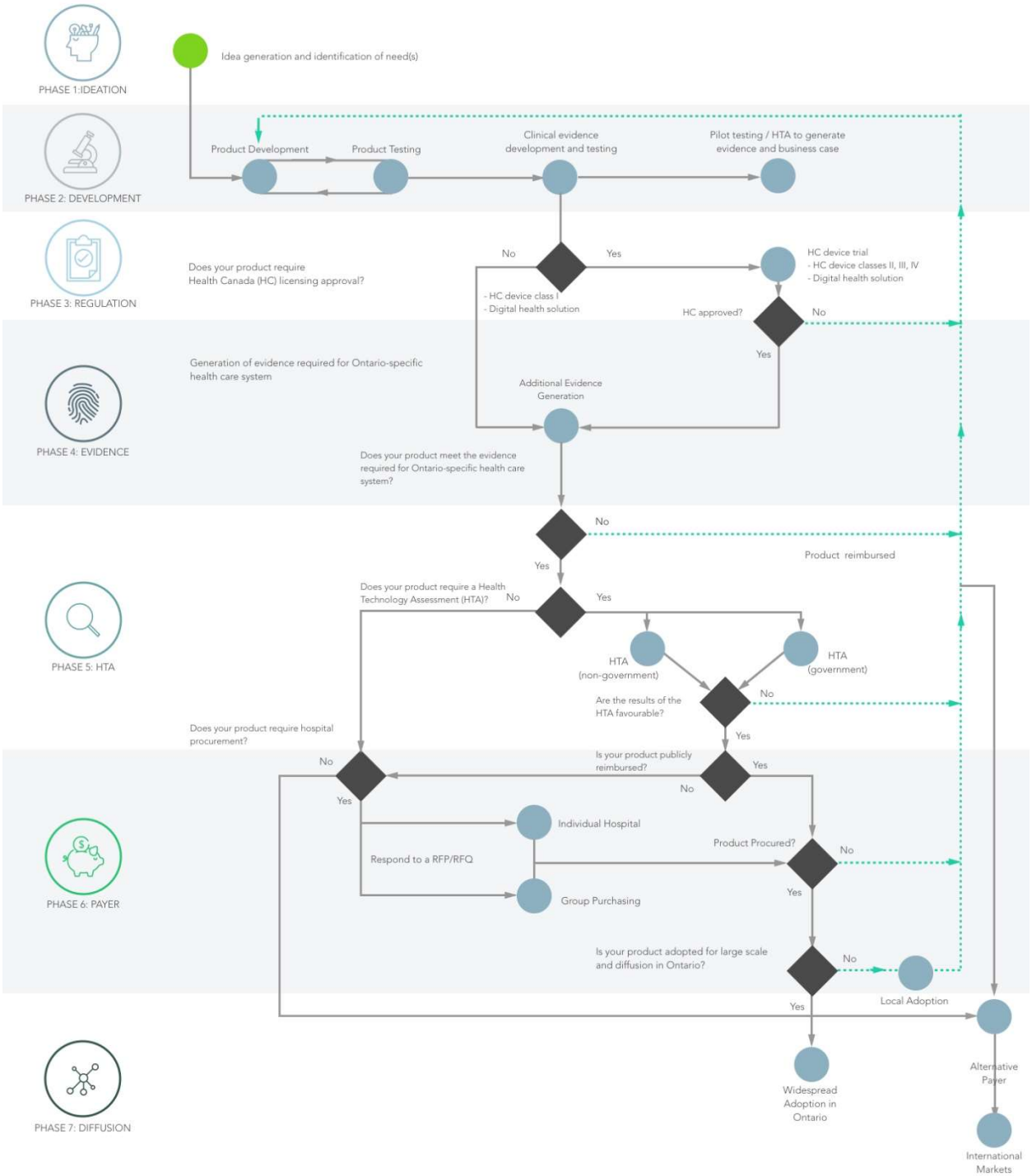


Figure 6. Process map for government reimbursement of health technology in the Ontario health innovation ecosystem

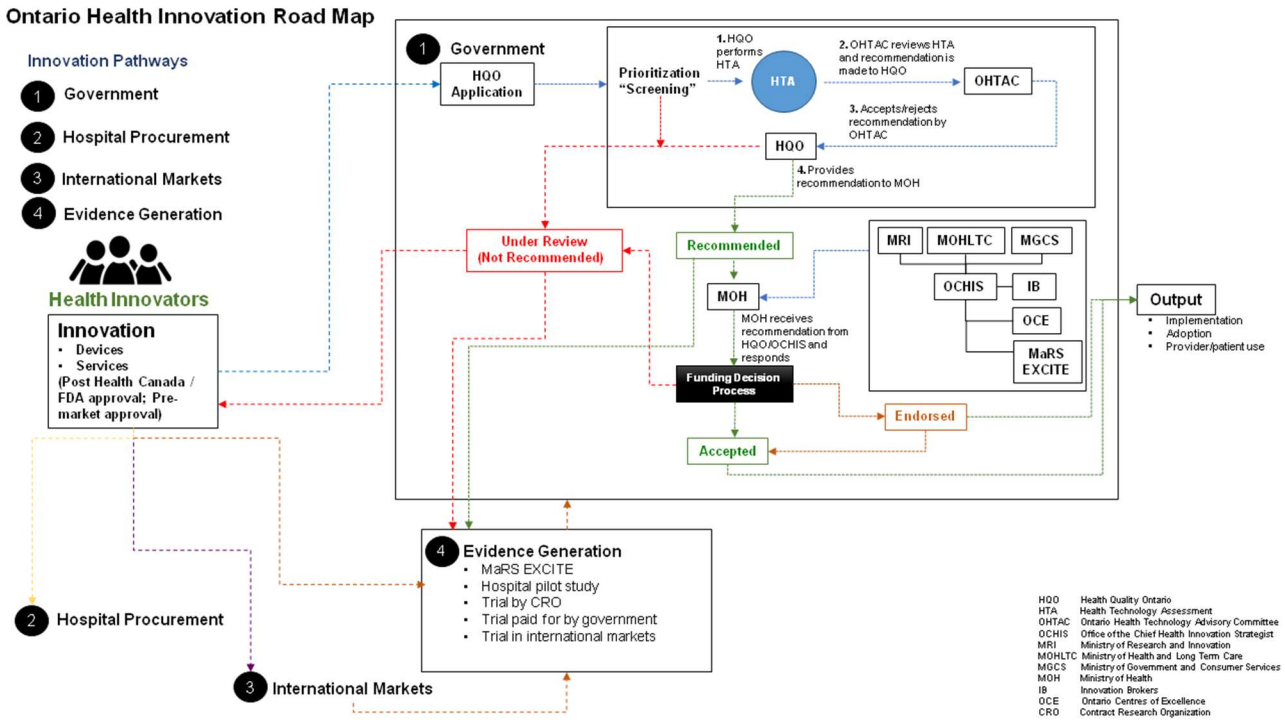


Figure 7. Structure of an individual hospital budget

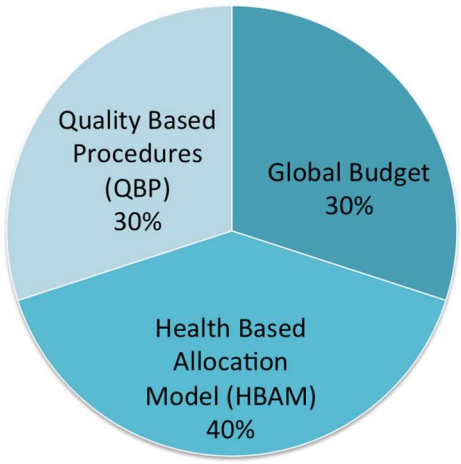
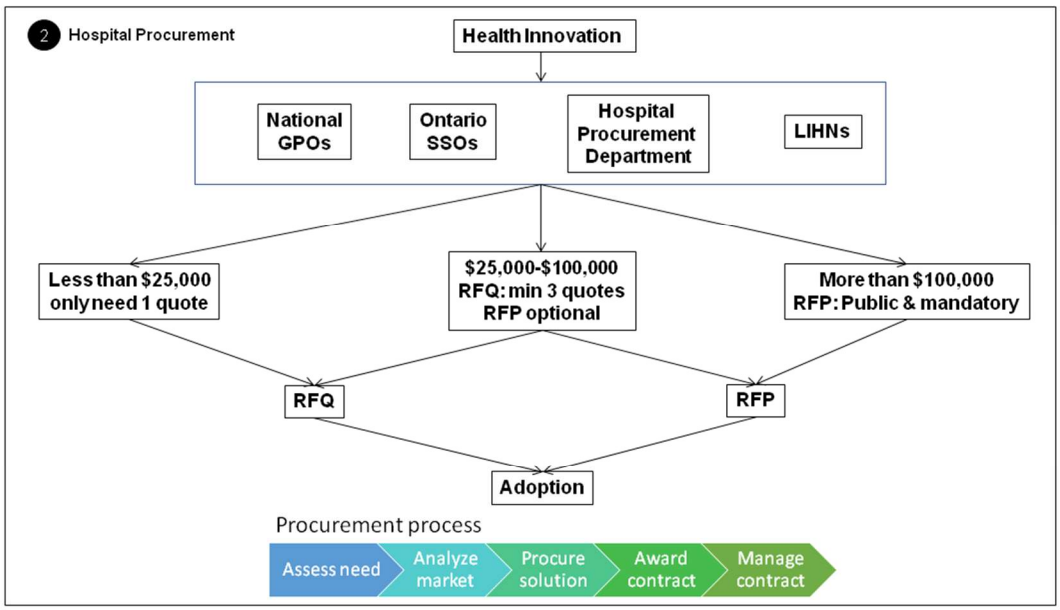


Figure 8. Overview of the procurement process, as mandated by the Broader Public Service (BPS)



BPS = Broader Public Sector
GPO = Group Purchasing Organizations
SSO = Shared Service Organization
RFP = Request for Proposal
RFQ = Request for Qualification

Appendix C: Evaluation Phase

Evaluation Phase: Stakeholder Evaluation using the Delphi Technique
As part of our final deliverable, our team is currently validating the HIIO resource for its accuracy and usefulness based on stakeholder feedback using a Delphi technique. The HIIO resource was developed in collaboration with the Studio Y fellows from MaRS and through a series of co-design meetings and information obtained from stakeholders as part of this Capstone project (see Figure 3).

- **Phase 1:** Stakeholder evaluation of the HIIO resource for accuracy and usefulness using the Delphi technique.
- **Phase 2:** Health Innovator evaluation of the HIIO resource for accuracy and usefulness using the Delphi technique.
- **Phase 3:** Usability testing to evaluate and refine the HIIO resource based on user testing and input about the site structure and function.

This phase is still ongoing.

**Note: The evaluation methods for Phase 2 and 3 will be informed by the results of Phase 1 and are beyond the scope of this Capstone project.*

Phase 1: Stakeholder Evaluation using the Delphi Technique
Study Design and Participants
The Delphi technique (Dalkey, 1969) will be used to gather expert opinion and determine consensus regarding the HIIO resource on content and structure. The Delphi technique uses a multistage self-completed questionnaire with individual feedback, to determine consensus from a large group of experts (Jones & Hunter, 1995; Ludwig, 1997). A panel of experts in health innovation and implementation will be formed. Experts will include a representative sample of stakeholders from academia, industry, health care, and government. We will approach up to 30 eligible stakeholders to participate in this evaluation. A sample size of 15-20 experts is suitable for this evaluation (Jones & Hunter, 1995; Ludwig, 1997), however all interested experts will be included for the purpose of this study. Experts will participate in at least two anonymous review rounds (Jones & Hunter, 1995). Following the two review rounds, the criteria for consensus will be reached in a third round.

Expert sample selection
A sample of experts will be invited to participate using three approaches:

- Networking at relevant health care and medical technology conferences and seminars.
- Canvassing companies and/or organizations with expertise in health innovation or implementation.
- Direct referrals by leaders in the field and through the study team's professional network.

Procedure
An email invitation will be sent to all stakeholders our team engaged throughout the course of this project. The invitation email will include information about the HIIO tool and its purpose, as well as a link to the website for review and survey to provide feedback. By completing the survey, stakeholders give implied consent as participants. Consenting participants will be informed that the tool will require at least two rounds of review and will be asked to participate in a third round to obtain consensus (see Figure 3). Participants will perform each review by

responding to a series of intensive questionnaires interspersed with controlled opinion feedback. The privacy and anonymity of each reviewer will be maintained through anonymous survey data.

Delphi process

For each round of Delphi review, participants will be asked to complete a pre-determined list of questions on an evaluation questionnaire. Items will be adapted accordingly after each Delphi round. Panel members will complete each questionnaire electronically via SurveyMonkey. Questionnaires will include open-ended and Likert-scale type questions (rounds 1, 2 and potentially a third round). Panel members will evaluate the relevance, clarity, format and structure for each item corresponding to the HIIO resource. Participants will be given 3 weeks to complete each evaluation questionnaire. Questionnaire responses will be collated, and feedback will be reviewed independently by each study team member (AJ, RS). Team members will then discuss the results of the questionnaires. Based on feedback scores and discussion by the project team, revisions to questionnaire items will be made and the HIIO resource will be iterated upon. Responses to the first-round questionnaire will be used to create the second-round questionnaire, and so forth. All rounds will follow the same process for reviewing, returning, collating, discussing and amending the tool and questionnaire items. If consensus is not reached following the second round, participants will be invited to participate in additional rounds until consensus is reached (Lofmark & Martensson, 2017; Vandelanotte, Dwyer, Van Itallie, Hanley, & Mummery, 2010).

Data Analysis

Quantitative data from the Delphi process will be analyzed using descriptive statistics. Two methods will be used to analyze results: the median score and interquartile range (Jones & Hunter, 1995). The median score will be used to calculate a score for each item that falls exactly in the middle of a group of scores for the agreement on the relevance or importance of each item. Consensus on scored items will be calculated using the interquartile range (IQR) (Jones & Hunter, 1995; Rayens & Hahn, 2000). In order for consensus to be achieved, 51% to 70% of panel members must be in agreement for each questionnaire item (Polit & Beck, 2004). If 50% of panelists or fewer are in agreement for a given item, then the item will require revision. The study team will also use qualitative comments from panel members to guide revisions (Löfmark & Mårtensson, 2017; Robinson, Oades, & Caputi, 2015; Schulz et al., 2009; Vandelanotte et al., 2010).

Expected outputs and implications

This study directly impacts an under-served area of support for health innovators who want to implement their innovation in the Ontario health care system. Validating the HIIO resource using the Delphi technique will result in a tool that can support health innovators as they navigate the complex implementation pathways in Ontario. A tool like HIIO has the ability to change the way health innovators understand and navigate the health innovation implementation space in Ontario. The HIIO resource can also be used as a supplementary tool for stakeholders and innovators to support successful implementation efforts in the Ontario health care system.

Limitations and Identified Alternatives:

Inherent challenges exist when making recommendations for improved services, and this has guided our decision to focus on validating the HIIO resource as the first step to accurately mapping the innovation implementation space in Ontario. The HIIO resource may not be suitable for all health innovators. Some innovations may not meet the criteria for the navigating the implementation pathways and/or some health innovators may choose not to use HIIO. We cannot guarantee that our tool will reach a sample that will be representative of all health

innovations and innovators using the tool. Efforts will be made to adapt the road map for a broad range of health innovations for adoption within the Ontario health care system.