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Enabling health technology innovation in Canada: Barriers and facilitators in policy and regulatory processes

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ABSTRACT

Objectives: Health care innovation and technologies can improve patient outcomes, but policies and regulations established to protect the public interest may become barriers to improvement of health care delivery. We conducted a scoping review to identify policy and regulatory barriers to, and facilitators of, successful innovation and adoption of health technologies (excluding pharmaceutical and information technologies) in Canada.

Methods: The review followed Arksey and O'Malley's methodology to assess the breadth and depth of literature on this topic and drew upon published and grey literature from 2000–2016. Four reviewers independently screened citations for inclusion.

Results: Sixty-seven full-text documents were extracted to collect facilitators and barriers to health technology innovation and adoption. The extraction table was themed using content analysis, and reanalyzed, resulting in facilitators and barriers under six broad themes: development, assessment, implementation, Canadian policy context, partnerships and resources.

Conclusion: This scoping review identified current barriers and highlights numerous facilitators to create a responsive regulatory and policy environment that encourages and supports effective co-creation of innovations to optimize patient and economic outcomes while emphasizing the importance of sustainability of health technologies.

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1. Introduction

Canada has a strong reputation in clinical trials, health services research, and evidence-based medicine, but less so in successfully implementing new knowledge in practice. A recent national advisory panel on health care innovation found that “entrepreneurs across Canada are finding it difficult to introduce, sustain and scale up their innovations in the health care system” [1]. Several contributing factors have been identified and may include policy gaps such as jurisdictional issues in the provision of health care across the country [2] and an emphasis on pilot projects that do not transform promising and valuable health care innovations

and technologies nationally [3–5]. With an aging population and more individuals being diagnosed with frailty and multiple chronic conditions, a nimble and responsive regulatory and policy environment supporting effective innovation to ensure better use of scarce resources becomes imperative [6].

Definitions of innovation are varying, but most emphasize new approaches or products that result in meaningful improvements; these can include the generation, development or implementation of new or better ideas that produce, policies, products, strategies, services, procedures, models, or other solutions that add value over the status quo, such as social or economic value [7–10]. Within the health care context, the Canadian Advisory Panel on Healthcare Innovation (the Naylor Panel), defined innovative activities as those that “generate value in terms of quality and safety of care, administrative efficiency, the patient experience and patient outcomes” [1]. The definition of ‘health technologies’ also varies; according to the World Health Organization, these refer to “the application of

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organized knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of lives,” whereas the International Network of Agencies for Health Technology Assessment defines a health technology as “an intervention that may be used to promote health, to prevent, diagnose or treat acute or chronic disease, or for rehabilitation, and may include pharmaceuticals, devices, procedures and organizational systems used in health care”. [11,12]. “Despite the various benefits of many health technologies, some innovations have been criticized as a driver of rising health care expenditures [13,14]. Recent reviews have shown this relationship between innovation and expenditures may be complicated by the use of cost-ineffective innovations [13,14]. Therefore, access to technological innovations should be mediated by consideration of which innovations offer the best value-for-money, for which patients [13,14].”

Factors that foster the adoption of health care innovations have been studied and reported on in the context of a range of countries internationally [15]. With this paper, we aim to address a knowledge gap and further the existing body of evidence by describing documented policy and regulatory barriers and facilitators to the adoption of health technologies and medical devices in Canada. With a small market and a negative trade balance for medical devices, the Canadian context is similar to a number of other countries [16]. Canada is geographically adjacent to the United States, which represents the largest global medical device market share, similar to smaller countries that border larger medical device markets such as those in Germany, France, or Japan [3,16].

2. Methods

In this scoping review, we utilized a five-stage methodological framework as outlined by Arksey and O'Malley to identify the breadth of key concepts and the main types and sources of exist-

ing evidence [17]. We selected a scoping review to address a broad, complex and exploratory research question that spans a number of diverse disciplines, and identifies gaps in the existing literature. This approach also gave us the flexibility to include a variety of studies, including grey literature (which is especially relevant to health policy research), and studies of varying quality [18]. Additionally, this approach allowed us to determine the feasibility of a future systematic review [18].

2.1. Stage 1: identifying the research question

Our review aimed to answer the question, *What are the policy and regulatory barriers to, and facilitators of, successful innovation and safe adoption of health technologies in Canada?*

2.2. Stage 2: identifying relevant sources

We conducted a comprehensive search of all published English language literature using both MEDLINE and Scopus databases for the period January 2000–October 2016. Search terms were developed via an iterative process, in consultation with a health sciences librarian, and included: Canada, technology, medical device, government, policy, regulatory, approval process, marketing, decision-making, and health technology assessment (HTA). Grey literature was searched using The Canadian Agency for Drugs and Technologies in Health (CADTH) Grey Matters Search Tool, a comprehensive checklist of national search websites and databases, drug and device regulatory agencies, and health economics resources [19].

2.3. Stage 3: study selection

All publications (e.g., commentaries, editorials, and reviews) were included if they involved a health technology or medical

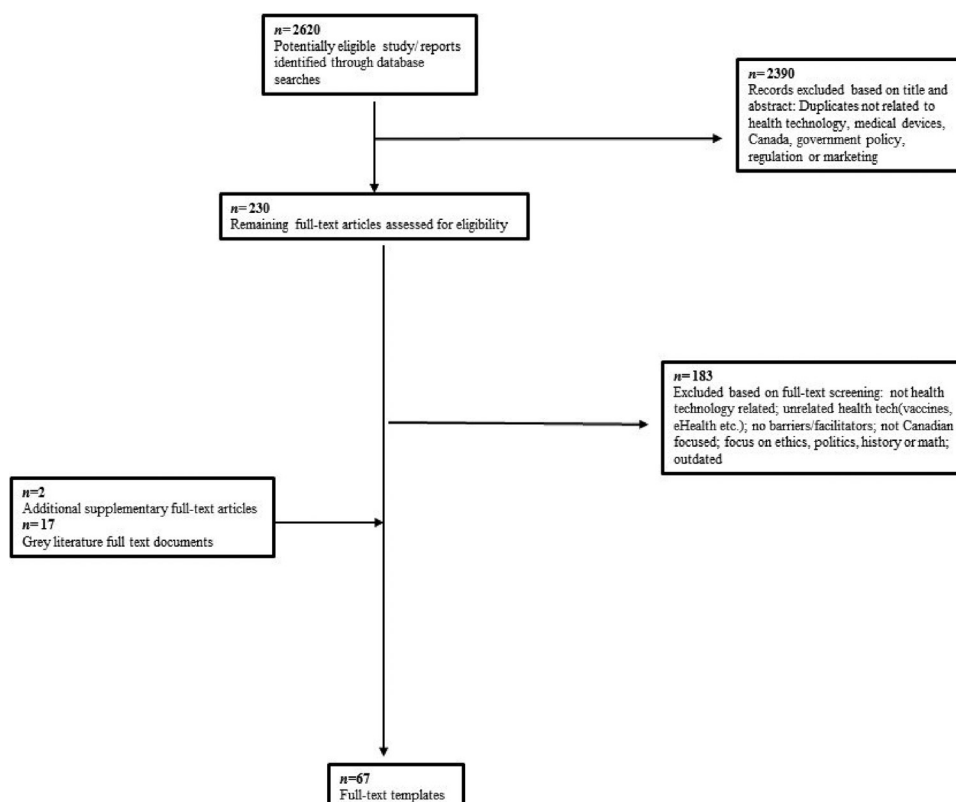


Fig. 1. Flow diagram of literature search and selection of papers.

device and discussed the barriers to and/or facilitators of policy, regulation, approval processes, marketing, decision making, and health technology assessment in Canada. Sources that focused on pharmaceuticals or information–system focused e-health technologies (such as electronic medical records or e-prescribing systems) were excluded. No restrictions were placed on the demographics or health status of the study participants.

Search results were exported to RefWorks, a reference management software, and divided into four lists for review by four researchers. Each reviewer screened out publications with irrelevant titles and abstracts, and independently evaluated the full texts of the remaining sources. Reasons for exclusion were documented for all sources that did not meet the inclusion criteria. During this process, a random sample of 10 articles were selected to assess the interrater reliability of application of the inclusion criteria among the four researchers using Fleiss' Kappa Fleiss' Kappa agreement between the four researchers was 0.73, representing 'substantial' agreement [20,21]. The average percent agreement [22] between the researchers was 95%.

Fig. 1 illustrates the study selection process.

2.4. Stage 4: charting the data

Each researcher recorded their results in a summary table in Excel, similar to that of Arksey and O'Malley [17], which included the author(s), year, publication type, context or topic of the article, and any listed barriers and facilitators to health technology innovation and or adoption found in each reference. This provided data amenable to the theming and summarizing characteristic of stage five.

2.5. Stage 5: collating, summarizing and reporting results

The researchers adopted a directed approach to content analysis as described by Hsieh and Shannon [22]. Within this approach, existing literature can be used to identify key concepts as initial coding categories [22]. Based on our knowledge of existing innovation frameworks (e.g. Innovation Adoption Journey, The Health Technology Innovation Cycle) we considered that the stage of innovation was relevant to the policy and regulatory issues encountered [1,2]. With direct coding, we summarized and organized the barriers and facilitators which were extracted in stage four, across three stages of innovation commonly found in the literature (i.e., development, assessment and implementation) [1,2]. Two researchers (MM and MK) read through the extraction table to familiarize themselves with the data, and then independently categorized findings into one of the three categories (stages); the two researchers then discussed the categorizations to achieve consensus. The categorizations were then reviewed by other members of the research team (including CS, SG and PS). Data that could not be coded within the existing categories were analyzed in a second phase; this phase generated three over-arching themes (policy context, resources, and partnerships) using emergent coding [22]. Literature findings not previously categorized were then coded into these three categories using a process similar to the first analysis phase. Within each of the now six categories, findings were then re-labelled as barriers or facilitators depending on the part of the extraction table from which they were drawn.

3. Results

Sixty-seven sources are categorized and displayed in Table 1 as identifying facilitators and/or barriers across common stages of the innovation process, including:

- Development, e.g. research and device prototyping;
- Assessment, e.g. regulatory approval and health technology assessment (HTA); and
- Implementation, e.g. an implementation plan, adoption and diffusion.

An additional three themes emerged beyond these stages in relation to the Canadian policy context, resources, and partnerships. The concepts found within these themes tended to me more overarching, spanning multiple innovation stages. Table 1 summarizes the sources included in the review and Fig. 2 indicates the distribution of papers per theme. Examples of source excerpts are included in Table 2.

4. Development

Development barriers occur when innovations inadvertently exclude groups, reinforce hierarchical social arrangements or impede social progress [60]. Canadian policymakers are often isolated from the practical aspects of health care delivery, resulting in the development of innovation policies that are not always reflective of the goals and needs of the health care system [53]. For example, innovations that are primarily oriented towards readily commercializable technologies or to the interests of venture capitalists may not satisfy the health system or particular user groups [67,57]. Also, developers without health care contacts, encounter additional barriers when they overestimate the value of their technology; make costly and avoidable mistakes; form assumptions on behalf of clinicians, or narrowly focus on empowering physicians with their technology [53,50,52,54,60].

Canadian technology developments are often funded by and oriented to American markets where the technologies may be more rapidly commercializable and profitable; this orientation is potentially inconsistent with the cost-containment and sustainability aims of a publicly funded health care system [68]. This orientation may also draw talent, technology and tax revenues away from Canada [38], and lead to the creation of innovations which do not respond to the most pressing needs in Canadian health care systems [57,68,38].

Several important approaches were identified to facilitate further innovation in the development phase, including:

- Providing additional local/national seed funding or venture capital opportunities to spur innovation activities and decrease dependence on foreign investment [73,81];
- Building awareness and understanding among developers of unmet health system priorities [56]; and
- Creating opportunities for innovators to consult with clients and health care professionals early in the development phase and incorporating their feedback on how technological innovations would fit within health systems to facilitate the development of more appropriate innovations [54,57,52].

5. Assessment

Health technology assessments (HTAs) are systematic evaluations of technologies using evidence to consider the direct and unintended consequences of the technology [12]. The main purpose of conducting assessments is to inform policy decision-making, however when HTAs do not meet policymakers' needs, the resulting recommendations may not be implemented [39]. Given the time involved in producing an HTA report (typically one year), the results when produced may no longer align with decision-makers' priorities [65,39,60]. Additionally, reports may not be useful to policymakers if they are too technical and difficult to understand, or if

Table 1
Summary of Included Studies and Identified Themes.

Author, Year	Study/publication Type	Context/Topic	Development	Assessment	Implementation	Canadian Policy Context	Resources	Partnerships /Communication
Abelson (2013) [18]	Qualitative study	Patient and caregiver involvement in HTA		✓				✓
Abelson (2016) [19]	Literature review	Public and patient involvement in HTA		✓				✓
Agrawal (2006) [20]	Retrospective review and regression analysis	Licensing for medical devices		✓				
Akpınar (2006) [21]	Review	Economic evaluation		✓		✓		
Assasi (2014) [22]	Review	Ethical assessment in HTA		✓				✓
Baltussen (2006) [23]	Review	Multi-criteria decision analysis		✓				
Battista (2006) [24]	Commentary	Expanding methodology types in HTA		✓				
Bercovitz (2007) [25]	Quantitative study	Technology transfer			✓			
Blomqvist (2016) [8]	Grey literature- Institutional report	The Naylor Report and health policy in Canada			✓	✓	✓	
Bombard (2011) [26]	Mixed-methods study	Ethical and social values in HTA		✓				✓
Brehaut (2005) [27]	Grey literature- Institutional report	Using research evidence in policy development		✓				✓
Bubela (2010) [28]	Commentary	Technology transfer			✓			
Burls (2011) [29]	Survey	Ethical issues in HTA		✓				
Carbonneil (2009) [30]	Review	Access with evidence generation		✓		✓		
Chafe (2010) [31]	Case study	Access with evidence generation		✓				
Challinor (2016) [32]	Grey literature- Institutional report	Recommendations to support health science sector innovation	✓		✓	✓		
Cuyler (2014) [33]	Commentary	Cost effectiveness analysis in HTA		✓				✓
Health Technology Assessment Task Group (2004) [34]	Grey literature- Institutional report	Recommendations to support the management of health technologies across the lifecycle: innovation through obsolescence		✓				
Holmes (2012) [35]	Grey literature- Institutional report	Stakeholder consultation to develop a medical device strategy for Canada	✓			✓	✓	✓
Husereau (2015) [36]	Grey literature- Institutional report	Entry of new medical devices into Canada's publically-funded health care system		✓				
Husereau (2011) [37]	Grey literature- Institutional report	Challenges and opportunities to using HTA to develop provider fees in Canada		✓		✓	✓	
Khayat (2015) [38]	Grey literature- Institutional report	Online commentary on health technology innovation	✓			✓	✓	
Lavis (2008) [39]	Multi-method study	Use of research evidence in policymaking		✓			✓	✓
Lavis (2010) [40]	Review	Using research evidence in health system policy making		✓				
Lee (2003) [41]	Case study	Developing a regional HTA implementation unit		✓			✓	✓
Lehoux (2012) [42]	Case study	Medical devices				✓		
Lehoux (2015) [43]	Qualitative study	Venture capital in medical innovation				✓		
Lehoux (2016) [44]	Qualitative study	Venture capital in medical innovation	✓			✓		
Lehoux (2000) [45]	Commentary	Expanding methodologies in HTA	✓	✓	✓	✓		✓
Lehoux (2005) [46]	Case study	Dissemination of HTA reports		✓		✓		✓
Lehoux (2008) [47]	Qualitative interviews	Relationships between evaluators and regulators in HTA		✓				✓
Lehoux (2008) [48]	Commentary	Policy research agenda for Health innovation	✓			✓		✓
Lehoux (2013) [49]	Practical guidance	Knowledge transfer	✓					✓
Lehoux (2013) [50]	Commentary	Health care innovation policy				✓		
Lehoux (2014) [51]	Study protocol	Ethical and social issues in HTA						✓
Lehoux (2014) [52]	Mixed-methods study	Academic spinoff companies	✓			✓	✓	
Levin (2015) [53]	Qualitative study	Harmonization of regulation and reimbursement		✓		✓		✓
Lukzack (2012) [54]	Case study	Regulatory approval for medical devices		✓				

Martin (2016) [55]	Qualitative study	Hospital-based/Regional HTA	✓	✓				
McDaid (2003) [56]	Interviews	Economic evaluation		✓		✓		
McMillan LLP (2010) [57]	Grey literature- Institutional report	Overview of legislation related to health care in Canada for businesses				✓	✓	
MDI ² (2011) [58]	Grey literature- Institutional report	How to improve development and commercialization of Canadian medical devices to the global market	✓			✓	✓	✓
MEDEC (2011) [59]	Grey literature- Institutional report	Stakeholder consultation: Ontario business sector strategy for medical technologies			✓		✓	
Menon (2009) [60]	Commentary	HTA in Canada: production and use, current issues, lessons learned	✓	✓		✓	✓	✓
Menon (2008) [61]	Review	Patient involvement in HTA		✓	✓			✓
Menon (2011) [62]	Survey	Patient involvement in HTA		✓				✓
Miller (2009) [63]	Ethnographic Study	Technology transfer for health innovation	✓	✓	✓			
Ministry of Research and Innovation (2015) [64]	Grey literature- Institutional report	Ontario's innovation agenda			✓			
Mitton (2014) [65]	Commentary	Program budgeting and marginal analysis			✓		✓	
Mortenson (2013) [66]	Interview analysis	Power mobility in rehab settings					✓	
Naylor (2015) [1]	Grey Literature- Institutional Report	Recommendations about how to support Canadian health care innovation			✓	✓	✓	
Ontario Health Innovation Council (2015) [2]	Grey literature- Institutional report	Stakeholder consultation: Recommendations to enable person-centred care and grow Ontario's Health technology sector	✓		✓	✓	✓	✓
Prada (2015) [7]	Grey literature- Institutional report	Research organization: online commentary			✓	✓		✓
Prada (2016) [67]	Grey literature- Institutional report	Research organization report: Recommendations about applicability of competitive dialogue in Ontario and Canada			✓	✓		
Prada (2007) [68]	Grey literature- Institutional report	Research organization report: suggestions to improve Canada's capacity for technological innovation in health systems	✓		✓	✓		
Prada (2011) [69]	Grey literature- Institutional report	Research organization report: suggestions about implementing innovative procurement policies	✓		✓	✓	✓	✓
Pratesi (2013) [70]	Review	Technology design, development, implementation						✓
Ross (2015) [71]	Literature review	Life cycles of medical devices		✓				✓
Scott (2015) [72]	Literature review	System level adoption and diffusion of medical devices			✓		✓	
Sebastianski (2015) [73]	Review	Innovation in public health care systems		✓	✓	✓	✓	✓
Shultz (2015) [74]	Survey	Willingness to pay for technologies				✓	✓	✓
Snowdon (2011) [3]	Grey literature- Institutional report	Medical devices	✓			✓	✓	✓
Tarride (2008) [75]	Secondary data analysis	Economic evaluation		✓				
Tesfayohannes (2007) [76]	Secondary data analysis	Industrial research and development institutions	✓			✓	✓	
Tsoi (2013) [77]	Literature review	Harmonization of regulatory and reimbursement activities		✓			✓	✓
Verma (2016) [78]	Invited essay	Policy framework to promote health system transformation				✓	✓	
Xie (2011) [79]	Expert Review	Summary of HTA supporting decision-making in Ontario and Canada		✓	✓			✓

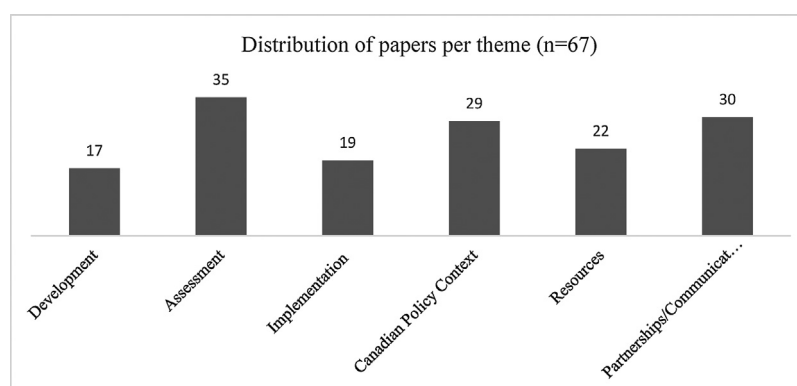


Fig. 2. Distribution of papers per theme.

Table 2
Examples of source excerpts.

Focus stage or theme	Article example	Reference
Development	"Encouragingly, there have been some efforts in recent years to curb capital drought through programmatic changes in both the public and private sectors. For example, giving special attention to those commercialization challenges experienced in the development cycle "valley of death", the government has launched initiatives like MaRS Innovation/MaRS Discovery District."	(Challinor, 2016) [38]
Assessment	"This study addresses this gap by reporting on the development and outputs of a comprehensive framework for involving the public and patients in a government agency's HTA process."	(Abelson, 2016) [25]
Implementation	"Regional implementation—While there is a need for a coordinated federal and provincial/territorial policy framework for innovation procurement, the U.K. experience suggests the need for a strong regional focus. Governments should give health regions an explicit mandate as health-care innovators and should support the development of regional innovation hubs."	(Prada, 2011) [75]
Canadian Policy Context	"Decision-makers and administrators complained of policy and managerial gridlock, confiding on occasion that attempts at reform in the public interest were sometimes co-opted to the short-term benefit of providers or politicians. Policy experts emphasized the clumsiness of the current fee-for-service mode of remunerating physicians, and asked why Canada had failed to adopt integrated delivery subsystems, exemplified by leading American group health plans. Professionals highlighted the ways that cumbersome regulations and perverse incentives were stifling their creativity and ability to play a bigger role in Canada's healthcare systems."	(Naylor, 2015) [1]
Resources	"There is a lack of funding opportunities to support successful regional initiatives to become national initiatives. While economies of scale work in favour of national incentives, lack of stable operating funding at the national level impede these efficiencies. Turning a successful regional pilot into a successful national initiative requires the commitment of a stable funder."	(Naylor, 2015) [1]
Partnerships	"Around the world, a feature of successful jurisdictions that have fostered a strong medical device industry is the close collaboration that venture capital firms, universities and other academic institutions enjoy."	(Snowdon, 2011) [3]

they take a global perspective, without adequately considering how a new technology impacts budgets or care pathways at an individual health care organization level [39,51,78,60]. Some reports may not adequately target their findings when they integrate many perspectives (social, ethical, legal) from a wide consultation process [51]. Since HTA organizations are not responsible for whether their recommendations are applied or not, they may not collect data on implementation for fear they may lose credibility if they are perceived to be too close to the policy process [51,44].

Identified facilitators in the assessment stage include:

- Collecting data about the use of HTA reports in decision-making, these data could inform efforts of HTA organizations to include implementation of HTA recommendations as part of their remit [51]. Such a database was created in 2014, and contains HTA reports from Canada from 1991 on and international HTA reports from 1989 on [96].
- Encouraging the use of evidence from HTA reports completed in other jurisdictions through an information-sharing platform accessible to, and populated by, different regions and coordinated by a national HTA agency [85,37,60]. Pre-existing HTA reports may require contextualization if they lack the specificity required to be useful for decision-makers [43,60].
- Where existing information may not be available on a new technology, field evaluations and access with evidence generation are

techniques that allow for promising technologies to be adopted and assessed simultaneously [40].

- Formalizing the process for patient involvement in HTA reporting by considering options such as citizen juries, committee membership, patient review of HTA recommendations, or presentation of testimonials [52,65].
- Tools such as multi-criteria decision analysis and decision-making frameworks for hospital technology approvals can help health care systems to consider the many ways health technologies impact opportunity costs, organizational issues and budgets [29,60].

6. Implementation

Adoption of innovations is more likely for those that require the least amount of financial and infrastructure investments [77], and normally occurs through a procurement procedure that is extremely risk averse, disconnected from innovation activities, and focused on cost-containment rather than on value generation [5,74]. In general, procurement is treated as an administrative function of the health care system that involves blind, competitive bidding to ensure fairness among potential candidates [72,73]. An issue with the current competitive model of procurement is that, by definition, innovative technologies will not have comparators with which to compete. Current procurement policies that focus on the

least expensive item in the short-term are not accommodating to innovative technologies, which may have results or value that are more apparent in the long-term [78]. In this sense, Canada is considered a laggard in procurement policy innovation and ranks 55th of 140 countries on the Global Competitiveness Index of Government Procurement of Advanced Technology [72,38]. Going forward, the procurement policy context may be slow to change as needs and priorities for health procurement sector have not been identified [5].

The procurement process can also be a barrier for small innovation companies when group purchasing organizations (GPOs) (e.g., groups of hospitals) extend their buying power through procuring supplies in bulk quantities. Smaller innovation companies cannot compete with the volume that the GPOs require [78]. In Canada, there are a few large GPOs and many smaller payers such as hospitals or clinics, creating a fragmented market. This is challenging for local innovators to demonstrate and validate the effectiveness of new products, sell to early adopters, or spread and scale a technology widely across the system [5,73,78].

Technology transfer offices (TTOs) are common across academic institutions as vehicles to transfer research innovations into the marketplace; however, in some cases their processes may hinder health technology adoption. Some TTOs have limited human and financial resources, and insufficient understanding of health care delivery. With a reward structure, that values tangible outputs such as the number of patents, spinoff companies and royalty income generated, TTOs focus on innovations with the most commercial promise. This can be problematic in the case of public health research that is not patentable [34,69]. Focusing on innovations with the greatest commercial potential may also be detrimental to those designed for rare conditions or targeted to particular user groups, and may limit funding for validation or proof-of-principle studies [34,73]. In other cases, TTOs may let the personality characteristics of innovators influence their funding decisions by making assumptions about how engaged developers are in the commercialization process and choosing not to support those who are perceived to be difficult [68].

TTOs also play a major role in negotiating challenging and time-consuming intellectual property (IP) agreements, which vary greatly within industry and across academic institutions [3,31,68,69]. Different norms regarding commercialization exist between researchers and industry, which may lead researchers to shield innovations from TTOs so as not to risk publication delays that can accompany the search for an industry partner or exclusive licensing agreements that block access to research tools and methods [34,31]. In other cases, TTOs can be pressured by unrealistic expectations regarding outputs from researchers and university administration [82].

This review found that many strategies and approaches to more effectively facilitate implementation of innovations have been identified; these include:

- Facilitating alternative proposals that enhance collaboration and give innovative technologies access to procurement by considering reforms such as risk-sharing, negotiation, and value-based pricing [3,38].
- Moving to a value-based (as opposed to cost-focused) procurement process that is concerned with the life cycle of the technology and integrating budgets and incentives that support better patient outcomes [5,1]. Outcomes could be monitored to support continual refinement of the process.
- Developing materials for innovators, including a procurement how-to handbook; standard bid templates and procurement best practices [64].

- Encouraging government stimulus to offset the cost of a move to value-based procurement, which requires up-front costs in favor of long-term savings [74].
- Developing royalty-sharing incentives between TTOs and a faculty member's lab [31].
- Developing flexible agreements such as those that enable universities to hold Intellectual Property rights on publically funded research [69];
- Developing metrics for evaluating the effectiveness of technologies that consider societal impacts of health innovations as opposed to using standard technology transfer office metrics such as number of patents, licensing partnerships and intellectual property agreements [34];
- Encouraging more research on the role that TTOs play in shaping how technologies are/are not paired with industry partners impacting development; and
- Supporting TTOs in better understanding and responding to end-user needs to benefit the health care system [68].

7. Canadian policy context

The reimbursement hurdles resulting from the thirteen unique provincial and territorial jurisdictions create a constrained Canadian policy context. Each has different priorities, privacy legislation, provider organizations, centralization models, and intake and procurement systems [3]. These multiple jurisdictions create a complicated labyrinth of pathways for innovators trying to scale up their technology adoption and diffusion across the country. The challenge of multiple jurisdictions is exacerbated by an absence of national level standards and strategic priorities in the health innovation sector [71,1,40,53].

Canadian health care system funding is directed toward the delivery of patient care – with innovation functions generally falling outside of the scope of most health organizations other than select tertiary providers. Within the federal government, the health and innovation departments are siloed with different and often conflicting goals: innovation departments seek out technologies perceived to be the most profitable, while health departments look to maximize patient outcomes and acquire revenue-saving technologies [53,44]. Silos also lead to different times for intervention in the innovation process [53]. For example, at the provincial level the innovation department might intervene early with grant funding to the innovator, with the health department only intervening later in a technology's development through regulatory or reimbursement action. Silos between the departments that fund research and those that regulate it mean that new health technologies can be “pushed” onto health systems without an understanding of their usefulness or receptiveness from the health care sector [58]. As a result, innovations that might be effective in improving health care delivery may be ignored while other technologies are developed that do not enhance health care or service delivery for Canadians.

Important facilitators to enable health technology adoption in Canada include:

- Removing silos between the health and innovation policy departments and encouraging better linkages between the two departments' policy efforts and the analysts who devise them will facilitate health technology innovation [53]. This bridging and targeted financing could extend to mobilizing and supplementing the interest and influence of venture capital investors on innovation with that from health policy experts [50] and health care providers. Balancing innovation policy with health sector expertise will ensure public investment is responsibly allocated to technologies with a high utility for the health care sector.

- Developing an innovation ecosystem where public and private stakeholders work together to identify, stratify and target investment opportunities in the health technology area [38] that are responsive to unmet public health care needs. An ecosystem approach facilitates technology innovation, and results in a return on investment for innovators by helping to spread and scale up technologies [43,38].

8. Resources

A lack of resources constrains technology innovation and adoption, particularly during the early, high-risk stages of technology development, when there are very few public and private seed capital options available to innovators [63,74]. Health science sector innovations are highly impacted by these constrained resources because development cycles are long, achieving proof of concept is expensive, and market access is regulated [38]. Working in an environment of constrained financial and human resources limits flexibility and available funds are quickly depleted in situations where projects stall [78,3].

Strategic resource allocation is important, however half of Canadian health care decision-makers report they lack a formal process to do this [84]. The resulting risk is that decision-makers may be allocating scarce resources based on historical precedent or political factors, which could disadvantage investment in new technologies. Additionally, these innovations require significant upfront investment, which is at odds with tightly managed government funds and a focus on cost containment [71,78,5]. Rigid government funding structures do not allow the transfer of funds between and among departments or across fiscal years. This environment makes it difficult for decision-makers to see past the cost of technology to its potential benefit or value to patient outcomes, especially if value is accrued to another department or sector, or only recuperated years after the initial investment [67,62,3,43].

The current allocation of resources to physicians who are compensated on a fee-for-service basis further impedes health technology innovation. There is little incentive for physicians to participate in development, testing or procurement processes for new innovations, because provider codes are not aligned with these activities [1,4]. In addition, there is no incentive to offer services that have good value-for-money, as fee codes are based on the costs to deliver the service, not the value a service provides [42]. Time that physicians might spend working on innovation projects is time taken away from their patients, diminishing their income stream.

Several strategies were identified to better facilitate the flow of resources to innovators and thus improve the adoption of health technologies in Canada:

- Developing a national medical devices partnership fund (a public private enterprise) to generate resources to invest (by funding prototypes, proof of concept research, or pre-market evaluations) in promising medical devices [2].
- Creating research and development tax credits, and optimizing existing innovation-oriented tax credits incentivize and better accommodate innovators working in the health science sector [38].
- Scaling up and increasing investment in existing successful funding programs, Canadian examples include: British Columbia's Angel Investor Tax Credit, The Council of Academic Hospitals Ontario's ARTIC (Adopting Research to Improve Care), MaRS EXCITE (Excellence in Clinical Innovation and Technology Evaluation), the Ontario Chief Health Innovation Strategist Health Technologies Innovation Fund, and the TEC Edmonton Health Accelerator in Alberta [3,38,86].

- Adopting the Triple Aim philosophy to mobilize health resources around the three goals of: population health, improved patient experience, and reduced or stable per capita costs. Specific Triple Aim health system payment reforms include value-based purchasing in procurement, pay-for-performance schemes, bundled payment mechanisms, and shared savings models between public and private stakeholders to better align incentives to health system goals [82].
- Consider an alternative funding model where health funding is tied to achieving regional innovation goals [74].
- At the consumer level, programs which combine government funding with private pay to increase accessibility of technologies may facilitate their adoption [80].

9. Partnerships/communication

In the development stage, understanding and incorporating the needs of patients and health care providers is essential to the success of targeted innovations, however technology companies consult with these partners inconsistently [53]. Innovators struggle to gain access to clinician insight to improve the relevance and appropriateness of their technologies [53,5], and health care organizations' specific needs and any plans for innovation are not typically externally accessible [74]. Technology companies also lack important partnerships with venture capital firms, hospitals, health care providers and universities that would provide the mentorship they need to better navigate bureaucracy and access seed funding [3]. The disconnect between innovators, health care providers, and payers is problematic when it translates into a difference of opinion related to the value of a technology [47].

Communication at the assessment stage is a barrier for many groups and partnerships. For example, the medical device industry is not well connected to the regulators and funding agencies who assess their devices [50]. When the two groups communicate, it can be challenging as HTA assessment requirements are complex and difficult to translate into plain language [51,52]. Relationships between HTA organizations and policy makers can be tense and may be conflicted by differing motivations and priorities [46,44]. HTA organizations are further challenged to successfully incorporate patient and public perspectives into HTA reports. This requires organizations to understand and apply appropriate patient engagement methodology, and then to incorporate these perspectives in a meaningful and robust way [25].

Recommendations to better facilitate partnerships and communication include:

- Encouraging, aligning, and managing partnerships and communication between stakeholders involved along the innovation pathway – forming partnerships early and seeking patient and clinician input on important health system needs [75,53,78,3,58].
- Involving patients and clinicians in early testing of assistive technologies to increase quality, utility, effectiveness and ease of adoption [53].
- Forming partnership entities, such as Industry Canada's Networks Centres of Excellence (NCE) program, which bring together public and private stakeholders in industry, research and health care to better translate research into health technology innovations [79,53,3].
- Creating an environment that considers collaboration, trust, information sharing, time, and cost, and that provides communication tools to ensure stakeholders understand one another's different roles [48,86,83,33,52].

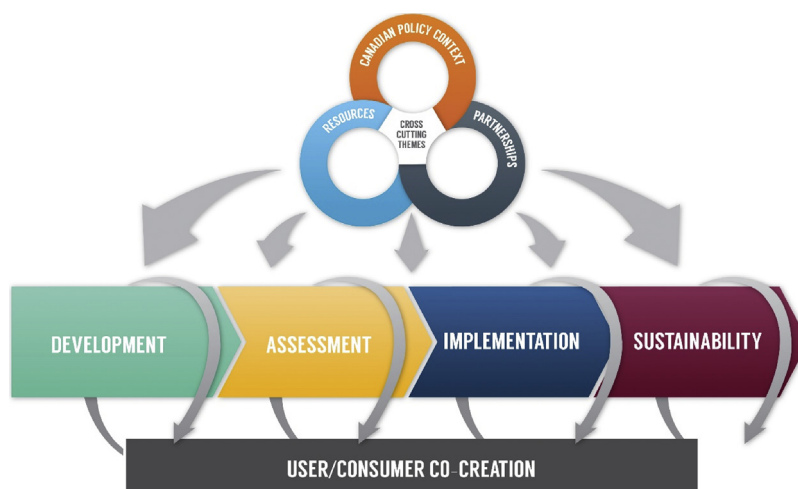


Fig. 3. Graphic depiction of innovation stages and crosscutting influences.

10. Discussion

Our scoping review found significant research on the policy environment around health technologies and medical devices with a focus on existing barriers and facilitators to adoption of these innovations. We present a graphic depiction (Fig. 3) depicting the stages along the innovation pathway and the crosscutting influence of the Canadian policy context, resources, and partnerships and communication on technology development, assessment, and implementation. In addition to these stages, we are aware of emerging areas within the health technology assessment literature, which emphasize the importance of evaluating health technologies over their life cycle [87,88]. Ongoing evaluations and delayering innovations plays an important role in creating budget flexibility to support adoption of new technologies [15], and a sustainable system over time. Rather than ending at implementation, the innovation pathway requires sustainability. Another emerging theme is the recognition and current effort focused on engaging users in co-creating relevant technologies [89–91]. The meaningful engagement of patients and caregivers in the development and adoption of useful innovations has been echoed internationally [15] and regional innovation ecosystems [93] have been proposed as a mechanism through which to engage these users to ensure technologies are aligned with health system needs. Though outside the scope of our search, we have incorporated these findings into a revised graphic depiction of Canadian health technology innovations, and support an ongoing emphasis of engagement of users throughout the innovation process.

The influence of the Canadian policy context found in this study aligns with other international findings that point to the influence of macro-level factors such as political structures and macroeconomic and fiscal policies on health innovation diffusion [15]. Although micro level factors did not emerge strongly in this scoping review, others have suggested a focus on the culture at the front lines of health care, which may be more amenable to intervention than macro system factors [15].

Despite the many hurdles that exist, Canada is well positioned to successfully implement health technologies, with numerous assets including: a highly educated workforce; a stable financial system; a stable innovation system with relative certainty, a close proximity to lucrative American medical device markets; strengths in information technology; a public health care system with strong research capacities; a strong track record for conducting clinical trials; and a capacity at the local health level, in health care delivery and research [5,49,3,40].

Our findings will be of interest to three audiences that compose the Triple Helix model of innovation [92] including industry, who are addressing health system needs through technological innovations; policy-makers, who seek to understand barriers to health technology innovation diffusion, and; researchers who are studying the factors influencing health technology innovations and the regulations and policies surrounding them. Results may also be of interest to specific groups such as Aging Gracefully across Environments using Technology to Support Wellness, Engagement and Long-Life (AGE-WELL) a federally funded research network in Canada. As part of its work, AGE-WELL aims to make recommendations for how innovation in health technologies for seniors can be accommodated and stimulated within existing policy and regulatory frameworks, as well as how these frameworks might be modified to support and accelerate the safe adoption of promising and effective technologies.

Our team is part of the AGE-WELL NCE and we have a specific interest in technologies that are particularly relevant for older adults. We found few studies or reports that dealt specifically with barriers to and facilitators of technology innovation to support healthy aging. We see this as an area warranting further investigation; in our own work, we plan to explore these topics in consultations with researchers, policy-makers, and industry representatives, as well as with older adults and family caregivers. We anticipate that developing and implementing technologies for older adults may be particularly challenging. Older adults often experience complex health challenges and multiple co-morbid conditions, which can make technological design problematic. For example, use of an assistive technology that supports mobility may be compromised by cognitive or communication impairments. These health and communication challenges can also make it difficult to engage older adults in design processes [94,95].

11. Limitations

Based on the broad nature of our topic, it was difficult to identify search terms that would ensure comprehensive retrieval of relevant sources. As an example, this review identified a number of issues relevant to reimbursement, although we did not explicitly include reimbursement as a keyword in the search. Doing so may have generated a more thorough understanding of reimbursement-related issues. To some extent, limitations of the search strategy could be addressed through the expert consultation phase that has been suggested as an optional sixth step in the scoping review process [17]. We are currently undertaking an extensive consultation

process that will be reported in a separate paper. Through Health Technology Assessment international (HTAi), we are also beginning conversations with experts from other countries that will allow some comparison of experiences across jurisdictions.

We note that while we did not feel a systematic review or realist synthesis would be appropriate for our purposes, such a review may be a useful approach for further study of ways to address specific facilitators or barriers identified in this paper.

12. Conclusions

Overall, our findings provide a comprehensive summary of facilitators and barriers to technology development, assessment and implementation, and how those stages are crosscut by barriers and facilitators in the Canadian policy context, resources and partnerships/communication. There is a lack of literature on barriers to and facilitators of technology innovation process to support healthy aging. We suggest future studies may explore these barriers and facilitators, particularly as they relate to technologies to support healthy aging.

Conflicts of interest

None.

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