Policies and Regulations to Enable Innovation and Adoption of Health Technologies for Older Adults: Documented Problems and Proposed Solutions

by

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AUTHOR'S DECLARATION

This thesis consists of material all of which I authored or co-authored: see Statement of Contributions included in the thesis. This is a true copy of the thesis, including any required final revisions, as accepted by my examiners.

I understand that my thesis may be made electronically available to the public.

STATEMENT OF CONTRIBUTIONS

Maggie MacNeil was the sole author for Chapters 1, 3, 4, 5 and 6 which were written under the supervision of Dr. Paul Stolee and were not written for publication.

This thesis consists in part of a manuscript written for publication. Exceptions to sole authorship of material are as follows:

Research presented in Chapter 2:

Dr. Paul Stolee and Dr. Don Juzwishin were the primary co-investigators on an Aging Gracefully Across using Technology to Support Wellness Engagement and Long Life (AGE-WELL) grant which supported conducting this work. Dr. Ayse Kuspinar, Dr. Pascale Lehoux, and Melissa Koch, were co-investigators on the grant and are co-authors on publications relating to this work.

This research was conducted at the University of Waterloo by Maggie MacNeil under the supervision of Dr. Paul Stolee. Dr. Paul Stolee, Dr. Don Juzwishin, Dr. Ayse Kuspinar, and Melissa Koch contributed to study design. Dr. Ayse Kuspinar, Melissa Koch and Jackie Stapleton contributed to designing the search. Dr. Ayse Kuspinar, Melissa Koch and I were the primary coders. I was responsible for carrying out data collection and analysis, and drafting and submitting manuscripts. Dr. Don Juzwishin and Dr. Pascale Lehoux provided feedback on draft manuscripts.

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ABSTRACT

Introduction

Technologies can help older adults live independently in their homes, but innovators often struggle to get their technologies in the hands of older people, their families and the systems that help to care for them (Naylor et al., 2015). Governments and older adults agree that aging at home for as long as possible is the goal. Technologies exist to help health care institutions, older adults, and caregivers to manage health and wellbeing of older adults (Quinn, O'Brien & Springan, 2018), but the layers of jurisdiction combined with silos across types and levels of care settings are complex for innovators to negotiate. To ensure older adults and their caregivers see the benefits of innovative technologies as quickly as possible, innovators need to better understand the Canadian policy and regulatory landscape, and policy-makers need to better understand policy recommendations which could facilitate innovation and adoption of technologies. The objectives of this research are to i) document and understand facilitators and barriers to health technology adoption in Canada across all stages of innovation; ii) understand how these facilitators and barriers might impact technologies for older adults and caregivers; and iii) create an evidence-informed policy agenda for health technology innovation for older adults.

Methods

A scoping review guided by Arksey and O'Malley (2005) looked at the barriers and facilitators to health technology innovation and adoption in Canada in published and grey literature. A graphic depiction was developed to explain scoping review results which outlined the stages along the innovation pathway (development, assessment, implementation, sustainability) and how some facilitators and barriers to technology innovation and adoption

exist within certain stages, and others are common across stages (Canadian policy context, resources, partnerships).

Forty-six qualitative interviews with innovators, industry representatives, researchers and policymakers were analyzed using framework analysis (Ritchie & Spencer, 2003). Deductive coding guided by the graphic depiction developed in the scoping review as well as inductive coding to further explain phenomena within each theme guided data analysis.

Through the scoping review and the qualitative interviews, an inventory of facilitators and barriers of health technology innovation was developed. Content analysis (Hsieh & Shannon, 2005) was used to code facilitators and barriers into policy actions. Group concept mapping was used as a systematic approach to integrate group brainstorming, sorting, and rating of policy action statements on their relevance and feasibility (Kane & Trochim, 2007).

Results

The scoping review generated 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.

Qualitative interviews show resource constraints specific to innovation and adoption of the home and community care sector. Interviews revealed a complex home and community care sector where care delivery activities crowd out the possibility of considering or adopting a technology, exacerbated by the lack of funding for evaluation and implementation of technologies.

Group concept mapping identifies which evidence-informed policy options are deemed the most relevant and the most feasible to be implemented, based on input from a diverse

stakeholder group. Results reflect funding and system constraints in health care, and the value of diverse partnerships across all stages of technology innovation.

Conclusions

This work generated an understanding of facilitators and barriers to health technology innovation and adoption; how aging-related technologies might experience barriers and facilitators to health technology innovation and adoption; and expert stakeholders' perceptions about the relevance and feasibility of potential policy options. These results can inform a policy agenda to facilitate innovation and safe adoption of health technologies for older adults.

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CHAPTER ONE: GENERAL INTRODUCTION AND RESEARCH OBJECTIVES

1.1 General Introduction

Older adults represent 'the core business of health care', composing 50% of visits to general physicians, 70% of home care visits, and 90% of nursing home care (Mezey, Capezuti & Fulmer, 2004; Canadian Home Care Association, 2016). Older adults tend to consume more healthcare resources because they are commonly the most complex patients (Canadian Institute for Health Information, 2011). Nevertheless, over 85% of older adults have expressed their desire to age in place in their homes, even if their health status were to change (Canadian Mortgage and Housing Company, 2015). Technologies can empower older adults to age in place and delay placement to long-term care (Peek et al., 2016). Technologies have supported aging-in-place through their use in a variety of disease states including: palliative care, chronic disease management, mental health and behavioral health, supports for family caregivers, transitional care for heart failure and home-based primary care for frail older adults (Quinn, O'Brien, Springan, 2018). Technologies which can support older adults and caregivers to age in place in and delay placement into long-term care could contribute to health system sustainability by reducing long-term care costs, which represented around 13% of total Canadian health expenditures in 2013 (Grignon & Spencer, 2018).

The Canadian government supports technology innovation through investments in research, such as a $35 million investment in the AGE-WELL research network, which has funded projects on technological innovation, policy innovations and service innovations to facilitate aging in place, and increase quality of life for older adults and their caregivers (AGE-WELL, 2018). Industry Canada's $2 billion investment in a Strategic Innovation Fund is open to innovators operating in any sector, including health (Government of Canada, 2018). Innovation

may be a national priority, but innovators developing health technologies innovators find it difficult to navigate multiple sets of policies and regulations across Canadian jurisdictions to bring their technologies to market in Canada (Naylor, Fraser, Girard, Jenkins, Mintz and Power, 2015). As a response to this network of innovation policy between federal, provincial and regional jurisdictions, many Canadian innovators bring their technologies to market in other countries. It may take as long as 17 years before innovations integrate into usual practice (Balas and Boren, 2000).

To ensure older adults and their caregivers see the benefits of innovative technologies as quickly as possible, a better understanding of the Canadian policy and regulatory landscape is required with specific areas for policy innovation. A clearly articulated health technology agenda is required with specific actions for different actors at different institutional levels which characterize the Canadian health care system (Snowdon, 2017; Padfield, 2017). This work responds to calls in the literature for a "whole systems approach" to understanding how facilitators and barriers at different institutional levels can be translated into viable solutions for policy problems (Greenhalgh et al., 2004).

1.2 Research Objectives

The overarching goal of this study is to create an evidence informed policy agenda to support health technology innovation for older adults. The main objectives are:

i.   Document and understand facilitators and barriers to health technology adoption in Canada across all stages of innovation;

ii.   Understand how these facilitators and barriers might impact technologies for older adults and caregivers, (such as those being developed inside the AGE-WELL research network); and

iii.   Engage diverse stakeholders to create an evidence-informed policy agenda for health technology innovation for older adults.

The following research questions guided the study in meeting its objectives:

1. What are the policy and regulatory barriers to, and facilitators of, successful innovation and safe adoption of health technologies in Canada?

2. What do experts (researchers, innovators, industry representatives, policymakers) perceive to be the most relevant and feasible policy options to facilitate health technology innovation and adoption for older adults?

3. How do older adults and their caregivers perceive key policy issues relevant to health technology innovation and adoption?

CHAPTER TWO: Enabling health technology innovation in Canada: Barriers and facilitators in policy and regulatory processes[1]

2.1 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" (Naylor et al., 2015). Several contributing factors have been identified and may include policy gaps such as jurisdictional issues in the provision of health care across the country (Ontario Health Innovation Council, 2015) and an emphasis on pilot projects that do not transform promising and valuable health care innovations and technologies nationally (Snowdon, Zur, & Shell, 2011; Bégin, Eggertson, & Macdonald, 2009; Savage et al., 2009). 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 (Canadian Institute for Health Information [CIHI], 2011).

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,

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procedures, models, or other solutions that add value over the status quo, such as social or economic value (Prada, 2015; Blomqvist & Busby, 2016; Ontario Bioscience Innovation Organization [OBIO®], 2013; World Health Organization [WHO], 2015). 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" (Naylor et al., 2015). These definitions reinforce the notion that innovation in health care is not simply invention, and this project does not wish to promote a technological imperative in health care- but to better understand how to get safe, effective innovations (which generate value for patients and the health care system) adopted as quickly as possible. With this broad understanding of health technologies the term health technology will be used through out to reflection this broad range of innovations in health.

The definition of 'health technologies' also varies; according to the World Health Organization, these refer to "the application of 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", (Agency for Healthcare Research and Quality, n.d.; International Network of Agencies for Health Technology Assessment [INAHTA], 2006).

Despite the various benefits of many health technologies, some innovations have been criticized as a driver of rising health care expenditures (Chandra & Skinner, 2012; Sorenson,

Drummond, & Bhuiyan-Khan, 2013). Recent reviews have shown this relationship between innovation and expenditures may be complicated by the use of cost-ineffective innovations (Chandra & Skinner, 2012; Sorenson et al., 2013). Therefore, access to technological innovations should be mediated by consideration of which innovations offer the best value-for-money, for which patients (Chandra & Skinner, 2012; Sorenson et al., 2013)."

Factors that foster the adoption of health care innovations have been studied and reported on in the context of a range of countries internationally (Keown et al., 2014). 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 (International Trade Administration [ITA], 2016). 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 (Snowdon et al., 2011; ITA, 2016).

2.2 Methods

2.2.1 Rationale

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 existing evidence (Arksey & O'Malley, 2005). 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 (O'Brien et al., 2016). Additionally, this approach

allowed us to determine the feasibility of a future systematic review (O'Brien et al., 2016).

2.2.1 *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?

2.2.2. *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 (Canadian Agency for Drugs

and Technologies [CADTH], 2014).

2.2.3 *Stage 3: study selection*
      All publications (e.g., commentaries, editorials, and reviews) were included if they

involved a health technology or medical device and discussed the barriers to and/or facilitators of

pol- icy, 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. Both Scott et al. (2015) and Varabyova et al. (2017) have excluded these types of

technologies from systematic searches as their adoption trajectories are seen to be distinct from

medical technologies. This also serves to limit the scope of the search and increased the feasibility of data extraction for the project. 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 between the four researchers was 0.73, representing 'substantial' agreement (Fleiss, 1971; Landis & Koch, 1977). The average percent agreement (McHugh, 2012) between the researchers was 95%.

Figure 1: Flow diagram of literature search and selection of papers

n=2620
Potentially eligible study/reports
identified through database
searches

n=2390
Records excluded based on title and
abstract: Duplicates not related to
health technology, medical devices,
Canada, government policy,
regulation or marketing

n=230
Remaining full-text articles assessed for eligibility

n=183
Excluded based on full-text screening: not health
technology related; unrelated health tech(vaccines,
eHealth etc.); no barriers/facilitators; not Canadian
focused; focus on ethics, politics, history or math;
outdated

n=2
Additional supplementary full-text articles
n=17
Grey literature full text documents

n=67
Full-text templates

2.2.4 Stage 4: charting the data

Each researcher recorded their results in a summary table in Excel, similar to that of

Arksey and O'Malley (2005), 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.

2.2.5 Stage 5: collating, summarizing and reporting results

The researchers adopted a directed approach to content analysis as described by Hsieh

and Shannon (2005). Within this approach, existing literature can be used to identify key

concepts as initial coding categories (Hseih & Shannon, 2005). 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 (Naylor et al., 2015; Ontario Health Innovation Council, 2015). 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) (Naylor et al., 2015; Ontario Health Innovation Council, 2015). Two researchers (MM and MK) read through the extraction table to familiarize them- selves 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 (Hseih & Shannon, 2005). 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.

2.4 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 partner- ships. 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.

Table 1. Summary of Included Studies and Identified Themes

Author, Year	Study/publication Type	Context/Topic	Development	Assessment	Implementation	Canadian Policy	Resources	Partnerships /Communication
Abelson (2013)	Qualitative study	Patient and caregiver involvement in HTA		✓				✓
Abelson (2016)	Literature review	Public and patient involvement in HTA		✓				✓
Agrawal (2006)	Retrospective review and regression analysis	Licensing for medical devices		✓				
Akpinar (2006)	Review	Economic evaluation		✓		✓		
Assasi (2014)	Review	Ethical assessment in HTA		✓				✓
Baltussen (2006)	Review	Multi-criteria decision analysis		✓				
Battista (2006)	Commentary	Expanding methodology types in HTA		✓				
Bercovitz (2007)	Quantitative study	Technology transfer			✓			
Blomqvist (2016)	Grey literature- Institutional report	The Naylor Report and health policy in Canada			✓	✓	✓	
Bombard (2011)	Mixed-methods study	Ethical and social values in HTA		✓				✓
Brehaut (2005)	Grey literature- Institutional report	Using research evidence in policy development		✓				✓

Bubela (2010)	Commentary	Technology transfer			✓			
Burls (2011)	Survey	Ethical issues in HTA		✓				
Carbonneil (2009)	Review	Access with evidence generation		✓		✓		
Chafe (2010)	Case study	Access with evidence generation		✓				
Challinor, (2016)	Grey literature-Institutional report	Recommendations to support health science sector innovation	✓		✓	✓		
Cuyler (2014)	Commentary	Cost effectiveness analysis in HTA		✓				✓
Health Technology Assessment Task Group (2004)	Grey literature-Institutional report	Recommendations to support the management of health technologies across the lifecycle: innovation through obsolescence		✓				
Holmes (2012)	Grey literature-Institutional report	Stakeholder consultation to develop a medical device strategy for Canada	✓			✓	✓	✓
Husereau (2015)	Grey literature-Institutional report	Entry of new medical devices into Canada's publically-funded health care system		✓				
Husereau (2011)	Grey literature-Institutional report	Challenges and opportunities to using HTA to develop provider fees in Canada		✓		✓	✓	
Khayat (2015)	Grey literature-Institutional report	Online commentary on health technology innovation	✓			✓	✓	
Lavis (2008)	Multi-method study	Use of research evidence in policymaking		✓			✓	✓
Lavis (2010)	Review	Using research evidence in health system policy making		✓				
Lee (2003)	Case study	Developing a regional HTA implementation unit		✓			✓	✓
Lehoux (2012)	Case study	Medical devices				✓		
Lehoux (2015)	Qualitative study	Venture capital in medical innovation				✓		
Lehoux (2016)	Qualitative study	Venture capital in medical innovation	✓			✓		
Lehoux (2000)	Commentary	Expanding methodologies in HTA	✓	✓	✓	✓		✓
Lehoux (2005)	Case study	Dissemination of HTA reports		✓		✓		✓
Lehoux (2008)	Qualitative interviews	Relationships between evaluators and regulators in HTA		✓				✓
Lehoux (2008)	Commentary	Policy research agenda for Health innovation	✓			✓		✓
Lehoux (2013)	Practical guidance	Knowledge transfer	✓					✓

			1	2	3	4	5	6
Lehoux (2013)	Commentary	Health care innovation policy				✓		
Lehoux (2014)	Study protocol	Ethical and social issues in HTA						✓
Lehoux (2014)	Mixed-methods study	Academic spinoff companies	✓			✓	✓	
Levin (2015)	Qualitative study	Harmonization of regulation and reimbursement		✓		✓		✓
Luczak (2012)	Case study	Regulatory approval for medical devices		✓				
Martin (2016)	Qualitative study	Hospital-based/Regional HTA	✓	✓				
McDaid (2003)	Interviews	Economic evaluation		✓		✓		
McMillan LLP (2010)	Grey literature-Institutional report	Overview of legislation related to health care in Canada for businesses				✓	✓	
MDI² (2011)	Grey literature-Institutional report	How to improve development and commercialization of Canadian medical devices to the global market	✓			✓	✓	✓
MEDEC (2011)	Grey literature-Institutional report	Stakeholder consultation: Ontario business sector strategy for medical technologies			✓		✓	
Menon (2009)	Commentary	HTA in Canada: production and use, current issues, lessons learned	✓	✓		✓	✓	✓
Menon (2008)	Review	Patient involvement in HTA		✓	✓			✓
Menon (2011)	Survey	Patient involvement in HTA		✓				✓
Miller (2009)	Ethnographic Study	Technology transfer for health innovation	✓	✓	✓			
Ministry of Research and Innovation (2015)	Grey literature-Institutional report	Ontario's innovation agenda			✓			
Mitton (2014)	Commentary	Program budgeting and marginal analysis			✓		✓	
Mortenson (2013)	Interview analysis	Power mobility in rehab settings					✓	
Naylor (2015)	Grey Literature-Institutional Report	Recommendations about how to support Canadian health care innovation			✓	✓	✓	
Ontario Health Innovation Council (2015)	Grey literature-Institutional report	Stakeholder consultation: Recommendations to enable person-centred care and grow Ontario's Health technology sector	✓		✓	✓	✓	✓
Prada (2015)	Grey literature-Institutional report	Research organization: online commentary			✓	✓		✓

Prada (2016)	Grey literature-Institutional report	Research organization report: Recommendations about applicability of competitive dialogue in Ontario and Canada			✓	✓		
Prada (2007)	Grey literature-Institutional report	Research organization report: suggestions to improve Canada's capacity for technological innovation in health systems	✓		✓	✓		
Prada (2011)	Grey literature-Institutional report	Research organization report: suggestions about implementing innovative procurement policies	✓		✓	✓	✓	✓
Pratesi (2013)	Review	Technology design, development, implementation						✓
Ross (2015)	Literature review	Life cycles of medical devices		✓				✓
Scott (2015)	Literature review	System level adoption and diffusion of medical devices			✓		✓	
Sebastianski (2015)	Review	Innovation in public health care systems		✓	✓	✓	✓	✓
Shultz (2015)	Survey	Willingness to pay for technologies						✓
Snowdon (2011)	Grey literature-Institutional report	Medical devices	✓			✓	✓	✓
Tarride (2008)	Secondary data analysis	Economic evaluation		✓				
Tesfayohannes (2007)	Secondary data analysis	Industrial research and development institutions	✓			✓	✓	
Tsoi (2013)	Literature review	Harmonization of regulatory and reimbursement activities		✓			✓	✓
Verma (2016)	Invited essay	Policy framework to promote health system transformation				✓	✓	
Xie (2011)	Expert Review	Summary of HTA supporting decision-making in Ontario and Canada		✓	✓			✓

Figure 2: Distribution of papers per theme

Distribution of papers per theme (n=67)

Development	Assessment	Implementation	Canadian Policy Context	Resources	Partnerships/Communicat…
17	35	19	29	22	30
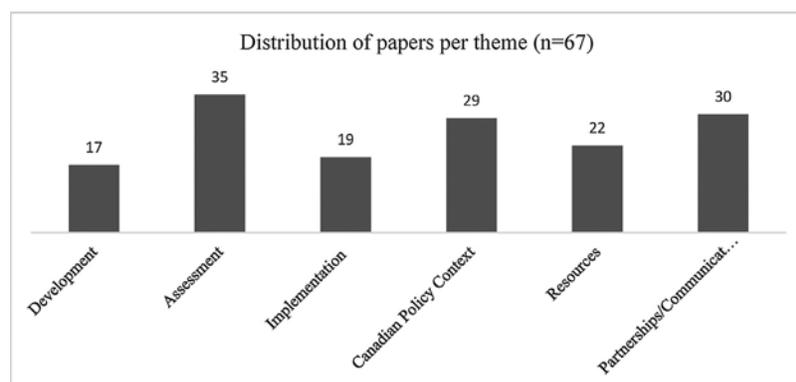
Table 2: Examples of source excerpts

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)
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)
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)
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)
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)
Partnerships	"Around the world, a feature of successful jurisdictions that have fostered a strong medical device industry is the close	(Snowdon, 2011)

	collaboration that venture capital firms, universities and other academic institutions enjoy."	

2.4.1 Development

Development barriers occur when innovations inadvertently exclude groups, reinforce

hierarchical social arrangements or impede social progress (Lehoux & Blume, 2000). 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 (Ontario Health Innovation Council, 2011). 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 (Lehoux, Miller, &

Daudelin, 2016; Menon & Stafinski, 2009). 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 (Lehoux & Blume, 2000; Lehoux, Miller, &

Daudelin, 2013a; Lehoux, Daudelin, Hivon, Miller. & Denis, 2014b; Lehoux, Williams-Jones,

Miller, Urbach, & Tailliez, 2008b; Ontario Health Innovation Council, 2015).

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 (Challinor, 2016). This orientation may also draw talent,

technology and tax revenues away from Canada (Challinor, 2016), and lead to the creation of

innovations which do not respond to the most pressing needs in Canadian health care systems

(Lehoux et al., 2013a; Lehoux et al., 2016; Lehoux et al., 2014b).

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 (Tesfayohannes, 2007; Conference Board of Canada, 2007);

•   Building awareness and understanding among developers of unmet health system priorities (Lehoux, Miller, & Daudelin, (2013a); 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 (Lehoux, et al., 2008b; Lehoux, Gauthier, Williams-Jones, Miller, Fishman, Hivon, & Vachon, 2014a; Khayat, 2015).

2.4.2 Assessment

Health technology assessments (HTAs) are systematic evaluations of technologies using evidence to consider the direct and unintended consequences of the technology (INAHTA, 2006). The main purpose of conducting assessments is to inform policy decision-making, however when HTAs do not meet they take a global perspective, without adequately considering how a new technology impacts budgets or care pathways at an individual health care organization level (Health Technology Assessment Task Group, 2004; Sebastianski et al., 2015; Martin, Polisena, Dendukuri, Rhainds, & Sampietro-Colom, 2016; Lehoux, Denis, Tailliez, & Hivon, 2005). Some reports may not adequately target their findings when they integrate many perspectives (social, ethical, legal) from a wide consultation process (Lehoux et al., 2005; Bombard, 2011). 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 (Lehoux et al., 2005; Lavis, Oxman, Moynihan, & Paulsen, 2008).

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 (Martin et al., 2016). Such a database was created in 2014, and contains HTA reports from Canada from 1991 on and international HTA reports from 1989 on (Martin et al., 2016; University of York, 2018);

• 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 (Chafe, Merali, Laupacis, Levinson, & Pre-existing HTA reports may require contextualization if they lack the specificity required to be useful for decision-makers (Lavis et al., 2010; Martin et al., 2016);

• 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 (Health Technology Task Group, 2004);

• 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 (Menon & Stafinski, 2009; Lehoux, 2008a); and

• 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 (Baltussen & Niessen, 2006; Martin et al., 2016).

2.4.3 Implementation

Adoption of innovations is more likely for those that require the least amount of financial and infrastructure investments (Scott, Pasichnyk, Harstall, & Chojecki, 2015), 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 (Challinor, 2016; Conference Board of Canada, 2011). 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 (Prada, 2016; Ontario Health Innovation Council, 2015). 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 (Sebastianski et al., 2015). 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 (Challinor, 2016; Prada, 2016). Going forward, the procurement policy context may be slow to change as needs and priorities for health procurement sector have not been identified (Ontario Health Innovation Council, 2015).

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 (Ontario Health Innovation Council, 2015). In Canada,

there are a few large GPOs and many smaller payers such as hospitals or clinics, creating a

fragmented market. (Ontario Health Innovation Council, 2015). 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 [(Ontario Health Innovation Council,

2015; Conference Board of Canada, 2007; Conference Board of Canada, 2011).

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 out- puts such as the number of patents, spinoff companies and royalty income

generated, TTOs focus on innovations with the most commercial promise (Bubela & Caulfield,

2010). This can be problematic in the case of public health research that is not patentable (Miller,

Sanders, & Lehoux, 2009; Bubela & Caulfield, 2010). 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 (Miller

et al., 2009; Bubela & Caulfield, 2010). 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 (Miller et al., 2009).

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

(Ontario Ministry of Research and Innovation, 2015; Miller et al., 2009; Snowdon et al., 2011;

Bubela, 2010). 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 (Ontario Ministry of Research and Innovation, 2015; Bubela, 2010) In other cases, TTOs can be pressured by unrealistic expectations regarding outputs from researchers and university administration (Tesfayohannes, 2007).

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 (Snowdon et al., 2011; Challinor, 2016; Prada, 2016; Sebastianski, 2015);

• 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 (Ontario Health Innovation Council, 2015; Naylor et al., 2015). 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 (MEDEC Canada, 2011);

• 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 (Conference Board of Canada, 2011);

• Developing royalty-sharing incentives between TTOs and a faculty member's lab (Bercovitz & Feldman, 2007);

•   Developing flexible agreements such as those that enable universities to hold Intellectual Property rights on publicly funded research (Ontario Ministry of Research and Innovation, 2015);

•   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 (Bubela & Caulfield, 2010);

•   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 (Menon & Stafinski, 2008).

2.4.4 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 (Snowdon et al., 2011). 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 (Ontario Health Innovation Council, 2015; Naylor et al., 2015; MDI2, 2011; Lehoux et al., 2008b).

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 (Lehoux, 2008b; Levin, 2015). Silos also lead to different times for intervention in the innovation process (Lehoux, 2008b). 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 (Lehoux, 2008a). 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 (Lehoux, 2008b). 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 [Lehoux, 2008b] 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; and

- Developing an innovation ecosystem where public and private stakeholders work together to identify, stratify and target investment opportunities in the health technology area (Challinor, 2016) 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 (Khayat, 2015; Ontario Health Innovation Council, 2015).

2.4.5. 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 (MDI 2, 2011; Conference Board of Canada, 2011). 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 (Sebastianski et al., 2015). Working in an environment of constrained financial and human resources limits flexibility and available funds are quickly depleted in situations where projects stall (Sebastianski et al., 2015; Snowdon, Zur, & Shell, 2011).

Strategic resource allocation is important; however half of Canadian health care decision-makers report they lack a formal process to do this (Mitton, Dionne, & Donaldson, 2014). 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 (Ontario Health technology Council, 2015; Sebastianski et al., 2015; Mortenson, Clarke, & Best, 2013). 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 (Snowdon et al., 2011; McMillan, 2010; Scott, Pasichnyk, Harstall, & Chojecki, 2015; Khayat, 2015).

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 (Bégin et al., 2009; Naylor et al 2015). 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 (Husereau & Cameron, 2011). 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 (Ontario Health Innovation Council, 2015);

• Creating research and development tax credits, and optimizing existing innovation-oriented tax credits incentivize and better accommodate innovators working in the health science sector (Snowdon et al., 2011);

• 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 (Ontario Health Innovation Council, 2015; Edmonton TEC, 2017; Verma & Bhatia, 2016; Challinor, 2016);

• 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 (Verma & Bhatia, 2016);

• Consider an alternative funding model where health funding is tied to achieving regional innovation goals (Conference Board of Canada, 2011); and

• At the consumer level, programs which combine government funding with private pay to increase accessibility of technologies may facilitate their adoption (Schulz, 2015).

2.4.6 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 (Lehoux, 2008b). Innovators struggle to gain access to clinician insight to improve the relevance and appropriateness of their technologies (Ontario Health Innovation Council, 2015; MDI 2, 2011), and health care organizations' specific needs and any plans for innovation are not typically externally accessible (Conference Board of Canada, 2011). Technology companies also lack important partnerships

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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 (Snowdon et al., 2011). 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 (Lehoux, Hivon, Williams-Jones, Miller, & Urbach, 2012).

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 (Snowdon et al., 2011). When the two groups communicate, it can be challenging as HTA assessment requirements are complex and difficult to translate into plain language (Lehoux et al., 2005; Lehoux, 2008a). Relationships between HTA organizations and policy makers can be tense and may be conflicted by differing motivations and priorities (Lee, Marshall, Waddell, Hailey, & Juzwushin, 2003; Abelson et al., 2016). 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 (Abelson et al., 2016).

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 (Assasi, Schwartz, Tarride, Campbell, & Goeree, 2014; Menon & Stafinski, 2008; Sebastianski et al., 2015; Snowdon et al., 2011; Lehoux & Blume, 2000);

- Involving patients and clinicians in early testing of assistive technologies to increase quality, utility, effectiveness and ease of adoption (Lehoux, 2008b);

- 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 (Snowdon et al., 2011; Lehoux, 2008b; Shultz et al., 2015); and

- 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 (Brehaut & Juzwishin, 2005; Shultz et al., 2015; Tsoi et al., 2013; Lehoux, Miller, & Daudelin, 2013; Scott, Pasichnyk, Harstall, & Chojecki, 2015).

2.5 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 (Scotland & Bryan, 2016; Bryan, Mitton & Donaldson, 2014). Ongoing evaluations and delayering innovations play an important role in creating budget flexibility to support adoption of new technologies (Keown et al., 2014) 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 (Holliday, Magee & Walker-Clarke, 2015; Baltalden et al., 2016;

Greenhalgh, Jackson, Shaw, Janamian, 2016). The meaningful engagement of patients and

caregivers in the development and adoption of useful innovations has been echoed

internationally (Keown et al., 2014) and regional innovation ecosystems (Etzkowitz &

Leyesdorff, 2000) 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.

Figure 3: Graphic depiction of innovation stages and crosscutting influences.
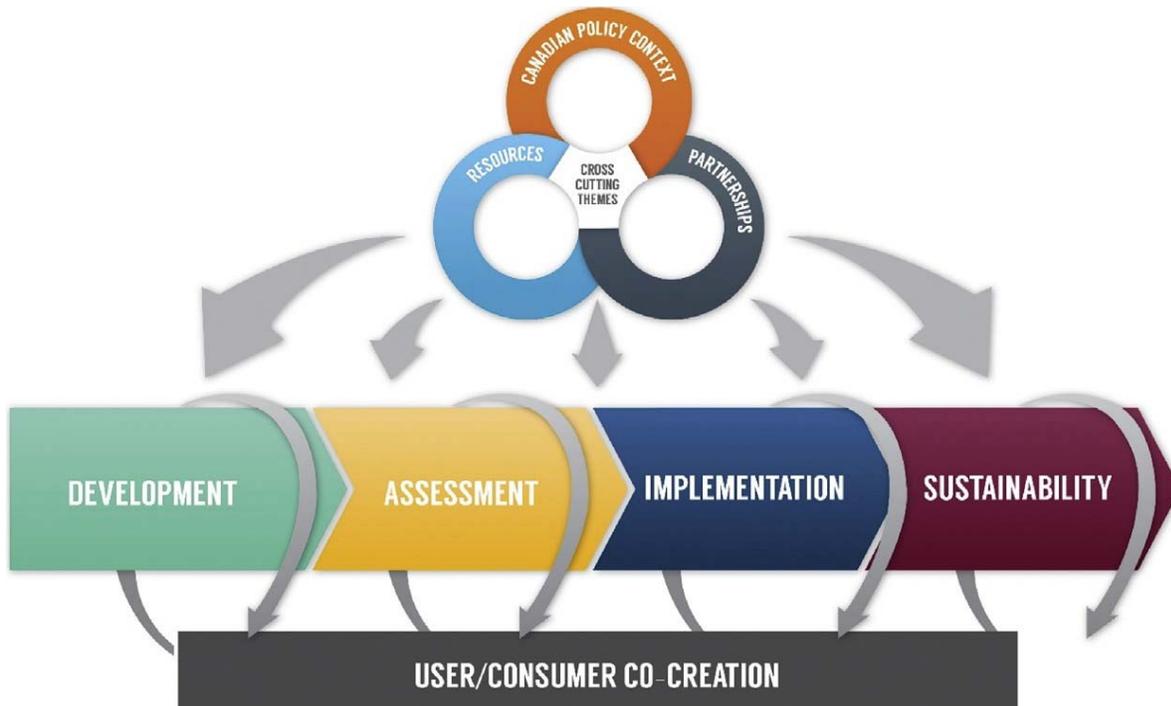
The influence of the Canadian policy context found in this study aligns with other

international findings that point to the influence of macro-level factors such as political structures

and macroeconomic and fiscal policies on health innovation diffusion (Keown et al., 2014).

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 (Keown et al., 2014).

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 (Savage et al., 2009; MDI2, 2011; Snowdon et al., 2011; Ontario Health Innovation Council, 2015).

Our findings will be of interest to three audiences that compose the Triple Helix model of innovation (Etzkowitz & Leyesdorff, 2000) 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 multiple co-morbid conditions, which can make technological design more complex. 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 (McNeil, 2017; McNeil et al., 2016; Newell, Arnott, Carmichael, 2007).

2.6 Strengths & 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 (O'Brien et al, 2016). 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.

2.7 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 partner-ships/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.

CHAPTER THREE: Stakeholder perspectives on facilitators and barriers to health technology innovation and adoption in Canada

3.1) Introduction

There are a variety of stakeholders involved in the development, assessment and implementation of a health technology. These include technology developers, venture capitalists, granting bodies, older adults, end-users, citizens, caregivers, health care providers, policy-makers, health system administrators and regulators, as well as health care services researchers who create or study health technologies and their assessments. All of these different stakeholders operate at different levels of the health technology sphere, which we understand to contain different jurisdictions each with their own goals, financing and routines.

This stage of the project is designed to better understand abstract findings from the scoping review by generating illustrative examples of specific facilitators and barriers. Preliminary work building the search strategy for the scoping review suggests that restricting the search strategy to the older adult population does not generate enough results for a fulsome review. This stage serves as a way to understand how facilitators and barriers to health technology innovation and adoption might affect technologies designed for older adults. This objective of this study is to continue to investigate the policy and regulatory barriers to, and facilitators of, successful innovation and safe adoption of health technologies in Canada.

3. 2 Ethics

Ethics clearance for the qualitative interview process has been obtained under ORE#: 21006 *Policy and Regulatory Issues in Enabling Technological Innovation* from the University of Waterloo research ethics board (see Appendix A).

3.3 Methods

Semi-structured interviews were conducted with policymakers, innovators, researchers and health care providers. A snowball sampling technique was used to generate participants with knowledge about health technology innovation and adoption and older adults (Palinkas, Horwitz, Green, Wisdom, et al., 2015).

3.3.1   Types of technologies for older people

To fully understand how facilitators and barriers to health technology innovation and adoption operate on technologies for older adults, some examples of the types of technologies available for older people are required. Technologies for older adults include those which can help to promote physical fitness, facilitate early diagnosis, enable monitoring of health status, increase social interaction, or ensure adequate treatment (Dishman, 2004). The types of technologies which are helping older people and their caregivers to achieve these aims include telemedicine and tele-homecare, wearable/sensor technologies, ambient smart-home systems, assistive robots, intelligent wheelchairs, digital games, and social networking applications (Dishman, 2004; Canadian Home Care Association, 2015; Sixsmith, 2013). This range of technologies is reflective of those being developed within the AGE-WELL research network (AGE-WELL, 2018).

This research focuses more readily on technologies which are used by older adults and caregivers directly at the medical-individual level, than those which are used at the fiscal-managerial level (such as algorithms which act as decision support and guide care allocation) or those technologies which operate at the strategic institutional decision-making system level

(where chief executives and boards of directors make choices such as opening a heart surgery unit) (Greer, 1985; Varabyova et al., 2017).

3.3.2   *Conceptual framework*

Recognizing the siloed nature of health technology innovation, and as a way to demonstrate the numerous and diverse stakeholders relevant to health technology innovation and adoption who operate at various levels, I developed a diagram to guide participant recruitment (Figure 4). The framework is adapted from the Social Ecological Model, which is often used in public health research to demonstrate the ways different social spheres (individual, interpersonal, institutional/organizational, community, social structure, policy, systems) have influence over individual behavior (Bronfenbrenner, 1992; Gregson, Foerster, Orr, Jones, et al., 2001). The social-ecological model arose in the 1990's as a way to understand five levels (intrapersonal, interpersonal/primary groups, institutional, community, public policy) which can interact to influence health behavior (Golden & Earp, 2012). The Social Ecological Model has been widely used to identify level-specific strategies for public health intervention, recognizing that individuals are embedded in social, micro, meso and macro level contexts (Golden & Earp, 2012). By identifying how these contexts interact to influence behavior, interventions can be designed which acknowledge these interactions and leverage them to change individual level health behavior (Golden & Earp, 2012).

Figure 4: Conceptual framework
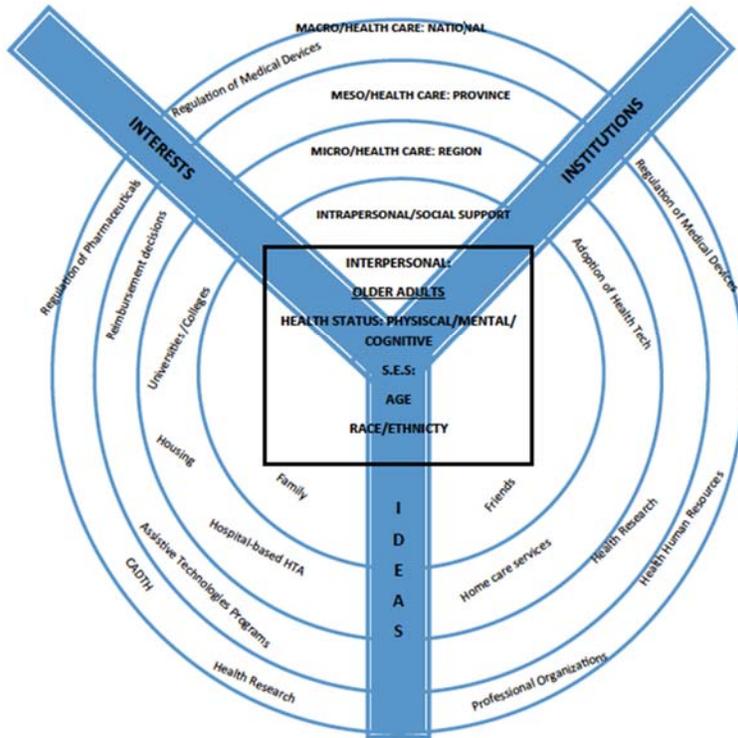
This work presumes that policy and regulatory barriers can operate in any of these social spheres, which, in health care policy, have different governments responsible for the policies operating at each level. The diagram serves as a paradigm or "lens" to consider all of the moving parts in a complex policy area.

Health status is at the centre of the diagram, which includes physical and mental health and ability to perform activities of daily living; cognitive health status, ethnicity, gender and socioeconomic status are all aspects of older adults' intrapersonal level that may dictate how a health technology policy affects them. Barriers and facilitators to technology adoption can also occur at the interpersonal level, or the sphere where family and social support influence behavior.

The micro-level is the site where local decisions about housing stock take place, and about other municipal services such as adult day programs (Marchildon, 2013). Home care services are generally allocated and delivered in the micro sphere. At the meso level, provincial reimbursement for drugs and medical devices takes place, with different provincial-level bodies in existence at each province. This is also the level of government where assistive technology programs exist, which impact older adults' ability to access aids to daily living such as wheelchairs, hearing aids and eye glasses. Different research bodies funding health care research also reside at the meso, or provincial health care level. At the macro level, there is federal jurisdiction for health care research, health human resources and regulation of medical devices and pharmaceuticals.

The interests, institutions and ideas framework (Kingdon, 1984) cuts across each level of the framework. Interests include those of policy actors inside and outside of government who act to influence or make policy, and are organized into 'communities, coalitions and networks' (Smith, Mitton, Davidson & Williams, 2014). Institutions include an organization's, formal and informal rules (Simeon, 1976; Gauvin, 2014). This includes the jurisdictional issues that exist in Canada as a result of being a federation of provinces, with separate mandates for regulation, research, and human resource planning at the federal level, and service provision at the provincial level (Gauvin, 2014). Ideas include perceptions, knowledge and beliefs about what "is" or what "should be" (Gauvin, 2014). This is where research plays a role, and can either be used symbolically, for political purposes; conceptually, which enlightens actors; or instrumentally, to solve a problem (Lavis, 2002). Values and cultures operate as ideas, both for individuals and for societies (Gauvin, 2014). Any policy analysis will have to consider how ideas, interests and institutions play out at each level of jurisdiction but also how they play out in

terms of older adults and their social support networks and health status, and other intrapersonal characteristics such as income and ethnicity.

The conceptual framework combines two widely used frameworks from policy and public health research (Béland, 2016; Golden & Earp, 2012) in order to conceptualize how health technology innovation operates at different contexts and track the role of ideas, institutions and interests. The framework serves a way to see how policies at different jurisdictional levels can impact interpersonal and individual spheres to influence technology innovation and adoption for older adults. By conceptualizing where certain policy and regulatory challenges occur and the relevant stakeholders involved, the framework creates a foundation for policy change that facilitates health technology innovation and adoption. The addition of this diagram helps to respond to calls in the literature for the 'next generation of research' on health technologies to be ecological in nature in order to consider how the interactions between technologies and their implementation contexts influences success or failure (Greenhalgh, Robert, Bate, Kyriakidou, 2004).

The framework helped organize recruitment of different stakeholder types. At the macro-level, health technology regulators and federal policymakers in the health portfolio; arms-length agencies such as Canada Health InfoWay and CADTH; as well as not-for-profit stakeholders such as MEDEC (lobby group representing Canada's medical device industry), MaRS (a commercialization hub in Toronto, ON offering programs and services for start-up technology companies) and the Conference Board of Canada, were contacted for participation.

At the meso level, provincial policymakers, including those working in assistive device programs, those making reimbursement decisions, those working in health technology areas, health technology assessment agencies, and health services researchers were contacted for

participation. At the micro-level, innovators (both academic and non-academic), regionally based HTA agencies, and representatives from the home care sector were contacted for participation. Researchers on the AGE-WELL project who are considered 'insiders' in health technology innovation were contacted to begin the snowball sampling (Palinkas et al., 2015). These insiders work as: a consultant in health economics and reimbursement, a provincial policymaker working in the area of health technology innovation, and a health technology innovation researcher.

Older adults and caregivers represent the interpersonal and intra-personal levels of the conceptual framework but were not interviewed in this phase of the project. I felt the time and abstract nature of the content required an educational component to have older adults participate meaningfully, and it was not feasible for me to offer this type of capacity building at this point in the project. Using the Change Foundation's Decision Tool around choosing whether or not to pay patients and caregivers for their engagement contribution, the project is in the advisable range to consider paying stakeholders for their participation, which was also not feasible for this project (The Change Foundation, 2017). The decision tool scores a project based on the impact on participants' time, equity, vulnerable population status, challenges and accountability, and removes points for positive impact, access, and recognition the engagement could offer participants (The Change Foundation, 2017). Due to the nature of the time and challenges associated with the project, it was decided to engage older adults and caregivers later in the project in a way that would be less resource-intensive and potentially more meaningful for these participants (Oliver, Kothari & Mays, 2019).

Different interview guides were used for each stakeholder group (policymakers, researchers, industry representatives and innovators). Each interview guide asks different

questions about what institution or company the participant works for, how they evaluate

technologies, what their research or technology focuses on, as well as what they perceive to be

facilitators and barriers to health technology innovation and adoption. Each guide asked if a

technology designed for older adults might go through the stages of innovation differently. The

last interview questions requested participants to recommend documents, reports or potential

participants to interview. Interview questions that are not relevant to a participants' experience

were skipped. The interview guides were piloted and revised with AGE-WELL affiliated insiders

for clarity. See Appendix C for the policymaker interview guide, which served as the basis for

the development of the other types of interview guides.

Participants were contacted by email, referencing the person who recommended their

involvement in the study, attaching an information letter, a consent form (Appendix A) and the

appropriate interview guide. The consent form asked permission to audio record the interview,

to use anonymous quotations in theses or publications, and if the participant is interested in

receiving results of the interview process. Nine researchers, thirteen government employees,

thirteen industry representatives and eleven innovators (n=46) were interviewed. Each interview

took about 60 minutes. Recruitment stopped once saturation was reached within each stakeholder

group, when no new themes emerged, which occurred around the eighth or ninth interview

(Morse, 1995).

3.4. Data Analysis

3.4.1 Introduction

This research uses framework analysis, which was designed in the 1980s in the UK for

policy research and is commonly used in health research (Ritchie & Spencer, 2003). This work

aligns with the applied policy research tradition, in that certain information is required for actionable outcomes - in this case, knowledge about policy and regulatory facilitators and barriers is required to make policy change that would enable health technologies' adoption by older adults.

This method is used to analyze semi-structured interview transcripts with thematic analysis, producing a framework matrix in the process to categorize data based on the following stages: familiarization; developing a working framework; indexing the framework; charting data into a framework matrix; and interpreting data (see figure 4) (Ritchie & Spencer, 2003). In framework analysis, themes or categories can be developed in advance of coding as well as during coding, as the data dictate (Dixon-Woods, 2011). This flexibility means that framework analysis can move between theory-driven and hypothesis-driven approaches (Gale et al, 2013). This contributes to transparent coding, and allows for the new work to build on previous work (Carroll, Booth and Cooper, 2011). This aligns with the aims of this research to respond to the dearth of literature about facilitators and barriers to health technology adoption for older adults. Framework analysis can help to define concepts, map the range and nature of phenomena, find associations, provide explanations, or develop strategies (Ritchie & Spencer, 2003).

Figure 5: Stages of Framework Analysis

3.4.2 Familiarization

The goal of this stage is to become familiar with the data by reading transcripts, making notes about recurring themes or key issues (Ritchie & Spencer, 2003). The interviews were recorded and transcribed verbatim. During each interview, I took note of the date, which interviewee recommended them, key inferences from each interview, or comments made that linked to other interviews. Debriefing with other team members present in the interviews helped to make linkages in the data across interviews. Preparing conference presentations on this project aided in the familiarization process as I read through each transcript to find quotes that might contextualize preliminary themes and findings.

3.4.3 Identifying a thematic Framework

In framework analysis, the thematic framework or index is informed by pre-existing literature and issues. It is designed to act as a way to parse out the data into manageable chunks (Gale et al, 2013).

A graphic depiction was presented in Chapter two outlining the stages along the innovation pathway (development, assessment, implementation, sustainability) and how some facilitators and barriers to technology innovation and adoption exist within certain stages, and others are common across stages (Canadian policy context, resources, partnerships) (MacNeil et al., 2019). This depiction suggests that all technology innovation and adoption efforts should be grounded in an effort to co-create technology with end-users. It should be noted that the categories of 'sustainability' and 'co-creation' did not specifically emerge in the data from paper one, but were part of the depiction in that they respond to recently emerging trends in health technology assessment (Scotland & Bryan, 2016; Bryan, Mitton, & Donaldson, 2014) and health care services research (respectively) (Shipee et al, 2013).

This was the inspiration for the use of framework analysis to refine this framework and to see where the interviewees could shed light on potential issues specific to older adults' use of health technologies. The index contained the following labels: development, assessment, implementation, sustainability, policy context, resources, partnerships, co-creation, and aging/older adults focus. Multiple coders were used to ensure quality of the data analysis; to ensure consistency across coders, a codebook was developed with definitions of each label (see Appendix E) (MacQueen, McLellan, Kay, & Millstein, 1998). Coders trialed the codebook by using it to code one interview from each stakeholder type. After the trial, coders met with the research group and refined the codebook. This process of meeting and discussing results of coding is a form of debriefing which enhances the dependability of the findings (Lincoln & Guba, 1985).

3.4.4 Indexing

Indexing is the process of applying the thematic framework to the data (Ritchie & Spencer, 2003). Indexing creates notes within the transcribed interviews based on the labels in the thematic framework. Another independent coder and I worked through each of the 46 transcripts line by line to index portions of text with the labels from the framework: development, assessment, implementation, sustainability, policy context, resources, partnerships, co-creation, aging/older-adult focus.

3.4.5 Charting

Charting is a way of rearranging the data based on the labels of the framework; it is thought that by seeing representative excerpts from different interviews on the same label or topic, the author can better understand the nature of that label (Ritchie & Spencer, 2003). This

process involves more than just physical rearranging of text, but also abstraction and synthesizing of the data (Ritchie & Spencer, 2003). Using a thematic approach which identifies, analyzes, and reports patterns or themes within data (Braun & Clarke, 2006), I, along with the second coder and two other researchers, worked to group all the excerpts related to each label together. After this process we created a description (including sub-headings), of the nature of the phenomena contained inside each label.

To address the subthemes contained inside each label, from the perspective of the different stakeholders, the charting process featured the label as the title of the chart, the sub-themes in the columns, and a cell for each stakeholder type at each sub-theme level (See Appendix F). In some cases, there were no sub-themes (sustainability, co-creation), and not every sub-theme had coverage from every stakeholder type. A blank cell in the chart indicates a spot where there was no quotation affiliated with a stakeholder type. The chart was filled in with a representative quote and identified as either Innovator, Researcher, Government, or Industry representative (Ritchie & Spencer, 2003).

3.4.6 Mapping and Interpretation

During the mapping stage, the notes created during the indexing stage and the charts created in the charting stage are reviewed to compare perceptions, identify patterns and look to explain phenomena occurring within the data (Ritchie & Spencer, 2003). I looked through notes and charts to explain facilitators and barriers to technology adoption within each theme (development, assessment, implementation, sustainability, co-creation, older adults, Canadian policy context, partnerships, resources) from the perspective of different stakeholders.

3.5. Results

Each theme was coded and new sub-themes emerged within each theme. Figure 6 depicts a summary of the themes and sub-themes.

Figure 6: Themes and sub-themes identified through framework analysis
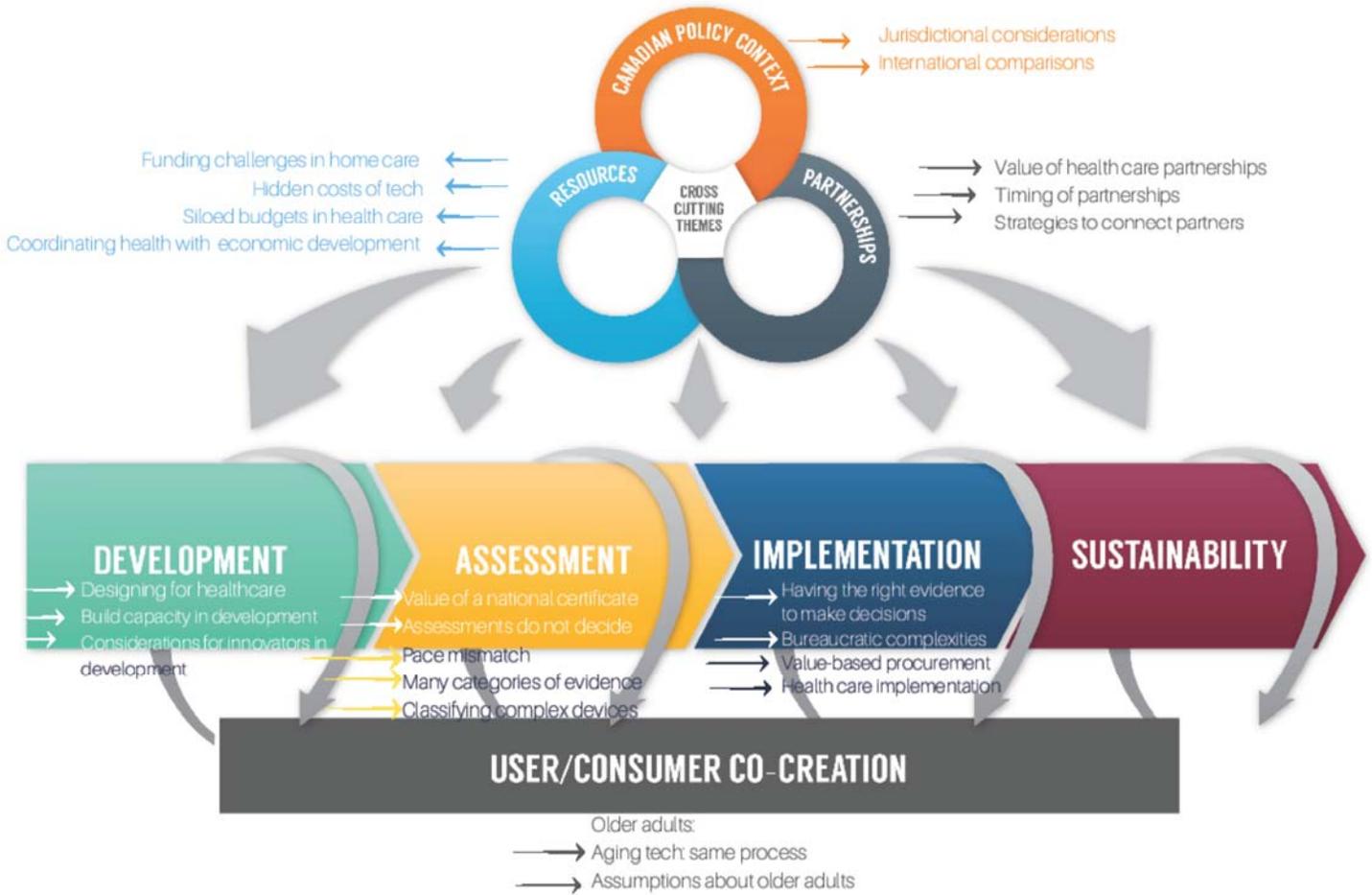
3.5.1 Older Adults

Two sub-themes were identified in the older adults theme: aging technology: same process and assumptions about older adults. Government, industry and research participants agreed that the process of technology adoption was the same for all technologies regardless of their target population. One participant noted:

"*everybody I talk to, no matter whether you're talking about rapid diagnostic test or an assistive device or an app… they all face the same barriers… so I don't think it will be that different*".

Government and industry stakeholders spoke about negative assumptions among policymakers and clinicians about older adults' capacity for technology use as a barrier which limits technology adoption:

"*there is still a cultural barrier in terms of perceptions of what seniors can do in terms of technology adoption. I speak with some colleagues and they're like 'my grandma's not going to be able to use an iPhone'… I'm like 'have you given an iPhone to your grandma?' Because if a three-year-old can use it, I'm pretty sure grandma can use it*"

One innovator we interviewed had positive assumptions about aging, which they felt facilitated technology adoption:

"*a joke within some of our sales force is that 80 is the new 60 because these people are still vibrant and don't want to give up living in their own homes*".

Researchers discussed the assumptions about older adults that are built into our measurement tools to assess technologies, which may not account for changes in what older adults prioritize. This researcher pointed out:

"*I would argue if we were to think about preferences properly we would probably look at technologies differently because we value them differently as we age*".

This theme outlined how technologies for older adults undergo formal processes related to adoption, in similar fashion as technologies for other populations. Comments in this theme

revealed that technologies for older adults are subject to assumptions (both positive and negative), which can help or hinder their adoption.

3.5.2 Co-Creation

All stakeholder types felt that co-creation of technologies was a facilitator to technology innovation and adoption for older adults, but some stakeholders pointed to problems in how co-creation is currently achieved. An industry representative contrasted the lucrative market for aging-related technologies with the difficulty recruiting patients to participate in their development:

> *"the only way that Canadian companies will be able to position themselves and capitalize on that gross market is…if they can access the clinical and patient populations … at hospitals … Because the expertise and the capacities that exist in the hospitals can't be found any place else in the Canadian landscape".*

A researcher noted that the approaches to integrating patient-preference data into a health technology assessment are varied and often completed by proxies:

> *"how patient preferences get in, it's a dog's breakfast of approaches. So you have a lot of, a lot of deliberative decision-making processes, you'll have a lot of clinicians who will identify what patient preferences are… seeking input from patient organizations— typically only from patient organizations, and they do their best, or worst, …to gather some input, qualitative input, sometimes still too, quasi kind of research. Throw together a survey kind of questionnaire, hand it around to their membership...it's not high-quality evidence coming in".*

A government interviewee outlined a program which acted as a facilitator of co-creation of technology by matching companies with healthcare settings, patients, clinicians, reimbursors, and procurement officers. Although all stakeholders viewed co-creation as a facilitator of technology adoption for older adults, the comments in the co-creation theme revealed the difference between how different stakeholders view co-creation depending on their field. For industry representatives, co-creation enhanced the value of technologies created. Researchers were concerned with standardizing the ways co-creation is completed, while government stakeholders spoke about co-creation as a feature of their program.

3.5.3 Development

Three sub-themes emerged related to development: designing relevant technology for health care; building capacity through human/financial resources in development; and considerations for innovators in the development stage.

Industry and research representatives spoke about the barriers to designing for healthcare. One industry stakeholder discussed the need for innovators to align their technologies with the priorities of the health care system:

> "*If you're innovating, then innovate in the direction of where the health system is going…if they're looking at the strategic priorities of their hospital going in this direction, then very likely you will have a buyer*".

A researcher we interviewed spoke about the need for inexpensive technologies which address health system needs:

> "*We need to create technologies which the R&D is less costly…that will be more affordable and that will tackle system level challenges. Not just add clinical value to what*

we do already, but to transform health care systems so they can better address today's

needs, and ageing is one".

An innovator discussed the challenge associated with designing technology for use in

healthcare due to health information privacy legislation, which can impede access to a patient's

health information for clinicians and innovators. This innovator noted a general risk-aversion in

health care which is bolstered by rigid interpretations of health information privacy laws. A

government stakeholder noted challenges of deploying new technology in a nursing home

setting, without support staff present in case any problems arise:

> *"You don't have IT geeks running around an apartment that can reset technology, if*
>
> *that's required. Things have to be made entirely foolproof".*

In this sub-theme, industry and research stakeholders discussed how inexpensive

technologies and those that align with health system priorities are facilitators to technology

adoption. Innovators and government stakeholders noted how privacy laws about health

information and lack of technology support make it challenging to design health technologies for

health care, which inhibits technology adoption for older adults.

The second sub-theme, building capacity in development, was acknowledged as a current

strength of the Canadian ecosystem by an industry representative:

> *"we've got this really strong engine for R&D that works very well for our system as a*
>
> *whole. We've got the talent… we've got lots of really focused monies and, and, and talent*
>
> *that are honing in to the kind of things that would be relevant as our population ages. …*
>
> *educationally, knowledge, we've got it all".*

A researcher contrasted the statements of the industry representative in their description of a company that struggled with their capacity during the development stage:

> "*one spinoff that created home monitoring…what really hit this spinoff very hard was that they could not articulate a business model, it was really hard for them*".

The researcher goes on to comment on the different types of expertise required to commercialize a technology from the expertise which is usually involved in the technical development of an innovation. Similarly, an innovator commented on an example where inadequate capacity in the development of a technology (a student was asked to develop software) led to the failure of the software when deployed in the health care setting.

Stakeholders held different perspectives about the capacity required in the development stage of a technology. An industry stakeholder felt as a sector, Canada has a strong capacity of talent and funding in research and development, which acted as a facilitator, as compared with an innovator and a researcher who described situations where lack of capacity during development impeded technology innovation and adoption.

The third sub-theme in development was considerations for innovators in the development stage. An innovator discussed what they perceived to be a facilitator in their technology development- that they were not considered a medical device by Health Canada:

> "*because not having cumbersome regulatory oversight allows innovators and entrepreneurs to be more flexible especially in the development stages when you're still trying to understand what is the feature set required to deliver value to residents*".

That innovator went on to say that they felt Health Canada should be liberal in their regulation of non-invasive, low-risk technologies to ensure this flexibility for other innovators.

An industry representative spoke about their work giving patients access to their health data as a suggestion to improve technology development for future innovators:

> *"we deal with health solutions at the boundary between the consumer and the health system, where information right now doesn't really flow to the patient about their own data, their own body... we're trying to basically unlock that data and ...it's a flipping on its head of data ownership in healthcare"*.

A government representative used Microsoft Excel as an example to show how technologies are not always used to their potential:

> *"the power of Excel now is amazing... but the average person uses Excel to make tables ...entrepreneurs have to be aware that in some cases only one third of the functionality of your tools will only ever be adopted fully"*.

This sub-theme outlined advice for innovators developing a new technology. An innovator advised future innovators to enjoy the freedom that not being a regulated medical device can offer to new innovators working to determine the functions of their technology. An industry stakeholder encouraged the value of technologies that help patients control their health information and a government representative cautioned to innovators that most people do not use all capabilities of a new technology.

3.5.4. Assessment

There were five sub-themes under the assessment theme: the value of a national certificate; assessments do not decide; mismatch between the pace at which a technology is developed and the pace at which it is assessed; many categories of evidence to consider when evaluating technology; and difficulties assessing complex devices.

The sub-theme, value of a national certificate, contains comments from interviewees about the benefits or disadvantages to regulatory approval of a technology by Health Canada. A government interviewee noted that their group only considers technologies with regulatory approval. This could mean that technologies which are not classified as requiring regulatory approval may not be assessed in an HTA; this has implications for adoption since the HTA makes recommendations for adoption by health care systems. One researcher spoke about the value of Health Canada regulatory approval for companies internationally in that the approval processes in other countries are somewhat aligned. An innovator pointed out the discrepancy between the value for the company whose technology has Health Canada regulatory approval, and the value for the health care system:

> *"once you put them through the channel... and then say it has, it's now Health Canada approved, I suspect...decreases the accessibility of that product and now it's maybe 10 times the cost and ...it brings the competitive edge down because very few people can compete with that".*

The innovator suggests the value of the certification increases the perception among investors that the company is profitable and thereby legitimizes an increase in price of the technology, which in turn makes it harder for other companies to compete in this area, and making the technology more expensive for the health care system to purchase and adopt.

The second sub-theme in assessment was "assessments do not decide", which includes stakeholders' ideas about the fact that HTA reports simply recommend a technology for adoption and it is up to individual health systems to decide whether to action that recommendation or not. An industry stakeholder commented on the challenges associated with the elective nature of recommendations:

> *"there is no teeth to that recommendation…So the health system itself does not have to follow that recommendation. It's quite optional. And so linking those processes to the adoption of innovation … could be greatly improved to helping technologies through the system".*

A researcher suggested that the cost-effectiveness data, that a HTA report uses to generate recommendations, are not helpful for decision-makers in health care systems:

> *"cost effectiveness tells you nothing about the actual, sticker shock that goes along with technology adoption… these technologies involve process changes and organizational changes and feasibility of adoption questions from an organizational perspective. It's really very poorly analyzed within an HTA process… often times there is a budget impact analysis that is done, but I think they're quite poorly done which affects the real cost to the organizational level to adopt".*

In this sub-theme, an industry stakeholder addressed a potential misunderstanding about HTA recommendations in that they inform adoption decisions, but they do not make them. A researcher noted the types of data that are missing from health technology assessments to make them operational for health care systems.

The third sub-theme under assessment was the mismatch between the pace at which a technology develops and the pace at which it is assessed. A government interviewee contrasted the slow pace of assessment to the academic nature of evidence synthesis inherent in HTA production, with the fast-paced nature of health care service delivery where technologies are used:

> *"the academic world operates at a standard and at a speed that just isn't practical from the delivery side. The types of things that turn their cranks, that motivate them... are not necessarily as relevant to those who are responsible for delivering care".*

An industry representative commented on the slight differences between assessment procedures across countries, which leads to separate HTAs being completed when a technology is introduced in a new jurisdiction:

> *"every jurisdiction, every country – so Canada, the US, Europe, Australia do their own thing... it means that if you do bring a product to market in Australia rather than launch it in Canada, you have to repeat the process".*

This stands in contrast to the finding that regulatory certification can facilitate technology adoption in another country. As regulatory certification is only concerned with the safety of the technology, and roughly the same information is submitted to regulators in different countries. HTA is concerned with the clinical and cost effectiveness of a technology, and each country has its own set of usual procedures that the new technology would be compared with. This sub-theme recounts concerns from a government and an industry stakeholder about the speed of the HTA process, and whether it is efficient to complete a new HTA every time a technology changes jurisdiction.

The fourth sub-theme under assessment was the many categories of evidence to assess with a new technology, which gets at all the different types of evidence tracked in an HTA as well as discrepancies or problems when the evidence required by an HTA is not present. A government interviewee said:

"there is a lot of variability…in what an HTA entails, so what we are trying to do is get to a …minimum amount of data that you need as that healthcare setting to say 'ok, I am ok with the decision lets purchase this'…And hopefully that evidence packages will be enough for the next.. healthcare setting".

An industry interviewee commented that relevant evidence is not always collected:

" there's a lack of understanding of what is useful evidence generation, so a lot of things… [are] never really captured in a way that provides meaningful evidence on which we can make better decisions".

An innovator noted that they were torn between industry and academic influence when building the evidence base about their technology:

bridging the gap between academia and industry is …an ongoing issue… we don't wanna go run a $100 000 million dollar study …if at the end of the day, the design of the study is so academically focused and doesn't actually help us prove a case that then will result in driving adoption".

A researcher postulated the need for different types of data in the case where the traditional evidence base is not present:

"if you're looking at a medication, quite likely you will find or could do a systematic review of … randomized trials with straight forward outcome measures. That… cost effectiveness information that could then inform a decision. For many of the technologies that we're considering, the evidence base is not there. And is less likely to get there because these may not be the kinds of interventions that would necessarily lend themselves to randomized trials…maybe we need to look at different kinds of evidence".

This sub-theme picks up on earlier concerns about HTA informing decision-making, and relatedly, what information is required by decision-makers to make decisions about adopting new technologies. Government, industry, research and innovator representatives all had comments about the balance between how to create the necessary evidence without being overly time consuming or costly.

The fifth sub-theme under assessment is the difficulty associated with classifying complex devices. A government interviewee noted the challenges of keeping up with incoming technologies seeking Health Canada regulation:

> "*everything's innovative … it's new products and used in a way we've never used products before… the sheer challenges in terms of where devices fit right now... There's more and more things shoved into each submission, and you're trying to figure out what the different component parts are and what's approved and what's not approved… moving forward, it's a pharmaceutical, plus a natural health product, plus a device, plus it's actually three different types of device in the device …, and how you manage that from a regulatory perspective.*"

An innovator commented on the future of medical devices and the potential complexity if technology extends to personalized medical devices:

> "*we're getting into a realm where we could actually have individually produced medical devices. How on Earth do you figure out whether they are in spec?...From the regulator's point of view this was kind of mind blowing because wow, how cool is this, but at the same time … where would be the start, figuring out how to regulate it?*".

This sub-theme had two of the most relevant stakeholders in the health technology regulation process: government and innovators speaking about the complexity of new health technologies and the pressure that puts on regulators.

3.5.5. Implementation

Implementation contained four sub-themes: having the right evidence to make reimbursement decisions, bureaucratic complexities, value-based procurement, and implementation considerations across health care settings.

The sub-theme, having the right evidence to make reimbursement decisions, describes the difference between the types of information that innovators collect about the functionality of their technology versus the type of information required to make reimbursement decisions (often cost and clinical effectiveness data generated through randomized controlled trials). A government interviewee commented about the need to "pull information out of" innovators and translate it into metrics that will be relevant to decision-makers.

That interviewee gave the example where decision-makers were unsure about the value of a wound care technology, because innovators had not collected information about the time it took to apply the technology. Without knowing how long the new technology took staff to apply, decision-makers were not able to compare the technology to existing procedures in wound care to know if the new technology was worth adopting and implementing. The government interviewee spoke about having to "pull" the time-to-administer information from the innovators, as that is the evidence the decision-makers needed to understand the value of the technology.

An industry representative spoke about the challenge of responding to pressures from clinicians and patients to adopt new technologies:

"we just don't know how to deal with the crowded nature of all these technologies

dying for attention and all of them equally un-evidenced and unstudied, all of them

looking equally fine but having nothing specific to make decisions upon. And patients

and society being very ill-informed of what they're demanding, generally wanting the

new and shiny ...and so do clinicians".

A researcher commented on the challenge for innovators in that regulators usually require

different sets of evidence than do HTA producers, and that moving towards better coordination

between regulatory and HTA bodies could be a facilitator for adoption:

"coordinate regulatory and reimbursement processes... they need to be both at the table

because..., especially for the device side, they should be collecting the evidence that

they need to get reimbursement decisions".

This sub-theme contains comments from government, research and industry stakeholders about

how different evidence is required across different stages of the innovation pathway in order to

have health technologies adopted, and the problematic assumption that exists among some

stakeholders equating new technology with progress, without careful examination of evidence.

In the second sub-theme, interviewees commented on bureaucratic processes which slow

technology implementation. An innovator noted that health care systems can be supportive, yet

slow partners:

"the health care professionals that we work with are really welcoming new ideas ... but

health care is a very, very long process for changing things. Although they are very

enthusiastic on a new project to come on board ... there's a lot of protocols to be

changed to introduce a new product ... they can't actually just make a decision in one

day … there's protocols, processes, people … that need to actually be made aware of it

- it takes a long time".

An industry representative gets at the bureaucratic complexity even within governments:

"one of the other barriers that might not seem as sort of apparent is, is within

government, the lack of inter-ministerial sort of coordination and cooperation".

A government stakeholder suggests that:

"building relationships with the healthcare organizations individually and working with

the ones that are easiest to work with and then that might actually be a faster pathway to

reimbursement than it is trying to jump through bureaucratic hoops- they're just not

business friendly"

as a method to overcome bureaucratic complexity that impedes technology adoption. In this sub-theme industry, innovators and government stakeholders acknowledged bureaucratic complexity acting as a barrier to technology implementation. Stakeholders offered suggestions as to how to manage this complexity: awareness of silos within government; better knowledge of health care organizations to understand their process for implementing a new technology and building strong relationships with individual health care organizations.

The third sub-theme under implementation was value-based procurement. The role of procurement in Canada is to 'acquire the supplies and equipment healthcare facilities need to function on a daily basis, while addressing clinical needs for quality and policy expectations for cost control and regulatory compliance' (Miller et al, 2019). Group purchasing organizations have been created to pool procurement functions across large health regions and in some cases, entire provinces (Alberta, British Columbia and New Brunswick) (Snowdon, Zur & Shell, 2011).

Group purchasing organizations were designed to create economies of scale by streamlining purchasing decisions across multiple health care organizations, but recent comments expressed in the literature criticize rigid, cost-focused procurement in Canada's health care systems (Prada, 2016; Arshoff, Henshall, Juzwishin & Racette, 2012; Miller et al, 2019). Value-based approaches to procurement are promoted as a way to enhance: patient outcomes, longer-term health system performance, and innovative products which offer system-wide benefits (Prada, 2016; Miller at al.,2019).

Industry and government stakeholders referenced their involvement with value-based procurement initiatives in areas such as risk-sharing or pay for performance, where the health care system pays a vendor when outcomes that were promised are delivered. Interviewees noted that this new way of acquiring services based on outcomes (as opposed to cost) was well-received by vendors, even those who did not win the contract. A researcher commented on the difficulty even for big, province-wide procurement agencies, which serve all health sectors, to think about procurement in home and community care as acute care technology needs crowd out technology spending:

> *"single province procurement and supply chain and…shared service organizations that are serving health organizations … that extend into the home and community care sector, even there it's extremely hard for those procurement agencies to think about adoption in the home and community care sector because the, the ones that scream the loudest, the tyranny of the acute prevails. So, the highest cost expenditures are still the hips and knees. The most influential interests are still the acute care hospitals, the doctors and the surgeons".*

This sub-theme described interviewees' positive experiences with value-based approaches, but cautioned that these approaches may be more common in an acute care setting than in the home and community care sector.

The final sub-theme was health care implementation, which contained comments about the nature of health care systems, which make them more challenging settings in which to deploy a technology, than other industries. A government interviewee spoke about the far-reaching impacts of introducing a new technology into a complex system:

> " *you have to change how you deliver the care and that's hard, that's really hard. It's really slow and costly in the sense of the amount of time and effort needed".*

An industry stakeholder working in the home and community care sector spoke about the challenges associated with introducing a technology without earmarked funding for research or evaluation in their budget:

> *"some way to tap into dedicated grants or funding that would enable homecare organizations to do the testing, do the evaluation and then support knowledge dissemination would be incredibly helpful".*

The industry representative went on to comment*:*

> *"there's no mechanism to make it easy for us to do this".*

A researcher commented that in many cases a technology builds its evidence base according to the amount of time it will save health care staff, and cautioned about the human resource management implications of comparing a new technology with human delivered care.

This sub-theme addressed government concerns about the time and effort required when a new technology implicates changes in health care delivery, industry concerns about restrictive funding in the home and community care sector and a researcher's concerns about comparing technology-delivered care with human-delivered care.

3.5.6 Sustainability

The sustainability theme contained comments from interviewees about the processes that exist to ensure technologies are sustainable, including disinvestment processes when technologies or procedures are no longer delivering value to the health care system. A government interviewee explained the benefits of a health technology management approach:

> "*which is more of a life cycle approach to assessing technologies. It goes a little bit beyond an HTA… It would include disinvestment, while the technology is used to determine if it's still serving a real purpose or should it be disinvested… what are the best ways to use that technology. What should be the conditions for success to reap the most benefits from the technology throughout its life cycle*".

An industry representative spoke about the challenges of technology adoption without health technology management:

> "*the system I think just really needs to understand how to stop paying for a particular technology, de-listing these kind of items so that new things can come in*".

A government and an industry stakeholder described the features of a health technology management approach and the challenges to health technology adoption without a way to ensure their sustainability over the long term.

3.5.7 Canadian Policy Context

The Canadian Policy Context theme included comments related to the two subthemes: jurisdictional considerations and international comparisons. Interview comments were coded into the jurisdictional considerations sub-theme if they touched on issues related to shared jurisdiction in health between federal and provincial governments. A government interviewee spoke about health care being a provincial jurisdiction and how that leads to variation in which technologies are covered or reimbursed across the country. An industry representative added the challenges with scaling up a good idea across Canada when the provinces operate so separately:

> *"great pilots all over the place that are happening and then they just…stay happening in whatever area, or the pilot dies. I think one of the things we're trying to look at…is how do we bring that spread across a jurisdiction. How do you take a good thing happening in one community and … how do you take that spread across, but there is no formalized process for that in lots of different jurisdictions".*

An innovator commented on how jurisdictional considerations exacerbate what is already a small market in Canada for medical devices:

> "*the Canadian model is really messed up because of the interprovincial trade barriers… we have a tiny market which we have shrunken even more with these interprovincial trade barriers… as a start-up company… I wind up having to pay 10, 20, 30 percent of my capital on travel to go to markets where people don't have enough critical mass that it makes sense for you to try and sell them something… there's no way that the Canadian market is remotely big enough to support what I'm doing.*"

Innovators, industry and government commented how provincial jurisdiction over health care creates a fragmented national market where ideas and innovations are difficult and expensive to scale nationally leading to variation in what devices are covered by which provinces. The international comparisons sub-theme contained comments by interviewees about other countries which may be easier or more lucrative for innovators to bring their technologies to market. A government interviewee pointed out that North American free-trade laws interact with procurement policies, making it hard to favor local innovators:

> *"I've heard this… 'It's easier for me to sell into the US, than it is into my own province.'*
> *…A lot of it is procurement rules, because …I can't provide any favoritism, or any*
> *weighting to say, 'You're an Ontario-based company.' Because that's against the North*
> *American Free Trade laws".*

An innovator noted that single-payer health care systems in France and Germany attract more attention from innovators than being adopted in Canada. An industry representative noted that in Europe and the United States there are fast-track processes for approval of medical devices which have already been approved that make small changes in materials compared with Canada, where there are:

"substantive barriers especially around class II and class IV medical devices".

A researcher also contrasted the difference between Canada and other countries' medical device approval process, and noted that for some companies, Canada is an entry point to the North American market:

> *"the US is the market that has the gold standard for regulatory approval… they set*
> *meaningful standards around the regulation of medical devices that are higher than*

Canada's and they're infinitely higher than in Europe. … But Canada is… seen in some

ways from the regulation of medical devices as the entry place to test out… on the way

to… or at least can be a quicker entry to the North American market. The FDA has a

higher standard, so we're kind of the intermediate, we're close to the US, but, but we're

still easier… maybe it needs to be closer to the FDA, but certainly it doesn't need to be

closer to the EU".

Stakeholders' comments reflected on features of other jurisdictions which may make them more accessible to innovators. They noted that although Canada may have more stringent rules around regulation of high-risk medical devices, it is perceived as a gateway to lucrative American medical device markets.

3.5.8 Resources

The resources theme contained four sub-themes: funding challenges in home care; hidden costs of technology; siloed budgets in health care; and the need to coordinate health care with economic development. Funding challenges in home care contained interviewees' comments about resource-related considerations specific to technology adoption in the home and community care sector. A researcher commented on the good intentions of resource organizations working in home care:

"this sector is significantly underfunded in every way shape and form, significantly

under-resourced, massively complicated. No meaningful leadership, you know just a

nightmare to organize, but deeply mission driven, hundreds of little organizations,

mission driven, trying to do the best they can".

An innovator added that lack of resources (both time and money) can deter innovators from working in the home and community care space:

> *"cumbersome policies when it comes to reimbursement, kind of demotivate innovators or companies from focusing on the latest innovations in this sector, and so then what ends up happening as a result of that… basically all the key stakeholders … are not as progressive … not as technology forward, because they just don't have the money. They're cash strapped and they're already overburdened and so the barrier…to adopting innovation is quite high…so for innovators … in this space, you might have a great product that could add a lot of value but there's no dollars and cents to pay for it and nursing staff and administrators… have like ten other priorities that they seem to be dealing with and … there's lots of operators out there…who don't have the capacity to even look at innovations even if they wanted to because they're just so swamped with dealing with the day to day grind of running their business. It's very, very difficult, it's …disheartening".*

An industry representative described their experience with successful implementation of a technology in home care, despite lack of resources. This interviewee attributed the success to the fact that a physical space in the organization was set aside for use to bring together innovators, caregivers, and older adults to co-create technologies.

Interviewees' comments in this sub-theme focused on the value of co-creation in a resource-scarce sector of the health care system, which is focused on service delivery and lacks dedicated funding to the research, evaluation and trialing of technologies.

The second resource-related sub-theme was: hidden costs of technology, which contained comments about the costs of technology adoption beyond the list price of the technology. An industry interviewee commented that some products do not fit into normal patterns of use in health care and require changes to the way that care is approached to see the benefit promised. That interviewee went on to comment about the hidden costs associated with medical devices that cannot be used by a single individual:

> "*There are a number of medical devices that would be useful for the elderly that cannot be applied or used by the patient himself. So, he needs help. And in the homecare setting, to provide this support by either a visiting nurse or something like that, it can be very, very difficult to do*".

A government representative spoke about a program they ran which tried to acknowledge some of the hidden costs of technology adoption:

> "*an eligible expenditure includes any sort of training you might need to …get people in your office to be able to use this or even your patients to use it … any sort of culture and change management... any sort of supporting technologies so if you need software upgrades or … new computers or …a couple of smart phones to actually test out the app*".

Industry stakeholders discussed how technologies which change patterns of service delivery, and those which require assistance to be used have hidden costs in time, money or both to realize benefits. A government stakeholder recognized these 'hidden' costs as eligible expenses within their programming.

The third sub-theme under resources is titled siloed budgets in health-care. Stakeholders commented on how health care funding is allocated and transferred across units, and the impacts for a technology which operates across budget silos.

A government stakeholder noted it can be very challenging to demonstrate value in a health care system with siloed budgets:

> *"the way the budgets are organized it's very, very difficult for folks to move resources or release resources now that you've included this transition cost and getting the new technology in place can be challenging…Depending on how it's implemented you may just increase your costs".*

An industry representative commented that:

> *"siloes in the health care system are another huge issue"*

and went on to describe health care funding to be allocated in a way that does not reflect the types of patients being served, or their mobility across different sectors of the health care system. An innovator added their experience with trying to be compensated for an innovation which prevented costs to the health care system: *"you have now that gadget that everybody says that will save lives, so who's going to pay for it?".* They added: *"the savings in the hospital in terms of getting people out of the hospital earlier- you can calculate that, but the hospital is not going to give you money because you got the person out."*

Interviewees' comments reflected agreement that siloed budgets were a barrier to health technology adoption in that they made it difficult to: prioritize preventive technologies, demonstrate value and treat complex patients.

The fourth sub-theme under resources was coordinating the health care system with economic development agendas; which contained comments about the value of adopting promising local health technologies as a way to make the health care system more of an economic driver for governments (as opposed to importing all health technologies from companies in other countries). An industry stakeholder commented on this perspective becoming more prevalent:

> *"The system is being looked at as an economic driver and a way to prop up industry and as an industry in and of itself, because it is, it employs 2 million people in Canada and could lead to new industries that could drive Canada's economy. …so, that's a very, very big area".*

A researcher commented on their efforts to bring local innovations into Canadian health care systems:

"pilot initiatives and experiments around the point 1 percent of—3% of med technology adoption. That is, that is the budget allocated to medical technologies in the health care system. So fairly small and narrow niche of focus that's the sweet spot there is to bring together health system needs with the commercialization agenda or the economic development agenda. So you're looking for made-in-[province name] technologies seem to have actual promise."

Industry and research stakeholders reflected the drive to leverage the purchasing power of Canada's single-payer health care system to support local innovation, and how that could contribute to Canada's economic interests.

3.5.9 Partnerships

The partnerships theme contains three sub-themes: partnerships with health care stakeholders, innovation ecosystems, strategies to connect partners, and the timing of partnerships.

The partnerships with health care stakeholders contained comments about the value of partnering with health care stakeholders to ensure fit and potential for uptake. One industry representative commented that health care partnerships are the way forward to ensure adoption:

> *"technologies …should [have] the conversation with healthcare administrators and senior folks earlier…Otherwise it's kind of an old-fashioned model to develop something and kind of hope for the best… I think the way forward is…having very early conversations about what do people need and how is this and is this actually going to enjoy uptake".*

A government official added emphasis to the idea that innovators and health care stakeholders should partner early on in technology development:

> *"Reach out. Collaborate. We're all condemned to work together. … when you're with your little technology and you have an idea… you don't want this policy guy or the health research woman who will tell you, 'You have to tweak it because it won't fly'… It's better to have the cold shower right in the beginning and work together than to work five years, spend lots of money, make lots of proof of principle and at the end, say, 'Nope. We don't want to'".*

Industry and government stakeholders commented that the way forward is to develop multi-stakeholder health care partnerships for development of relevant technologies, which are aligned with health care priority issues.

The timing of partnerships sub-theme builds on the commentary about the value of healthcare partnerships, to include other non-health care stakeholders early in a technology's development. A government stakeholder speaks to the value of early discussions to inform a 'regulatory strategy' for the device:

> "*early engagement with regulatory authorities and asking the right questions to understand the obligations of an innovator who's entering into this space that's maybe uncharted territory for them … looking long-term about aspects related to regulations, uptake, and reimbursement. …having those early discussions and developing a regulatory strategy early on in the process is something that is very positive … playing catch-up after the fact is challenging*".

An industry stakeholder discussed the value of the medical device industry as a whole working closely with governments to better understand each other's needs. Industry and government stakeholders felt multi-stakeholder partnerships helped partners understand each other's needs over the long time period it takes to develop, assess and implement a technology.

The third sub-theme under partnerships is strategies to connect partners and this sub-theme contains examples used by interviewees related to connecting relevant stakeholders. A government stakeholder spoke about their efforts to bring together researchers, hospitals, innovation centers, and the rehabilitation sector to develop an ecosystem to support aging-related technologies. An industry representative noted government-created organizations around different disease-state or clinical areas as a venue to bring together partners:

> "*we've been working on an initiative with them to bring in medical technology companies, and then the [organization]…will talk to industry about what their health*

challenges are, and the companies can respond by presenting different technologies

that will improve the health of that type of patient".

An innovator added that technology incubator programs designed to provide them with

mentorship, advice, and networking opportunities were very helpful to them.

Government, industry and innovator perspectives cited the value of innovation

ecosystems, venues or events which bring together multiple partners and technology incubator

programs as ways to connect partners.

3.6 Discussion.

3.6.1 Ideas, Interests, Institutions

The conceptual framework conceived of numerous interconnected actors operating in the

health technology innovation policy landscape for older adults in Canada. By collecting

stakeholder perceptions about what is, and what should be, in the health technology policy arena

these findings present a set of ideas. The framework helps to understand how many sets of

interests interact, as facilitators and barriers are relevant at the intrapersonal, interpersonal,

micro, meso and macro policy levels. These interconnections are complicated by the fact that

health technologies for older adults may be used, administered, prescribed, regulated, evaluated,

purchased, invested in, and developed, all by different interests.

Facilitators and barriers to health technology innovation and adoption for older adults

operate within a complex web of institutional arrangements. Municipal, regional, provincial and

federal governments operate with individual mandates for health care and innovation. Private

stakeholders sell pharmaceuticals, assistive technologies, medical devices, health care services,

and insurance. Patient representatives, social movements and charity organizations work to have

their voices heard. Smith, Mitton, Davidson and Williams (2014) describe this institutional

complexity: "*these increasingly complex arrangements constrain both short and longer-term*

opportunities to reallocate resources as well as confounding decisions concerning who the

stakeholders are, and how they can be included in the process". The stakeholder perceptions

identified ideas and interests and suggested strategies to leverage partners and resources to

navigate complex institutional arrangements in the health technology policy arena.

3.6.2 Development

The findings of this process align with concerns in the literature around designing

technologies responsive to the needs of Canadian health care systems (Lehoux, Gauthier,

Williams-Jones, Miller, Fishman, Hivon et al., 2014; Menon & Stafinski, 2011). Our interviews

confirm that technology developed without health system expertise is a barrier to adoption and

use and suggest innovators developing a new technology should seek out health system partners

and documents to confirm that their technology aligns with health system priorities. Benefits of

consulting health care partners include: clinician feedback, access to patients, and pilot

opportunities. Put very simply, we heard: *"If you're innovating, then innovate in the direction of*

where the health system is going". This may be especially challenging for innovators who are

funded by partners (either public, private or not-for-profit) who value the potential for revenue

generation over the potential for a meaningful change in health outcomes.

3.6.3 Assessment

As others have found (Culyer, 2014; MEDEC, 2011), this research identified concerns

about the length of time formal assessment processes can take, which is exacerbated when

companies have to repeat assessment processes when introducing their technology in a market or

jurisdiction. Our interviewees generated new questions about how to support 'meaningful evidence generation' and what should be done in cases where clinical or cost effectiveness data are not available or are unlikely to become available. Our results provide a commentary about the future of regulating medical devices, as devices continue to develop at a rapid pace, becoming more and more complex and personalized. If device development continues to intensify and out-paces assessment processes, it may be relevant for innovators to consider that developing a technology that will not be regulated as a medical device can offer flexibility in defining the product's value.

3.6.4 Implementation & Sustainability

Our results echo findings in the literature noting the problematic nature of cost-focused procurement processes in health care (Prada, 2016; Arshoff, Henshall, Juzwishin & Racette, 2012; Miller et al, 2019). Processes with an emphasis on values or outcomes 'de-risk' the investment for the healthcare system in a new technology or innovation, which can be important when operating in a publicly funded health care system. As others have noted, (Scotland & Bryan, 2017; Bryan, Mitton & Donaldson, 2014), our findings had an emphasis on managing a technology throughout its life cycle, and disinvestment as a way to offset spending on new technologies. Although interviewees acknowledged the usefulness, in principle, of disinvestment to promote sustainability of technologies across their lifespan, they noted challenges in implementing a health technology management approach or *"how to stop paying for a particular technology"*. This aligns with the findings of Soril and colleagues (2017) that transitioning to a health technology reassessment approach is very difficult. Disinvestments are a form of resource allocation and can be a contested endeavor by different health care providers and insurers as they

impact volumes of services and the way they are delivered (Smith, Neale, Mitton & Williams, 2014). Health care systems may require support to know where and how to begin disinvesting.

3.6.5 Partnerships

Similar to the findings of Scott, Pasichnyk, Harstall & Chojecki (2015) where the technologies with the least amount of support infrastructure were the most likely to be adopted, our interviewees noted that change management, support technology, software upgrades, new computers and IT support staff during implementation all represent costs beyond the list price of a technology which can impede adoption into Canadian health care systems. Partnerships between innovators, health technology evaluators and health care systems may be required to make all costs of technology adoption apparent.

3.6.6 Canadian Policy Context

This work illustrates the frustrations that innovators have when trying to bring a technology to market in Canada. Provincial jurisdiction in health care, and the corresponding different policies of each health system, exacerbate Canada's already small market share in the medical device arena. Promoting Canada as an entry point to the medical device industry in the United States, as one of our interviewees suggested, may provide more incentive for innovators to consider bringing their technology to market in Canada. It may be misleading to present Canada as a gateway to American markets, since the two health systems are structured quite differently, which can impact how well a technology fits in two jurisdictions. Canada's health system is more similar to European health systems such as Germany and the U.K. than the American health care system (Lehoux, Miller, Daudelin, Denis, 2017).

3.6.7 Resources

Our interviewees commented on the sheer size of the Canadian health care system and the need for governments and policymakers to see health care as a way to drive economic development. Relatedly, our interviewees spoke about the opportunity cost to economic development when Canadian investments fund the co-design, development, and piloting of technologies, which go on to commercialize in other countries. This opportunity cost is magnified as Canadian health care systems import 75% of health technologies (International Trade Administration, 2019).

3.6.8 Partnerships

Different types of partnerships were presented as a way to enable technological innovation and adoption in Canada. Given health policy and technology policy operate in insulated silos from one another in Canada, with different portfolios, aims, and strategies to reach those aims (Henshall & Schuller, 2013; Lehoux, Miller, Daudelin, Denis, 2017) it is not surprising that bringing a technology to market in Canada is challenging for innovators, when layered with budgetary silos within health care and a lack of inter and intra ministerial collaboration within governments (issues which our interviewees brought up). Across stakeholder types, our interviewees stressed the importance of collaboration between innovators, regulators, HTA bodies, clinicians, patients, reimbursers, procurement staff and health care decision makers. The timing of when these partnerships should be formed was undoubtedly early in a technology's development. Stakeholders stressed how much waste could be avoided if partnerships leveraged partners' relevant expertise across the development, assessment, implementation and sustainability of a technology. Our findings suggest innovators are receptive

and appreciative of venues where they can form partnerships (such as government organized entities, or technology incubators) which will help shape the development of their technology.

3.6.9 *Older adults & Co-creation*

This chapter was designed to add insight to aging-related technologies and how they might experience barriers and facilitators to health technology innovation and adoption. The findings suggest unanimous agreement across stakeholder types that formal innovation and adoption processes would be the same regardless of the target population for the technology.

Our findings show resource constraints specific to innovation and adoption in the home and community care sector which are relevant for older adults as they represent 70% of Canadian home care clients (Canadian Home Care Association, 2016). An innovator noted that day-to-day care delivery activities of home and community care services crowd out the possibility of considering or adopting a technology. Our interviewees noted the complexity of the many home and community care agencies working separately to deliver care and attributed the lack of funding for evaluation and implementation of technologies as related to underfunding of the home care sector.

Interviewees mentioned that negative assumptions persist among policymakers and clinicians and about older adults' capacity for technology use. These assumptions affect the way technologies are formally assessed, as value-sets used to estimate changes in health-related quality of life are based on representative samples of the general population (Devlin, Shah & Buckingham, 2017) and do not consider the ways that preferences change with age, for example how emphasis on quality of life as opposed to length of life may change. Other research has

shown that older adults feel they are excluded from innovation partnerships due to ageism (McNeil et al, 2017).

Negative assumptions about older adults were contrasted with a strong commitment to co-creation of technologies across stakeholder types we interviewed. Governments could play a leading role in creating opportunities to link stakeholders across sectors and inform the co-creation of health technologies for older adults. Opportunities to partner and co-create technologies that are relevant to older adults and caregivers and responsive to health system needs should take place at the outset of technology development to prevent waste.

3.7 Strengths & Limitations

3.7.1 Limitations

This study used a framework analysis to interpret the findings of 46 qualitative interviews on facilitators and barriers related to health technology innovation and adoption for older adults. As this method chooses a framework in advance of analyzing data, some have pointed to a necessity of getting a good fit between the data and the framework, and the possibility of the framework 'stifling the vividness of insight' inherent with qualitative analysis (Dixon-Woods, 2011). The framework method does not address the frequency with each theme arose. Some themes were raised in nearly every interview; some in relatively few interviews. The categorizations between stakeholder types may be oversimplified as some stakeholders have worked across stakeholder types (for example researchers and innovators, or policy-makers and researchers).

As a participant pointed out, there are normative challenges related to asking the research question the way I chose to. Asking for facilitators and barriers relies on participants' subjective

definition of good and bad in the health technology policy arena, and stakeholders from different sectors (or the same sector) could potentially be in conflict. I have distinguished between stakeholder type throughout the results. Older adults did not inform this interview process, but will be consulted in a subsequent phase of this work to provide feedback on these findings.

Innovations operate within social contexts, and communication about new innovations between different actors over time influences whether or not an innovation gets diffused widely across a system (Rogers, 1995). Although diffusion and widespread use would fall under the implementation stage of the innovation pathway developed in this study, I did not study specifically the manners in which technologies become used widely or adopted but not used, which may have limited the work.

3.7.2 Strengths

Framework analysis can be a helpful way to structure a large set of data (Dixon-Woods, 2011), such as this one, with 46 qualitative interviews ranging from 45-90 minutes each). Framework analysis is also 'an excellent forum for driving forward interdisciplinary collaboration' (Gale et al, 2013, p.6) which may have helped to accommodate the different perspectives from four different stakeholder types.

3.8 Conclusion

Stakeholder perceptions present a complex arrangement of institutions, interests and ideas about facilitators and barriers to health technology innovation. By identifying the layered institutional arrangements, this work helps to explain the disintegrated nature of the Canadian health care system, and associated challenges with having innovations adopted and used in such a system. In many ways, stakeholder comments appear in these interviews as advice to

innovators about how to navigate a disintegrated system. This work offers a discussion, which can inform how to move forward in partnership with older adults, caregivers, innovators, researchers, policymakers and industry representatives to co-create a more integrated health care system enabled by health technologies.

CHAPTER FOUR: Ranking policy options to enable health technology innovation and adoption in Canada: A multi-stakeholder concept mapping process

4.1 Introduction

The earlier stages of this research identified facilitators and barriers to health technology innovation and adoption in Canada, as a necessary step in creating an evidence-informed health innovation agenda. More research is required to translate facilitators and barriers into policy options, and to then understand which of these are the most important, and most feasible. This work is in support of the development of a clearly articulated health technology innovation agenda, with specific actions for different actors at the different institutional levels, which characterize the Canadian health care system (federal, provincial territorial, regional) (Snowdon, 2017; Padfield, 2017).

Work has been completed to understand factors that facilitate or constrain health technology innovation and diffusion at the front lines of care, based on qualitative interviews with healthcare providers and industry representatives in eight countries (Keown, Parston, Patel, Rennie Saoud et al, 2014). A systematic review identified the diffusion, dissemination, and implementation of innovations within health service organizations (Greenhalgh et al., 2004). Other work has been undertaken to understand how to engage older adults in regional health innovation ecosystems (McNeil, 2017). What these reports have not covered, is a "whole systems approach" to understanding how facilitators and barriers at different institutional levels can be translated into viable solutions for policy problems (Greenhalgh et al., 2004).

Choi and colleagues (Choi, Pang, Lin, Puska, & Sherman et al., 2005) suggest that policymakers are specifically interested in policy options, which are agreeable to large constituencies of people. Concept mapping has been suggested as a method to integrate

viewpoints of a variety of stakeholders to offer insight to the complex, 'wicked' problems which characterize modern policy-making (Klenk & Hickey, 2011; Trochim & Cabrera, 2005).

The aim of this study was to use group concept mapping to compile opinions of policymakers, researchers, industry stakeholders and innovators to answer: what do experts perceive to be the most relevant and feasible policy options to facilitate health technology innovation and adoption for older adults?

4.2 Methods

4.2.1 Rationale

Concept mapping is a participatory mixed-methods approach which integrates qualitative individual and group processes with multivariate statistics to describe a topic (Rosas & Kane, 2012). Concept mapping is more participatory than focus groups or other qualitative interviews (since concept mapping participants provide and analyze results), and serves as a way to structure qualitative data (Burke et al, 2005). The outputs of concept mapping produce a visual depiction of the group's conceptualization, which can be useful for identifying properties of complex systems in policy contexts - maps can align vision with action (Trochim & Cabrera, 2005). Concept mapping has been identified as an important methodology to accommodate the complexity of health care systems, and its participatory, structured nature can bridge the different perspectives and identified silos in perspectives between innovation policy and health policy in Canada (Lehoux, Miller, Daudelin, Denis, 2017).

4.2.2 Six Stages of Concept Mapping

Figure 7: Six stages of Concept Mapping

| Preparation | → | Idea Generation | → | Structuring Ideas | → | Representing Ideas | → | Interpreting Ideas | → | Utilizing Ideas |

4.2.3 Preparation

In the preparation or focus formulation stage, the researcher decides who the participants are, how they will be recruited, which participants will help to decide focus prompt, and which dimensions participants will rate (Trochim & Cabrera, 2005). The focus prompt serves to "delimit boundary conditions for ideas or issues to be mapped" (Kane & Trochim, 2007). The focus prompt is structured so that participants fill in the blank after the prompt with their statements.

This concept mapping study took place in two phases. In phase one, participants completed brainstorming, sorting and rating activities of concept mapping electronically and interpreted results in an in-person workshop. In phase two, interviewees were re-engaged to complete sorting and rating activities online.

The framework outlined in Chapter three, which is adapted from the social ecological model, identifies relevant stakeholders associated with different social spheres where health technology innovation for older adults is created and implemented. An ecological approach to research on health technology innovation has been called for in the literature; and research which includes members of the Quadruple Helix model of innovation- users, industry, universities and public authorities is also increasingly relevant (Greenhalgh et al, 2004; Arnkil et al., 2010). This framework guided each phase's recruitment with the aim to have a representative sample across older adults, caregivers, innovators, researchers, policy-makers and industry representatives.

A committee member and I adapted the wording of the research question ("what do experts perceive to be the most relevant and feasible policy options to facilitate health technology innovation and adoption for older adults?") into the following focus prompt: What can be done to create a policy and regulatory environment that will support safe adoption of effective technologies (especially those for older adults)?

4.2.4 Recruitment- Phase 1 (March- April 2019)

An in-person workshop takes advantage of the participatory as well as individual components of concept mapping. An opportunity arose to conduct an in-person workshop adjacent to a scientific conference that many key stakeholders in the health technology innovation arena would be attending.

Recruitment for phase one used a snowball sampling method beginning with a policymaker who had experience working with health technology innovators, researchers and industry stakeholders (Palinkas, Horwitz, Green, Wisdom, et al., 2015).

4.2.5 Recruitment- Phase 2 (July-September 2019)

Stakeholders who were involved in our interview process (46 industry representatives, policymakers, innovators and researchers) were a relevant and appropriate sample for this stage of the project. As part of the qualitative interview process, the interview consent form had participants indicate whether they would like to be contacted again to receive results of the study. This presented an opportunity to reengage those stakeholders in the project.

We used a four-pronged strategy to increase these stakeholders' participation in online concept mapping, adapted from Dillman (2000). On June 25th every interviewee was contacted with a notification email with a brief explanation of the research aims indicating they would

receive a link to participate in an online concept mapping exercise in coming days. I sought out

email communication from the interview scheduling process to refer to as a way to remind each

interviewee (n=46) of their previous contribution to this research. As a way to show appreciation

for the associated time commitment with completing the concept mapping process (around 45

minutes), participants were entered into a draw for a gift card ($150 value).

Interviewees were re-contacted by email four days later with a link to the concept

mapping exercise, a short description of the activity and its associated time commitment, as well

as information about the participation draw (Dillman, 2000). The concept mapping exercise was

piloted with six researchers in Dr. Stolee's research lab, to understand the time commitment of

the sorting and the rating activities. In the recruitment email, participants were notified that each

activity (sorting and rating) would take around 20 minutes, or around 45 minutes if completed

altogether. Three weeks after the initial contact, participants were emailed a reminder that the

study would be closing at the end of the week, encouraging their participation. On September

23rd, participants were thanked for their participation, and the winner of the draw was notified.

The e-gift-card was sent to their email address.

4.2.6. Idea generation

This stage generates answers to or ideas about the focus statement. A brainstorming

process among participants or coding existing text/literature are common ways to generate

statements (Trochim & Cabrera, 2005). Most projects have a maximum of 100 statements, the

internet can be used to gather statements, or it can be completed in-person using pen and paper

(Kane & Trochim, 2007).

Two researchers worked to code the scoping review (Chapter Two) and the qualitative interview results (Chapter Three) to generate a list of answers to the focus prompt. Thematic analysis of the scoping review generated 69 statements that answered the focus prompt (Hsieh & Shannon, 2005). Thematic analysis of the qualitative interview data generated 78 statements that answered the focus prompt (Hsieh & Shannon, 2005).

Researchers used an idea synthesis process (Kane & Trochim, 2007) which: ensures each statement only represents one idea, that each statement is relevant to the prompt, that reduces the statements to a manageable number, and ensures each statement is clear and understandable for participants. The idea synthesis process eliminated irrelevant ideas and removed duplicate ideas, concluding with 80 answers to the focus prompt.

Snowball sampling generated ten stakeholders to participate in a mixed online and in-person concept mapping process. Six others were contacted for participation but declined. Phase one participants were contacted by email and invited to generate additional statements to those identified through previous stages of this research. Using the Concept Systems software (2015), participants individually and anonymously brainstormed fifteen additional statements, leaving the project with 95 statements, which is just under the recommended maximum of 100 statements (Kane and Trochim, 2007). See Appendix H for a list of statements.

4.2.7. Structuring ideas

At this stage, participants decide how the statements are related by completing an "unstructured similarity sorting" process – placing ideas in piles and naming them (Kane & Trochim, 2007). Concept Systems Incorporated is an electronic software which can organize the structuring stage (Kane & Trochim, 2007). Participants are reminded through the software to

choose one pile per statement, and encouraged not to place every statement in its own pile. It is typical of concept mapping to rate each statement on its relevance to the focus prompt and feasibility to accomplish (Kane & Trochim, 2007). As this work was interested in finding relevant and feasible policy options, these rating criteria were used. Researchers using concept mapping are often interested in how different groups complete concept mapping activities differently, and it is common to set up demographic questions which distinguish between groups (Trochim & Cabrera, 2005).

In April 2019, phase 1 participants (n=10) were invited to complete the sorting exercise 24 hours before the in-person workshop as pre-work. For phase one participants, the rating activity took place within the workshop. In July 2019, twelve previous interviewees completed both the sorting and the rating activities. The sample of twenty-two participants aligns with Rosas and Kane's (2012) recommended sample size of 20-30 participants.

4.2.8 Representing ideas

A similarity matrix is created which shows the number of participants who sorted each pair of statements together (Kane & Trochim, 2007). Next, multidimensional scaling takes the similarity and places points on a two-dimensional map (called a point map) resulting in a set of coordinates for each statement (Kane & Trochim, 2007). Stress tests diagnose the degree to which distances on the map vary from values in the similarity matrix. Lower values indicate better fit, while higher values mean the data are more complex or that they were not often sorted similarly by participants. (Kane & Trochim, 2007). Around 95% of concept mapping projects have a stress test value in the range of .205-.365 (Kane & Trochim, 2007). A hierarchical cluster analysis of the multidimensional scaling results groups the statements into non-overlapping

clusters. The analyst and a small participant advisory group decide the appropriate number of clusters, which is normally a function of the amount of detail required in the analysis (Trochim & Kane, 2005).

In this stage, bridging/anchoring analyses are completed to provide the analyst with an understanding of which individual statements and clusters of statements are anchored on the point map and which bridge across the data (Kane & Trochim, 2007). Bridging and anchoring help the analyst to understand the map and the dynamics at play between different sections of the map before the interpretation stage.

5. Interpreting Ideas is usually completed in a facilitated group meeting between the analyst and the participants of the concept mapping process, or a sub-group of the participants (Kane & Trochim, 2007). In this meeting the analyst presents the maps, discusses the clusters and their labels, and goes over the "go-zone map" which is a bi-variate plot of the rating data.

Phase one participants completed the interpretation stage. The participants were divided into two groups with special attention to having policy, research, innovator and industry perspectives represented within each group. I worked with a trained facilitator (MK) in concept mapping to lead each group through questions about: the number of clusters; the labels of the clusters; whether statements were classified properly in go-zones; whether there was overlap between statements; and the relationships between the clusters. Clusters were divided between the groups.

4.2.9. Utilizing Ideas

In this stage where participants put forward ways to use the concept mapping data. Common uses of the data are to organize action or program planning, to complete a needs

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assessment, to organize report writing, or to organize data synthesis and presentation (Kane & Trochim, 2007).

Phase one participants completed the utilization phase using a case example technology to ground the discussion (see Appendix K). This process was designed to simulate how these statements could be actioned to enhance innovation and adoption of health technologies for older adults. Each group was asked to: consider how the statements in the go-zone apply to this technology, and to create an actionable objective to promote this technology's uptake into the health care system. Participants were also asked to consider what information is missing from this case to be able to act on having it adopted.

4.3 Ethics

Ethics approval for the multi-stakeholder concept mapping process was obtained through the University of Waterloo Research Ethics Committee (ORE #30529).

4.4 Results

4.4.1 Participant information

For phase one, ten of the 16 invitees participated in sorting, rating and interpretation via the workshop. Five policymakers, two innovators, two industry representatives and one researcher participated.

Of the 46 interviewees, two people could not be invited to phase two. One person had retired from their role and another person was on an extended leave from their position. Twelve of 44 invited people participated in the second phase of concept mapping. Three other interviewees created an account to participate in concept mapping but did not complete the

exercise. There was very little drop off between sorting and rating exercises. Of the 22 people who completed the sorting exercise, 21 participants rated the statements on their relevance, while 20 users rated the statements on their feasibility.

4.4.2. Sorting

Using Concept Systems software, multidimensional scaling is applied to the similarity matrix (which identifies how each participant sorted each pair of points), to generate the point map, where each of the 95 dots represents one statement from the sort. Statements which appear closer together on the map indicate ideas which are similar to each other (Kane & Trochim, 2007). Hierarchical cluster analysis then grouped the statements in the point map into clusters using Ward's algorithm to create an aggregate of 'non-overlapping partitions in the data' (Kane & Trochim, 2007).

The stress value for this analysis is 0.288 after 19 iterations, indicating a good fit between the map and data. The stress value falls within the common range (.205-.365) for 95% of concept mapping projects (Kane & Trochim, 2007). Stress values are unpredictable below fifteen sorters and show diminishing returns for higher than 40 sorters (Rosas & Kane, 2012). Twenty-two sorts in this project are adequate for a consistent fit between the data and the point map (Rosas & Kane, 2012).

Figure 8: Point map

Participants sorted the 95 statements using between 4 and 14 clusters. For phase one, the group decided on a nine-cluster solution during the workshop. After adding phase two participants' data, the Concept Systems software was used to explore an appropriate number of clusters for this research. Working with a committee member and another researcher, we used the Concept Systems software ® to generate a point replay map for the range of clusters (4-14). A seven-cluster concept map was chosen as the best reflection of participants sorting choices.

Figure 9: 7 Cluster Concept Map
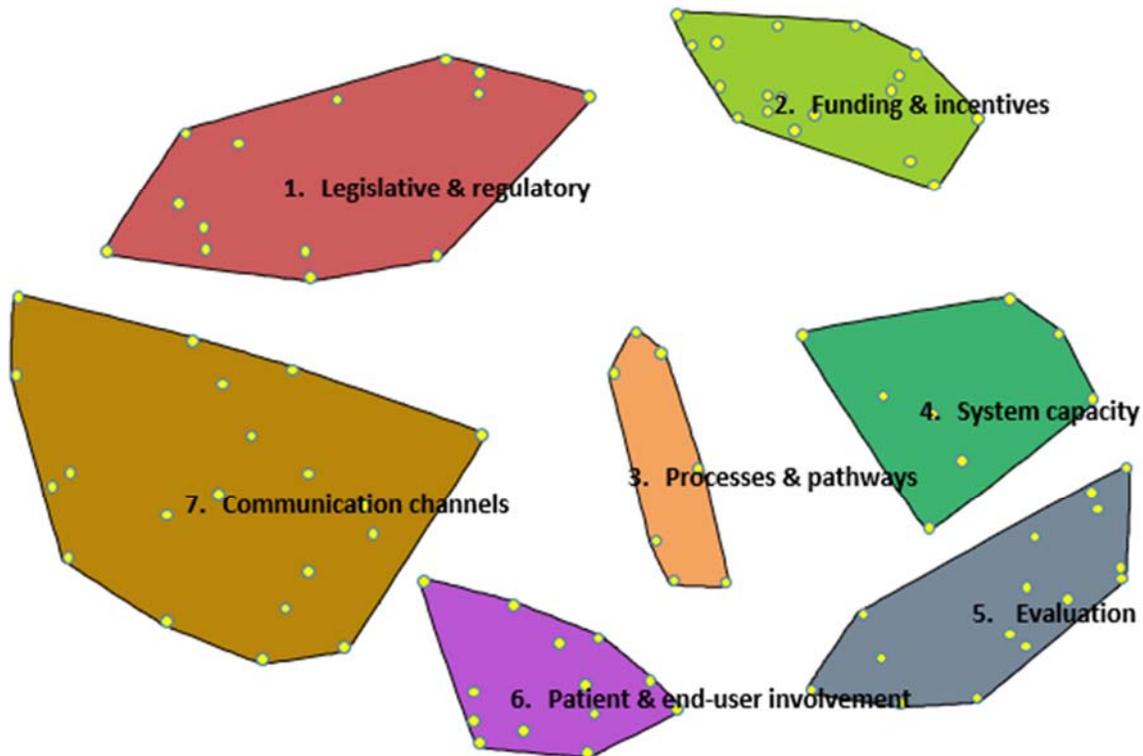
Statements with the lowest bridging values indicate statements which are more of an anchor on the point map, meaning many participants sorted that statement with those nearby it, and making it representative of the content around that place in the map (Kane & Trochim, 2007). Low bridging values help to indicate the essence of the cluster and can help with choosing a label for the cluster. The software generates ten options for cluster names based on participants' sort data. Using Concept Systems ® software, I created a point bridging map (see figure 10) which I cross-referenced with the seven-cluster concept map to give a representative name to each of the seven clusters. I was also able to order the statements in each cluster according to their bridging value. Table 3 lists the cluster number, and the statement with the

lowest bridging value and the final cluster name chosen. By looking at the lowest bridging value

in each cluster, I was able to see the point, which anchored the cluster. A committee member and

another researcher reviewed the cluster names.

Figure 10: Point Bridging map

Table 3: Bridging Values

Cluster #	Statement #	Statement with lowest bridging value	Bridging Value	Cluster Name	Average bridging value for Cluster
1.	55	More authority for local health care agencies to fund technologies	0.21	**Legislative & regulatory**	0.51
2.	21	Providing additional local/national seed funding or venture capital opportunities to spur innovation activities and	0.06	**Funding & incentives**	0.12

		decrease dependence on foreign investment			
3.	62	Decision timelines around adoption are articulated between innovators and healthcare system payers	0.28	**Processes & pathways**	**0.36**
4.	13	Define clear pathways that lead from real world trials to adoption at the start of adoption consideration and deliberation	0.39	**System capacity**	**0.52**
5.	15	Implementing user experience analysis and user acceptance testing during evaluation	0.26	**Evaluation**	**0.29**
	43	Formalizing methods for patient involvement in health technology assessment	0.26		
6.	68	Promote the development of innovation ecosystems (which can combine resources between partners, and link different regional partners)	0.29	**Patient & end-user involvement**	**0.25**
7.	29	Innovators/technology developers need to better understand the practical aspects of health delivery (e.g., resulting in more relevant technology)	0.19	**Communication channels**	**0.50**
	61	Encourage innovators to think ahead to implementation (where will their technology fit and who will pay for it)	0.19		

Figure 11: Cluster Bridging Map
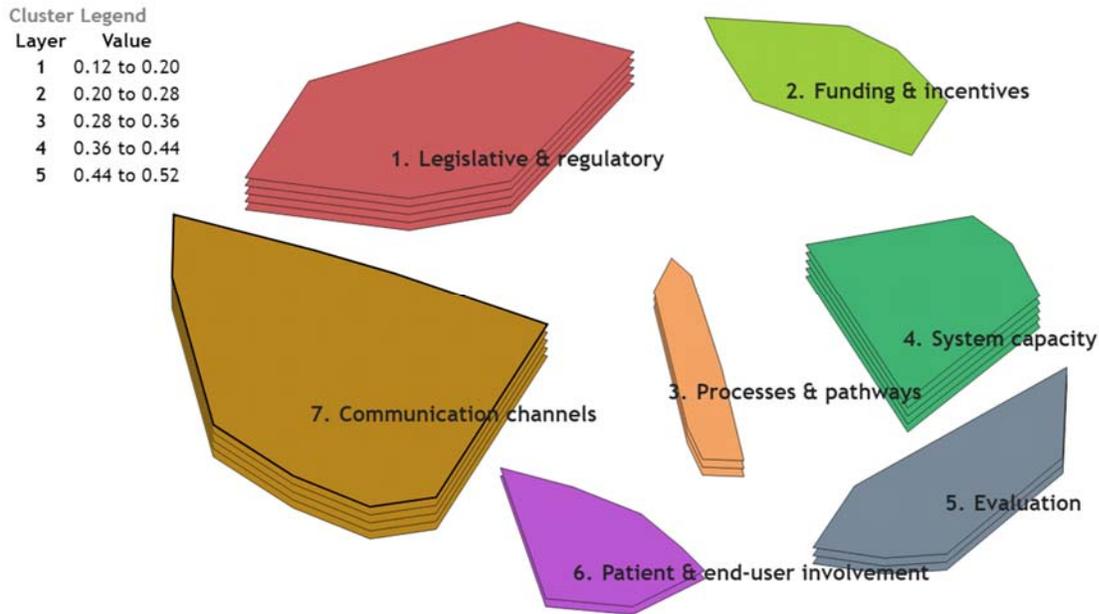
As seen in figure eleven, clusters one, four, and seven have five layers, and the highest bridging values, indicating that they contained points which were sorted in different ways by stakeholders. These clusters contained more bridging points, which interacted across the data as opposed to anchoring points, which were commonly sorted in the same cluster. Cluster four has four layers and Cluster six has two layers indicating some similarity in how participants sorted that data. Cluster two has only one layer, demonstrating that the points in that cluster were often sorted together.

Cluster one is titled "legislative and regulatory" and includes fourteen statements about macro-level policy actions. This cluster averaged a .51 bridging value, one of the highest of the seven clusters, meaning these statements were not always sorted similarly by participants. Statements covered a national policy to address costs of telecommunication when used for health applications, national level policy alignment between health and innovation portfolios, and better

understanding of how international trade agreements impact health innovation and adoption for older adults. This cluster is also where statements about health information privacy issues, intellectual property agreements and open data policies for health outcome information, were located. Statements about value-based procurement fell into this cluster including how to support innovative, value-based procurement and how to make these processes accessible to new innovators.

Cluster two is labelled "funding and incentives" and includes 19 statements about resource allocation in the health technology innovation arena. Cluster two has an average bridging value of 0.12, the lowest of clusters, indicating these statements were very often sorted together by participants. This cluster included statements about reforms in health care budgeting to: standardize resource allocation; allow for easy transfer of funds across years and across health care settings; and focus on patient outcomes. Statements in this cluster also identified specific times during the innovation trajectory where resources could be helpful: as venture capital, in development, to scale up good ideas, and to off-set the costs associated with value-based procurement in health care. Statements in this cluster also mentioned enhancing existing innovation-related tax-credits, and creating new innovation-related tax credits. Other statements covered how to create incentives to encourage health care providers to participate in innovation, including trialing promising technologies.

Cluster three is labelled "processes and pathways" and includes seven statements about pathways to health technology adoption. The average bridging value for this cluster was 0.36 indicating participants sorted these statements somewhat similarly. Statements included comments about the value of communication between stakeholders so that innovation failures are

not repeated, so that both parties understand decision timelines, and to ensure both parties understand willingness to pay for a technology. This cluster included comments to ensure versatile technologies are developed which can be scaled across countries - even those that have different levels of publicly funded health care.

Cluster four is titled "system capacity" and includes eight statements about ways to increase health system capacity to support innovation. This cluster had the highest average bridging value of all the clusters at 0.52, indicating that participants did not often sort these statements together. Increased capacity to recruit patients, co-design technologies, test technologies, and implement affordable technologies were topics covered by statements in this cluster. Specific strategies such as those which encourage usability and human factors analysis as well as those which help consider budget impacts of new technologies and how to dis-invest from technologies were included in the statements in this cluster.

The fifth cluster is labelled evaluation and contains fifteen statements about how technologies are evaluated. The average bridging value of these statements was 0.29 indicating participants sorted these statements somewhat similarly. Statements in this cluster note that technologies should be evidence-based and offer many components of evidence that a health technology assessment should consider (outcomes, feasibility, cost-effectiveness, budget and care pathway impacts). The statements in this cluster focus on integrating many perspectives into health technology assessments, and envision innovators who know what data they need to produce to participate in HTA, as well as open access to HTA reports completed in other jurisdictions. These statements also list ways to evaluate the opportunity cost of path dependency and societal impacts of health technologies.

The sixth cluster is titled patient and end-user engagement and contains thirteen statements, with a bridging value of 0.25 indicating somewhat similar sorting by participants. These statements address the need to have patients define problems which health technologies should address, and to involve patients and caregivers across all stages of innovation, including policy changes. A few statements in this cluster addressed the need for developing relevant technologies that meet health system needs and integrate with existing processes which are usable by health care providers - presumably because involving end-users will ensure these statements are addressed. This is also the cluster where some comments about older adults appeared, touching on the need to bust myths that older adults do not use technology but there is still a need to create technologies which are simple and easy to use.

The seventh cluster in the concept map is titled communication channels and contains 20 statements discussing ways for partners to work together. This cluster had a high bridging value of 0.50 indicating participants did not commonly sort these statements together. The statements in this cluster acknowledge transdisciplinary working, promoting innovation ecosystems and developing risk-sharing agreements as ways to promote communication. This communication channels cluster spoke about bringing together siloed departments at macro and meso levels of the health care system, as well as acknowledging that arms-length agencies can act as a hub for stakeholders from different sectors.

4.4.3. Rating

Relevance

Twenty-one of the 22 participants rated the 95 points on their relevance to the focus prompt. Using Concept Systems Software ®, I created a cluster rating map (See Figure 12) which shows on average how relevant the stakeholders perceived the statements to be. The

legislative and regulatory cluster and the patient and end-user engagement cluster are each five layers thick, demonstrating high relevance ratings for the statements they contain (4.15/5; and 4.17/5). System capacity (4.07/5); evaluation (4.06/5); and processes & pathways (4.02/5) were the next most relevant clusters. Funding & incentives (3.97/5) and communication channels (3.84/5) were the clusters with the lowest average rating of relevance.

Figure 12: Cluster Rating Map- relevance
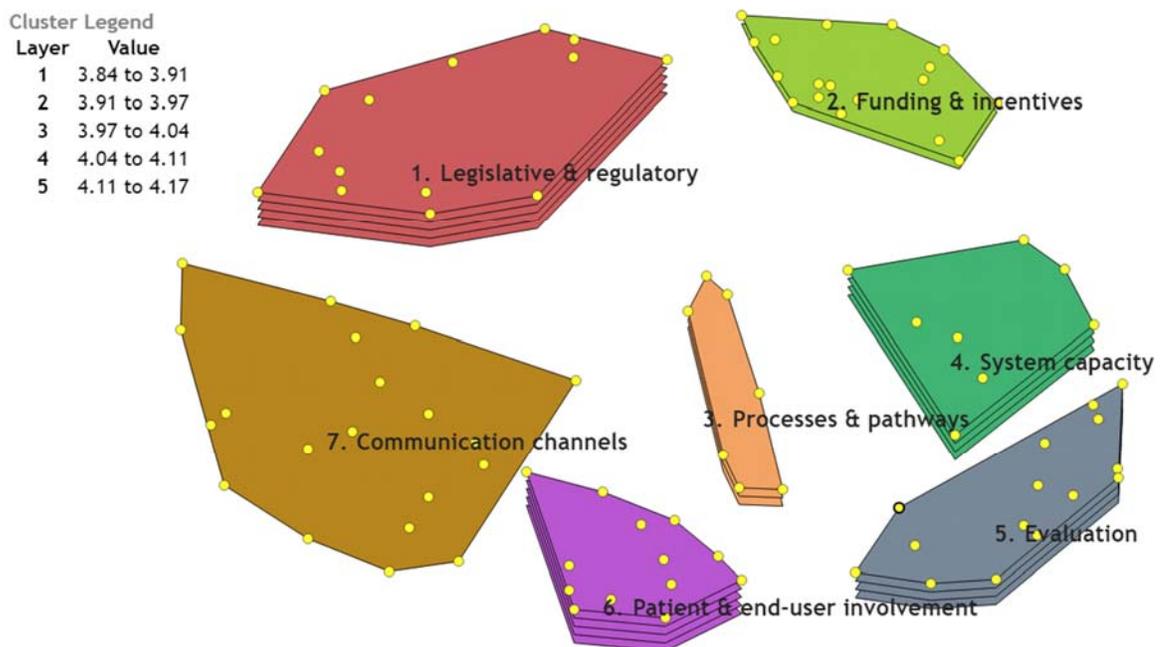
Feasibility

Twenty out of 22 participants completed the feasibility rating of the 95 statements. Figure 13 displays the cluster rating map for feasibility, where patient and end-user engagement cluster has the most layers (4.46/5) indicating participants perceived these options as (on average) very feasible. The evaluation cluster had the next highest feasibility rating (4.18/5), followed closely by the communication channels cluster (4.12/5) and system capacity (4.04/5). The funding and

incentives cluster (3.7/5) and the legislative and regulatory cluster (3.62/5) contained statements that were perceived to be not very feasible to implement.

Figure 13: Cluster rating map- feasibility
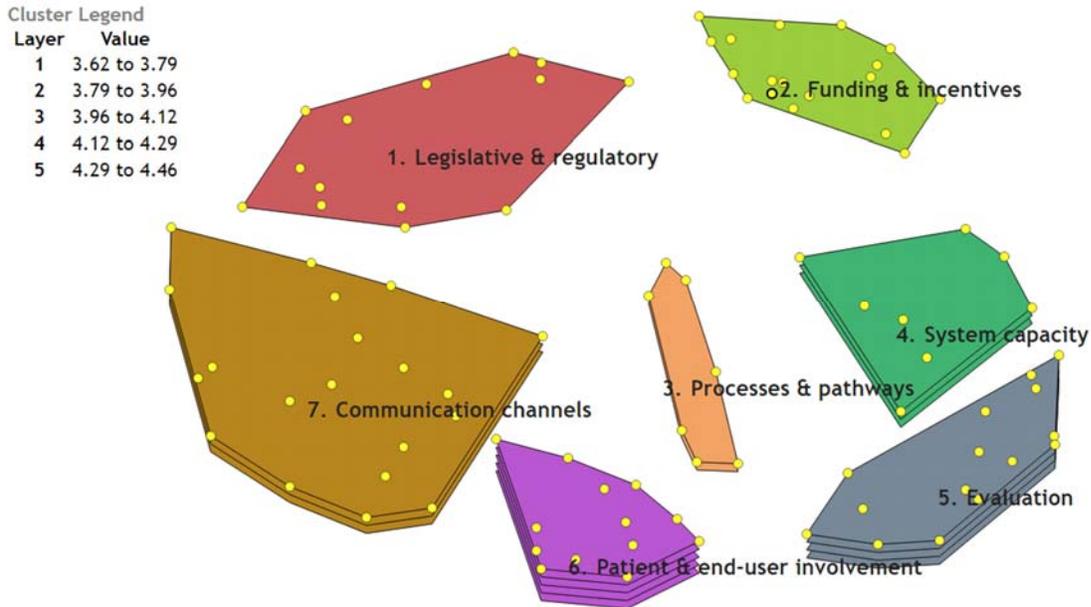
4.4.4 Pattern matching

The pattern-matching graphic is a ladder graph designed to show correlations between ratings. This graph (Figure 14) reveals disparities among average cluster ratings in terms of relevance and feasibility. The range of scores for relevance was 3.84-4.17 and the range of scores for feasibility was between 3.62-4.46. The patient and end-user involvement cluster was rated by participants as the most relevant group of statements as well as the easiest group to implement. The legislative and regulatory cluster was just behind patient and end-user involvement cluster in terms of its relevance to the focus prompt but was rated as the most difficult group of statements to implement. The communication channels cluster was rated on average as the least relevant, but the third most feasible to implement.

Figure 14: Pattern match graph: relevance x feasibility
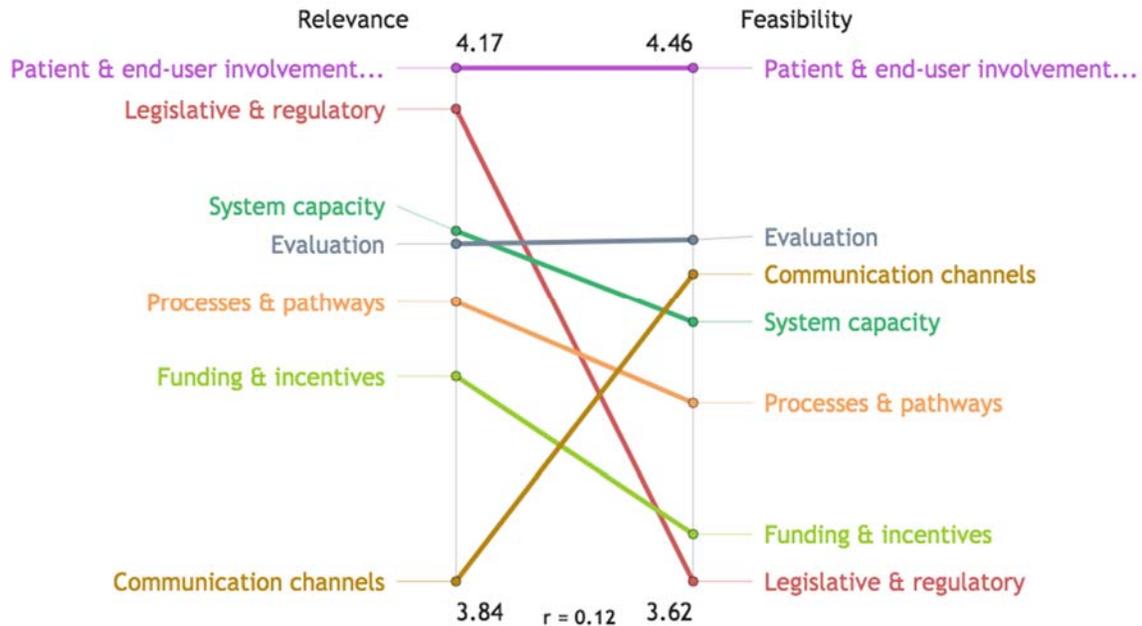
4.4.5. Go Zones

To go further in depth about which statements were rated the most feasible and the most relevant, a "go-zone" was created (Figure 15). This type of concept map uses a bivariate graph to place statements with higher than average rating scores on both relevance and feasibility into the top right quadrant. Statements with scores above average in terms of relevance but below average in feasibility appear in the bottom right quadrant. Statements with below average scores in relevance but above average scores in feasibility are in the top left corner and statements rated below average in both relevance and feasibility.

Twenty-seven of 95 statements were rated higher than average in terms of relevance and feasibility. Six of the 27 go-zone statements came from the evaluation cluster, five statements

came from the funding and incentives cluster. Patient and end-user engagement and system capacity each had four statements in the go-zone, while three statements came from the processes and pathways cluster.

Legislative and regulatory points in the go zone reflected the need for procurement policies that were accessible to smaller companies (65), and a better understanding about how international trade agreements can disadvantage local companies (38). Stakeholders also saw strategizing about privacy issues working with health information (64) as a relevant and feasible policy option.

In the funding and incentives cluster, stakeholders felt that allocating funds to trial technologies in healthcare settings (67) as a relevant, feasible policy option. Policy option fourteen was rated highly and suggested subsidies for technologies with a prevention or future cost-savings angle (14). Incentives for health care providers to participate in innovation (42) was seen as relevant and feasible, as was integrating health care budgets around patient outcomes (90) across a continuum of care as opposed to an episode of care (27). Combining government and private payer funding to increase technology accessibility was seen as above average in terms of relevance but was average in terms of its feasibility rating (34).

The statements rated as highly relevant and feasible in the processes and pathways cluster were supporting innovator/health care operator partnerships (63), clear discussion about willingness to pay for a technology (72), and decision timelines (62).

In the system capacity cluster, the highly relevant and feasible points were resources to support patient recruitment for co-creating technologies (35), and enabling the home care sector to be more self-sufficient in their funding, testing and implementing of new technologies (50). In

the evaluation cluster, it was seen as both relevant and feasible to implement open access to existing health technology evaluation reports (86). It was also seen as relevant and doable to increase innovators understanding of the data they require to participate in a health technology assessment (66). The communication channels cluster included highly relevant, feasibly rated statements which listed strategies to bring partners together such as innovation ecosystems (68), and trans-disciplinary working (78). Other go-zone points involving communication stressed the creation of opportunities to bolster partnerships (19) and to bring innovators, regulators and reimbursement representatives together early (26).

The highly relevant and feasible points which came from the patient and end-user engagement cluster included having patients define problems for developers (81), increasing awareness of unmet system needs (20), and the possibility of tech adoption beyond acute care (40).

Figure 15: Go Zone Map- All Statements
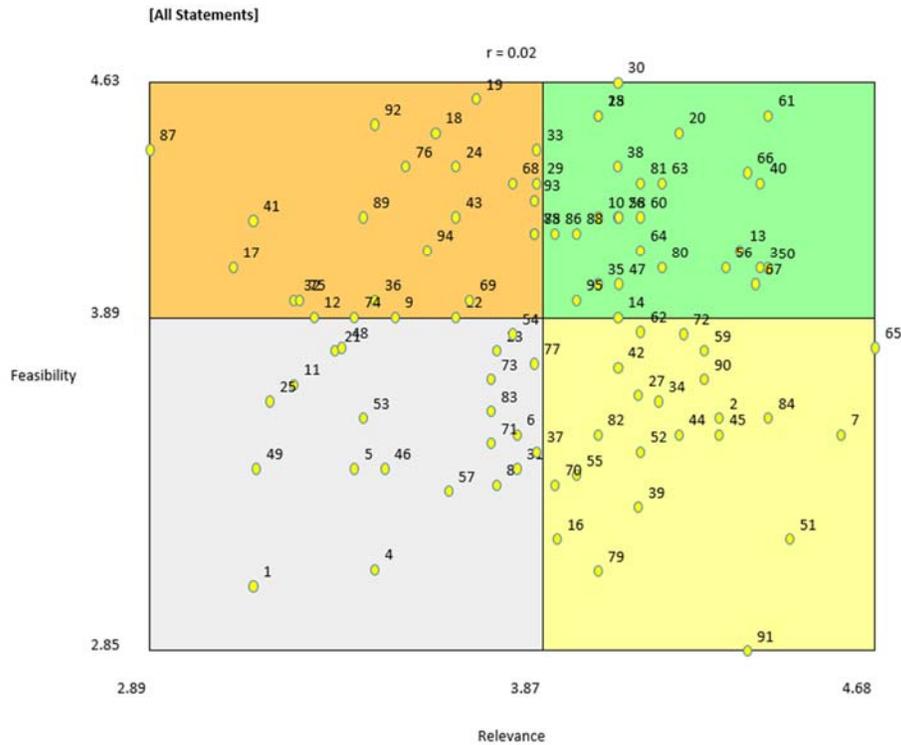
4.4.6 Interpreting ideas

We conducted an interpretation stage is to discuss the ideas from the concept mapping exercise with a sub-group of the participants. Ten people participated in a half-day workshop in Edmonton, AB on April 15th, 2019. The workshop took place from 1-4pm, just before the opening ceremonies of the Canadian Agency for Drugs and Technology in Health Symposium, which many of the participants were attending.

Format

The ten participants from phase one were divided into two groups. Group one contained one researcher, one innovator, two policymakers and one industry representative, group two contained one innovator, three policymakers, and an industry representative. Each group was assigned half of the cluster map. Every prompt question (the number of clusters; the labels of the

clusters; whether statements were classified properly in go-zones; whether there was overlap between statements; and the relationships between the clusters) appeared on a large sheet of chart paper, and participants had small post-it notes to post their ideas on the chart. After each participant had posted their ideas, they were invited to share them with the group. We concluded with a full-group discussion.

Number of Clusters/Cluster labels

When asked about the cluster number, the participants chose a nine-cluster solution. Participants were concerned with procurement policy issues and questioned why that topic was not apparent in the cluster labels. Concept Systems software named one of the clusters "contextual adaption" which participants' felt was jargon, and suggested renaming that cluster "patient and user involvement".

Gaps in the data

We also asked this group about gaps in the data, or ideas that could have come out better in the statements. Their comments reflected a desire to have the language of 'technologies for health' as opposed to 'health technologies' as a way to include technologies for health and wellness, not just those which are regulated by Health Canada. These participants felt that there was room for many technologies in the health and wellness space that could prevent health decline and promote better health for older adults. They also felt that these technologies could be impactful without the need to engage with regulation. Participants expressed that a broader perspective on 'technologies for health' could lead to development of technologies at more diverse price points, increasing accessibility.

The group discussion brought up that the points are focused on funding and policy drivers. Another participant contextualized this statement, saying that we have many supply side initiatives which 'push' technologies along the innovation pathway and onto the health care

system. They added that what is lacking is on the demand-side, which they perceived to be the 'pull' from the health care system. Another participant commented that the points focus on what innovators should do differently. They commented that innovators are not resistant to change, it is the system which resists change and needs to be nimbler and more adaptable to innovative ideas.

Participants brought up the concept of feasibility, and how to decide what feasibility meant in terms of policy options. Some participants brought up that an option could be considered more feasible if it did not require a reallocation of resources or "new money". Another participant brought up feasibility in terms of timelines, and questioned whether feasibility meant in three years, or five years or ten years. Another participant joked that feasibility was a function of how optimistic any person is.

The go-zone that was created using phase one participants' data appears in Appendix L. The group discussion added some context about certain points. Much of the discussion focused on patient and caregiver engagement. Phase one participants perceived that a gap in the statements was funding for compensating patient involvement, and they felt that patients should be part of policy meetings. Participants felt that family caregivers were not addressed in the statements. They commented that there are very few policy initiatives directed towards family caregivers who do a great deal of care work, which benefits health care systems and governments. Another participant brought up point 64 regarding health data privacy - they felt that ownership of health data was in transition and that standards were beginning to emerge to support sharing of health data.

4.4.7. Utilizing ideas

Characteristic of the utilizing ideas stage, phase one participants were asked to apply the findings from the Go Zone. Given timing constraints, only phase one (10 of 22) participants were engaged in this stage. Participants were asked to consider the points in the Go Zone and how they would relate to a case example (see Appendix M) technology- an in home monitoring solutions compiling older adults' temporal and spatial movements into data. They were asked to create at least one actionable objective to promote this technology's uptake and they were asked what information was missing from this case for it to be considered for uptake.

Participants treated the statements in the go zone as advice to the case example innovators, and in many cases they qualified the points to make them more detailed. Regarding point 15, ("implementing user experience analysis and user acceptance testing during evaluation") they felt that the innovators would need to distinguish between older adults and their caregivers, with both being users requiring consent to trial the technology. Regarding point 80, they felt that innovators would need to explain to health care providers what the benefit of integrating this technology would be in order to gain their buy-in. Statement 81 states that patients should outline the problem for developers to solve. Participants' felt that patients could be involved in designing the solution as well as the problem.

The participants were quick to list missing metrics that, if collected, would increase the likelihood of this technology being adopted. They were interested in how this technology could affect the opportunity cost of falls prevention efforts, related costs of surgery, and quality of life. Other missing data included: the cost to implement this technology, the impact to workflows and models of care, and training related to the sensors. They also felt there was a role for older adults and caregivers to decide on or co-develop meaningful metrics to measure the impact of the case example home sensor system.

Through preparing, generating, structuring, representing, interpreting, and utilizing ideas that were generated through the literature, and in consultation with innovators, policy-makers, industry representatives and researchers, concept mapping has helped to organize stakeholder perspectives on the most relevant and feasible policy options for innovation and adoption of health technologies for older adults.

4.5 Discussion

4.5.1 Introduction and Overview

This work responds to calls in the literature for a 'whole systems' approach to health innovation policy and provides an evidence-based list of policy options to support the innovation and adoption of health technologies for older adults. Multi-dimensional scaling and hierarchical cluster analysis of participants' data create visual maps representative of participants' thinking, and supports the complexity inherent in the health innovation policy arena (Trochim & Cabrera, 2005).

This work frames the discussion about how to move forward in health innovation policy by distinguishing between relevant and feasible policy options. Twenty-seven of the 95 statements had above-average ratings in relevance and feasibility indicating a starting point for policy interventions to support the innovation and adoption of health technologies for older adults. Twenty-one statements were rated below average in both relevance and feasibility, which narrows the pool of policy options to consider. Twenty- two statements were rated above average in terms of relevance but were perceived by stakeholders as difficult to implement.

The seven-cluster solution was chosen as the best representation of participants' sort data, and the stress value indicated a good fit between the data and the point map. Twenty-two

participants are within Kane and Trochim's recommended number of sorts to validate a concept mapping exercise (2007). Kane and Trochim indicate that the sorting stage of concept mapping requires the most time and the most expertise, and recommend supplementing recruitment for the rating phase if attrition occurs between stages (2007). In contrast, this project saw very little drop off between the sorting and rating stages from the twenty-two participants.

Eight policymakers, eight industry representatives, four innovators, and two researchers completed the sorting exercise. One industry representative did not complete the rating exercise, meaning twenty-one participants completed the rating exercise. Thirty-two interviewees did not respond to a four-pronged email recruitment strategy requesting their participation in an online concept mapping exercise. Technology-enabled engagement may facilitate recruitment across large geographic areas, but email invitations to participate in research may get lost in busy participants' email inboxes. Online engagement (completing the sorting exercise) allowed phase one participants to become familiar with material in the lead up to the in-person workshop. Rating took place during the in-person workshop.

Although this research was designed to find the most relevant and feasible individual policy options, the clusters organize the options into understandable policy areas. Each cluster will be described and the points which appeared in the go zone will be discussed.

4.5.2 Legislative & Regulatory Cluster

The legislative and regulatory cluster had a high bridging value, indicating that these points were sorted differently by different participants and bridged across the data. On average, participants rated this cluster as more relevant than feasible. Three points from this cluster were seen as highly relevant and feasible: better understanding of how competitive bidding can

disadvantage local innovators (38); strategies which address privacy issues of health information (64); and that procurement processes do not create barriers for small innovation companies (65).

Participants from the interpretation stage of this research suggested that privacy concerns are in transition, and that models were being developed to share protected health information, offering some explanation to why this point was seen as relevant and feasible.

An intergovernmental initiative signals attention to the problems created by current health procurement models. The recently announced CAN Health Network is a $20 million investment between federal and provincial economic development agencies to support innovative procurement models in health care and help to 'scale up' Canadian health technology companies, making them more competitive with bigger international companies (Innovation, Science, and Economic Development Canada, 2019).

4.5.3 Funding & Incentives

This cluster had the most statements and was the most anchored, meaning that participants very often sorted the points in this cluster together. Participants rated this cluster on average as more relevant than feasible, and there were five points that appeared in the go zone. Resources to: support technologies which decrease health care costs (14), trial technologies in health care settings (67), and create incentives for health care providers to participate in innovation (42), were seen as relevant and feasible policy options in funding and incentives. Payment reforms to health care budgets such as integrating budgets around patient outcomes (90) and funding a continuum of care as opposed to an episode of care (27), may appear in the go zone as there are six Bundled Care pilot projects in Ontario to trial this type of funding reform (Ontario Ministry of Health, 2018). New tax credits to support innovation (53), and more

resources to support technology development (83), were seen as neither relevant nor feasible points. Discussion during the interpretation session suggested that a clearer definition of what feasibility means in terms of resource allocation, and a timeline, could have contributed to more precise findings.

4.5.4 Processes & Pathways

This was a small cluster with a high bridging value, indicating that these points were sorted differently by participants and bridged across the data. Three of the eight points in this cluster were in the Go Zone. These three points reflect clear communication about: timelines for deciding about whether to adopt a new technology or not (62), and willingness to pay (72). Support for collaborations between innovators and health care operators (63) was also rated as relevant and feasible. These points about better communication and support for collaboration are rather passive and do not imply a great deal of new resources, which could contribute to their perception as being easy to act on. Accessible, affordable technologies (2) was seen as relevant but not feasible, which may indicate that some participants view technology as costly by nature. These stakeholders perceive there is more work that could be done to make technology accessible in Canada.

4.5.5 System Capacity

Cluster four was another small, bridging cluster indicating these statements served to connect other aspects of the map. Three of the eight statements were rated higher than average in terms of relevance and feasibility: to define real-world trials which lead to adoption (13); to have resources which support patient recruitment for co-design (35); and to better enable the home care sector to do their own funding, testing and implementing of technology (50). These points

refer to more resources to better build health system capacity, so it is surprising they were sorted as separate from the funding and incentives cluster.

Participants may feel that resources to support co-production of technology are relevant, and feasible as stakeholder engagement is becoming a normal part of the granting process (Oliver, Kothari & Mays, 2019). Oliver, Kothari & Mays (2019), point out the resource-intensive nature of the co-production of research has not fully been acknowledged despite widespread interest in co-producing research.

More support for the home care sector to fund, test and implement technologies aligns with calls from Home Care Ontario to empower care providers in planning, implementation and evaluation of eHealth technologies (2018). In New Brunswick, the federal and provincial government has invested $75 million to support the Healthy Seniors Pilot Project; which includes a community information technology strategy (Public Health Agency of Canada, 2019; Province of New Brunswick, 2017). At the federal level, the Minister of Health has been mandated to encourage the adoption of digital health technology; and to develop performance indicators to improve accessibility to home and community care (Trudeau, 2017). The federal and provincial interest in having technologically enabled home care sector is clear, which could contribute to why participants felt this was a feasible and relevant policy option.

Participants rating real world trials which lead to adoption as relevant and feasible may be in recognition of the trend towards access to evidence development as a tool to aid health technology decisions (Chafe, 2010; Carbonneil, 2009; Guerra-Júnior et al, 2017).

4.5.6. Evaluation

The evaluation cluster contains fifteen statements which are fairly anchored on the map, meaning they were sorted fairly similarly by participants. On average, participants rated the points in this cluster as slightly more feasible than relevant (4.18/5 compared with 4.06/5). Five of the statements fell into the Go Zone indicating participants perceived them to be relevant and feasible. Participants felt that innovator understanding of what data they need to participate in health technology assessment (66), and assessment processes more generally (30), were considered relevant and feasible. Stakeholders' felt that technology assessment incorporating many different evidence types was also relevant and feasible (88) and they felt user experience and user acceptance should be among those metrics (15).

These findings may indicate that our participants perceive that innovator communities and assessment communities could work more closely to better understand each other's requirements, which is a relatively low-cost endeavor.

4.5.7. Patient & End-user Engagement

The thirteen statements in the patient and end-user engagement cluster had a relatively low bridging value, indicating they were often sorted together by participants. Four statements were rated by participants as relevant and feasible: having patients define problems for developers (81), building awareness of unmet health system priorities (20), encouraging health technology innovators to think ahead to implementation (61), and increasing awareness of health technology implementation beyond acute care (40). These statements suggest patient engagement may not be enough when the health technology is embedded in a complex health care system with various actors beyond patients and caregivers.

These findings align with the move towards responsible innovation in health, which is defined by Silva, Lehoux, Miller & Denis (2018, p.5) as:

> "a collaborative endeavor wherein stakeholders are committed to clarify and meet a set of ethical, social and environmental principles, values and requirements when they design, finance, produce, distribute, use and discard sociotechnical solutions to address the needs and challenges of health systems in a sustainable way".

In this conception, any health technology operates in an environment among many individuals (investors, regulators, developers, users, policymakers and providers) and other technologies (Silva et al, 2018). Silos between health and innovation policy could be bridged; health care settings could be more integrated; innovators would be aware of health system problems as well as how their technology would fit in this environment; and technologies could consider health equity implications as well as minimize environmental impact (Silva et al.,2018)

4.5.8 Communication Channels

The communication channels cluster contained 20 statements that were sorted somewhat similarly by participants. On average, participants saw this cluster as less relevant than feasible, but it still contained five statements in the go zone. These statements centered around developing innovation ecosystems and sharing resources between different ecosystem partners (68). Transdisciplinary working within ecosystems (78) and creation of other strategies to promote communication and information sharing (19) were also seen as relevant and feasible actions by this stakeholder group. Channels to connect innovators with regulators and reimbursement representatives (26) and materials that would support innovators who are pursuing traditional procurement methods (28) were also seen as relevant and feasible by participants.

4.5.9. Pattern Matching

The pattern-matching graph illustrates how participants' viewed the feasibility of different clusters of policy options. Patient and end-user involvement was viewed as the most relevant and the most feasible place to start any policy intervention. This aligns with previous work on engaging older adults in regional innovation ecosystems (McNeil, 2018). Ensuring technologies respond to health system needs; allowing patients to define problems, conceptualize solutions, co-developing meaningful metrics to demonstrate value, and have patients attend policy meetings were some of the ways our stakeholders felt engagement could be undertaken. Our phase one participants pointed out that family caregivers' contributions to older adults' health, and special policies supporting family caregivers' technology use may be missing from these policy statements. Adler & Mehta have pointed out that caregivers' and patients' needs for technology differ, for example, caregivers might prioritize safety, while older adults prioritize autonomy (2010). This can lead to different ways of engaging with technology, which may require separate engagement from patients. Resources are required to support relationship building needed for meaningful participation of patients and caregivers in technology development, assessment and implementation initiatives.

Policy scholars may provide some insight as to why the legislative and regulatory category was ranked second highest in relevance but last in terms of feasibility. Large social programs such as Medicare create "lock in effects" which recreate institutional logics in a path dependent way which is only responsive to an external shock (Pierson, 2000; Béland, 2016). Shared jurisdiction between federal and provincial governments in health care is compounded by silos between health policy and innovation policy efforts at both the federal and provincial levels (Lehoux, Miller, Daudelin, & Denis, 2018). Stakeholders in this concept mapping exercise may

take these arrangements and silos as static. Programs such as the CAN Health Network can organize federal-provincial stakeholders to make procurement more innovative and accessible to Canadian health technology companies.

Evaluation was seen as an area that was as relevant as it is feasible; much of the feasible, relevant points addressed increasing knowledge among innovators about how health technology assessment works, and how to create data which will allow for a health technology assessment to be completed. In the interpretation session, participants noted that it is important to consider all health and wellness technologies and the role that both regulated and non-regulated health technologies can play in helping older adults live independently in their homes. They felt that metrics which demonstrate cost savings across different departments (emergency, surgery, mental health) would make it easier for policy makers to decide to implement them.

4.6 Strengths and Limitations

4.6.1. Limitations

Although this work recruited an appropriate number of stakeholders according to concept mapping recommendations (Kane & Trochim, 2007), only twelve of 44 people from the interview stage were recruited to participate in online concept mapping. This led to the underrepresentation of innovators (4/22) and researchers (2/22) as compared with industry (8/22) and policy-maker (8/22) stakeholders. These categorizations may not reflect the dynamic roles of participants who may conduct research in a policy role, or those who are academic-innovators.

Despite the four-pronged approach to phase two recruitment (Dillman, 2000), e-mail bounce-backs during the recruitment period (June-August) indicated that some participants were on holiday. Software problems were an issue for other participants. One participant reported that

they could not participate, as the Concept Systems ® software does not currently function on cell phones or tablets. Another participant reported that the font size of the statements in the software was challenging to read. Another participant found it time consuming to have to rate each of the 95 policy options individually (in two separate pages) on relevance and feasibility, and suggested having both rankings available simultaneously in the same screen.

Older adults and caregivers are notably absent from this concept mapping process. Other research has used card-sorting with success as an alternative to computer-based concept mapping with older adults (McNeil, 2018; Wilberforce et al, 2018). Behrens et al. (2019) successfully used computer-based concept-mapping with a small group of community-dwelling older adults and caregivers (n=3). Additional resources would be required to adequately support the recruitment and whole participation of older adults and caregivers in computer-based concept-mapping of a policy project. Older adults and caregivers were consulted on the results of this concept mapping exercise, and this is reported in a subsequent chapter.

Ninety-five statements in this concept mapping exercise were near the recommended maximum of 100 (Kane & Trochim). The time commitment of the entire exercise was 45 minutes. While the statements reflect the diversity of policy approaches that can be taken to enhance the innovation and adoption of health technologies for older adults, it may have been burdensome for some participants. This may explain the three participants who created an account in the software, but did not complete the sorting or rating.

4.6.2. Strengths

Ideally, the interpretation and utilization stages of concept mapping would be completed at the end of data collection. The mix of in-person and online participation was a strength of this

research and the Concept Systems ® software allowed for almost real-time analysis of rating data, which phase one participants completed during the workshop. Concept mapping is 'inherently a systems methodology', which allowed for the collection and organization of stakeholder perspectives on an evidence-based list of policy options. The software houses this project and can be repeated on up to 100 participants. Future work could include the use of Concept Systems ® software as a decision-support for policymakers if a policy intervention to support health technology innovation and adoption became a priority.

4.7 Conclusion

Twenty-two stakeholders completed a concept mapping exercise to sort and rate evidence-based policy options and to show which of 95 statements rated highest in terms of relevance and feasibility. This works frames any discussion about where to start in terms of a policy intervention in health innovation technology: better engagement of patients, caregivers and end-users of technology. This work has also outlined areas where change may be more difficult or require more collaboration from diverse stakeholders, such as making legislative or regulatory changes.

CHAPTER FIVE: Discussing Health Technology Policy Questions with Older Adults and Caregivers

5.1 Introduction

Collaborative research is an umbrella term for a variety of research practices including co-production, co-design, co-creation, stakeholder and public engagement, participation/involvement and integrated knowledge translation (Fransman, 2018). Collaborative research has moved into the mainstream as government funding agencies mandate engagement and or integrated knowledge translation in grant proposals (Oliver, Kothari, Mays, 2019). As an extension of the goals of Chapter 6, (to collect stakeholder perspectives about the relevant and feasible policy options to support health technology innovation and adoption), this research seeks the perspectives of older adults and caregivers on key policy issues relevant to health technology innovation and adoption for older adults.

5.2 Methods

Older adults were engaged using focus group methodology to gather their perspectives about key issues in health technology and innovation policy (Patton, 2002). Thematic analysis (Braun & Clarke, 2006) was used to recode Chapters 4 and 5 to discern key themes. Some of the key themes included: timing of engagement of end-users of technology; role of end-users in evaluation of technologies; value-based as opposed to cost-focused principles in acquiring new technology; deploying technology in different settings; who should pay for health technologies; data ownership in health technologies; how could ineffective technologies be de-funded; ensuring relevant technology gets developed.

Next, the key themes were re-worded to create discussion questions. This coding process generated thirteen discussion questions. The case example (used in the interpretation and utilization stages of Chapter 6- see Appendix #) was chosen to frame the discussion with older adults and caregivers, as a way to make health technology policy and regulatory issues less abstract. The case example discusses a home monitoring technology that creates data about older adults by tracking their temporal and spatial movements which can be used for a variety of purposes. A committee member and another researcher reviewed the questions.

Focus groups are seen as foundational research method in participatory research, acting as a bridging strategy between scientific research and local knowledge (Cornwall & Jewkes, 1995). Focus groups are an important way to gather perspectives on a topic within a social context (Patton, 2002). Focus groups are characteristic of the experience-based co-design literature, which is a set of procedures used to engage patients in health service improvements (The Point of Care Foundation, 2019).

The Seniors Helping As Research Partners (SHARP) group is composed of sixty older adults and caregivers who live in Kitchener, Waterloo and Guelph. The Geriatric Health Systems (GHS) Research Group partners with SHARP on health related research projects, community events, and to share information related to the health care system. In line with McNeil et al. (2016), this project was guided by the principle that the type of engagement should be defined by the older adults, and revisited throughout the project.

I worked with a SHARP Network member who had expertise as a legislator, in business, in health care, and in community supports to design the materials and structure of the focus group session. I met Mr. C at a SHARP event at the assisted living facility where he lives, where he took interest in my technology policy work.

I reached out to Mr. C by email to ask if he would meet me to comment on the discussion questions and the structure of the event. I met Mr. C with the research coordinator for the SHARP group in his home. Mr. C has trouble seeing so the case example and the questions were printed in a large font for the meeting.

Mr. C approved of the case example and said there was a similar technology being considered by his facility, which he felt would help participants visualize the case example. He suggested I read the case example out loud in case participants were slow to read or had trouble seeing. He felt that slides, although not necessary, might be conducive to keeping participants on topic, or helping to redirect conversation towards the discussion questions I wanted to explore during the session. He felt that a focus group style session with ten or fewer older adults would be familiar and appropriate for SHARP members to participate in this research.

Mr. C's comments helped to eliminate some of the discussion questions, and to re-order the questions with the aim to generate discussion early in the session and 'get people talking'. Some questions were removed after meeting with Mr. C, as he felt they were too complex. The removed questions covered what role older adults and caregivers could play in identifying processes or technologies to disinvest in; should university offices help to link academic innovators with older adults and caregivers; and how could older adults and caregivers help health care systems identify valuable technologies.

Seven discussion questions were prioritized for the 60-minute focus group (See Appendix M). Mr. C suggested the term 'solution' to be used with 'technology' to be clear to participants in the recruitment email. He recommended avoiding the term 'policy' in the recruitment email to the SHARP group, as he felt it might be misleading to the group and suggest that the session was to solicit political views. Going back to the case example, we used the language

'technology/solution to help older adults live independently in their homes' in the recruitment email (See Appendix J).

Fourteen older adults and caregivers were invited to the session. The session was audio-recorded and transcribed verbatim. Two independent researchers used NVivo 12 (2019) to code the transcript using an emergent coding strategy (Patton, 2002). The two researchers met to discuss codes and group them into themes.

5.3 Results

Four older adults participated in the focus group session. Two of the older people lived in the assisted living facility where the session was held, and two lived in the community. Two of the four older people were caregivers for a parent or spouse. Two coders identified five themes, which emerged throughout the focus group: integration, reporting relationships, varied abilities, government as a hub, and cost vs. benefit.

5.3.1 Integration: "*For us to just buy a piece of equipment and put it in the house, we need... We need help to attach it to the right people.*"

The older adults felt that the benefit of the case example technology would be if it were integrated with the wider health care system, and could transfer the information it collects to health care providers in different settings. One participant noted:

"*They should be very pleased to be able to get that kind of information back to the team*" as a way to help a care team schedule and allocate care, for patients who have rapidly changing health states which require different amounts of support. Another participant noted this could be helpful to interface between family doctors and acute care, and noted different software would need to be able to communicate with each other.

Participants also felt that certain partnerships which stack the expertise of multiple

different fields could increase the integration between a technology and the wider health care

system. An older adult commented:

> "*just the understanding that I, as an engineer have this piece of information, and that's*
>
> *my specialty. Well, there's so much more to that. I need to have all these people bring*
>
> *their specialty and their expertise and together we can create something*".

Participants felt that current levels of health system integration could be supplemented by a

home-monitoring system which was designed by multiple types of expertise and was

interoperable across health care settings.

5.3.2 Reporting relationships: "I'm not totally enthusiastic about the long-distance response systems"

Focus group participants contrasted the home monitoring system of the case example

with the call system which was in use at the facility where two of the participants lived. The call

system was a button which was worn on the resident and pressed if they needed help, which

would alert a staff member who could follow up in-person. One older person stressed the

importance of this in-person follow up:

> "*we're losing this - in-home, simple, cozy - which I like because it's very important*
>
> *when someone has a problem that someone is with them. It doesn't matter to me*
>
> *whether that person has medical [experience] … it's a matter of comfort, knowing that*
>
> *someone can come and stay with you*".

Alternatively, another participant felt that a remote system could be helpful for people with

diabetes, or high blood-pressure, in that it could report worrisome changes in real-time to health

care providers. The participants valued the preventive component of the case example technology, but recognized that:

"health plans don't pay for prevention". The older adults were skeptical about who would receive the information generated by the case example technology and what they would do with it: *"maybe the family doctor will get it or their office staff will get it. Will they respond? Nobody knows"*.

Ultimately, they felt that a monitoring system, even if it reported remotely, would be adequate if it enabled the person to live with dignity in their own homes as opposed to moving to an institutional setting.

Older adults contrasted the differences between monitoring for acute conditions and preventive monitoring, and who should be responsible with acting on data generated by home monitoring systems in this theme.

5.3.3. Varied Abilities: "we could go out and find you ten people at ten different levels of knowledge in terms of using the equipment"

The participants acknowledged some assumptions about older people's technology use are rooted in truth, and outlined vast differences in older adults' interest in and capacity for technology use. They felt with time, education and awareness, ageist attitudes about older adults' technology use would dissipate.

The participants felt there were many different levels of ability and interest in technology among older adults, which can lead to stereotypes. The group covered a variety of reasons why there might be negative assumptions about older adults' technology use. First, they admitted that:

"what we're saying is that some of those negative assumptions are well-founded".

This participant was a caregiver and said that her parents' capacity for technology use is very limited at their current stage, even though they used computers earlier on in their lives. The caregivers in the group said that older adults' reluctance to accept technology presented to them by their caregiver as encroaching on their independence:

"I don't need a babysitter, I don't need that thing that you put around my neck".

Other participants agreed that there are some cases where technology should be "hands-off", or very passive and in the background. The participants described other situations where an older adult was paranoid about the use of technology, or had a fear of being "connected" because of the risk of their information being hacked, but how that person still used a computer for their own record-keeping.

The older adults suggested education and awareness of the diversity of older adults as the primary strategy to overcome ageist attitudes about older adults' technology use:

"*it's like any other group…I think if they've [got to] develop to the level of what the person needs"*.

One participant outlined her own technology use, as it differs from younger people:

"*and I think I do pretty well on a computer and on my tablet but I don't carry them around with me. So, I don't have that constant input that younger people have"*.

Participants went on to comment that for people with ageist attitudes currently, their attitudes will change quickly as technology savvy baby boomers age, and technology use becomes mainstream:

"it's going to take care of itself, within a decade easily...I'm saying that you know, over

time this will change quite quickly and dramatically".

5.3.4 Government as a hub: "they could be the focal point…. It would be part of the responsibility"

This group felt that governments should be at the center of any health-oriented

technology solution. They felt government actors could assist those who need support to access

technology, share information about consumer technologies, which are working well, and hold

access as part-owners of health information.

Some of the participants felt that governments should be co-payers with older adults of a

home monitoring system such as the case example. They saw a role for health insurance as well

but were less certain about how something preventive in nature could be insured. The

participants felt that the ownership of the data generated by a technology should be offered as a

feature they could pay extra for or choose to opt out of.

Participants agreed that governments play a central role in identifying disadvantaged

groups of people:

"We have low income families, we have new immigrants - a number of layers of obstacles that

people might not know about it. So, how can we level the playing field, even before the

payment".

The focus group participants felt that by identifying disadvantaged groups, governments would

have knowledge of and ability to help groups of people who may have difficulties accessing

useful technology.

The group also discussed the role for governments in disseminating information about consumer technologies which are working well in the community. One of the caregivers described a technology she found online to organize and distribute medication to her mother, which was working well. She went on to mention three different types of health care providers who had been in her mother's home inquiring about the technology – they had commented that they did not know it existed. Another participant commented this was shameful that information was not better shared inside health regions about things which are working well for patients.

Focus group participants felt that governments should be a hub of information about technologies and a source of funding to level the playing field for disadvantaged groups, including enabling their access to technologies.

5.3.5 Cost vs. Benefit: "that's a hard formula, right?"

The participants spoke about the benefits of a monitoring technology such as the case example, as well as the costs, and the affordability of technologies. They spoke about the cost of the system to be implemented in the facility, and they anticipated that the cost would be prohibitive for some residents who might need it:

> *"it's going to be $80 for installation, 50 bucks a month for monitoring. So, there's going to be… a big decision on part of individuals. Do they want to get it or not, and I suspect that some of them will skip it because of the cost, when they could use it".*

One participant added that for the amount of money that the system was going to cost individuals they could afford to hire more staff, which would be preferable to them than a remote monitoring technology. The participants noted the system they were implementing would

implicate local emergency services to respond to an event such as a fall; they said the emergency services were already over-extended and importing services from other health regions to keep up with demand.

They also pointed out that any new technology has a cost to install and a cost for upkeep; they also noted that the updates continue. They wondered if accessing updates for the technology would include ongoing costs. Participants also noted how costs can be challenging to measure. A participant noted the challenges associated with finding the right formula to measure all the ways a technology such as the case example could save the health care system money:

> *"if you can do that benefit analysis where, if you're monitoring people that you're avoiding those emergency calls, and in an expensive long-term care home where the government has to pay anyways… but then that's a hard formula, right? Have to figure out what the benefit is, the value is down the road, how much it might reduce the number of beds needed"*

The cost implications of the case example were especially relevant for the group, since they were facing a similar decision about a technology in the facility where two of the participants lived. They outlined the installation costs as well as the ongoing costs of technology implementation, and the challenges associated with measuring the benefits to the health care system as well as the costs. They also noted the strain that monitoring systems can put on local EMS services.

5.4 Discussion

A small focus group interview was conducted to discuss key issues in health technology innovation and adoption with older adults and caregivers. Aligned with efforts to engage older

adults and caregivers (McNeil et al., 2016) and principles of partnership readiness for community-based research (Andrews et al., 2012), I worked with an older adult to design the recruitment materials, questions and the format of the session.

5.4.1. Recruitment

Working with an older adult familiar with the SHARP group and some of the policy issues relevant to health technology innovation and adoption helped me to design appropriate recruitment materials. Focus groups are familiar to the SHARP group and are seen as desirable for that reason. More detail in recruitment materials may be required if a new or unfamiliar methodology or form of engagement is to be used with a community group. Given that this focus group was conducted within two weeks of a federal election, I was advised not to have the word 'policy' play too prominently in the marketing for the session. This may speak to perceptions about policy and politics which are important to distinguish in advance of a community research endeavor.

Questions about disinvestment, value-based procurement and the role of technology transfer offices were removed from the question list as they were deemed too complex. These topics may require more background information in order for participants to engage meaningfully with them. There have been efforts to involve citizens in specific disinvestment deliberations using illustrative case studies, which could inform future work on older adult and caregiver perspectives about disinvestment decisions (Watt et al, 2012).

Nevertheless, one of the key themes of the session was the tension between costs and benefits of a home monitoring technology. The discussion covered the value of a home monitoring technology which could save the health care system money in the long-term or by preventing undesirable outcomes.

Older adults pointed out the contrast between a piece of equipment in a home and one which is connected to the right people inside the health care system. They perceived the latter as more valuable, and felt that health care providers' decisions about care allocations could be simplified with continuous, real-time information about patients with rapidly-changing health care states such as diabetes or hypertension. They envisioned an interoperable technology as a way to enable communication between different health care settings. This finding aligns with the mandate of Canada Health InfoWay to improve access for Canadians to digital health and 'interoperable health solutions' which connect patients to their health information across care providers (Canada Health InfoWay, 2019).

Participants idealized that a technology could surmount issues of health system integration but brought up a tension between the information created by a technology and the responsibility that information creates for action. Participants were skeptical of what family doctors would do with information generated by the case example technology. They also felt that in emergency situations, such as a fall, an in-person response is preferable than a remote response via the telephone. They thought that ideally, a home monitoring technology would be able to have different reactions for an acute emergency as opposed to a long-term change in behavior indicative of a change in health status.

Older adults identified issues of paranoia, declining health status, and desire for independence as mediators in older adults' interest and capacity for use of technology. Care recipients can be reluctant to accept technologies proposed by caregivers if they are seen as encroaching on their independence, aligning with the findings of Mattison et al. about the stigma associated with needing an assistive technology (2019). They felt that technology should be designed to address all the different needs and levels of capability they described.

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The focus group participants felt governments should be central in coordinating access to health technologies. They saw a role for government co-payment of health technologies, aligning with the finding that willingness to pay for technologies increases when governments are co-payers (Schultz et al. 2015). Older adults and caregivers thought that governments were a natural intermediary between disadvantaged groups and technology access. Mattison et al, describe efforts to improve coordination between health and social sectors of service provision as a way to enhance access to assistive technologies in Canada (2019).

The participants in this focus group were attuned to the difficulties in demonstrating value for a home monitoring system, which is aligned with CADTH's inconclusive findings about the safety, efficacy and availability of home monitoring technologies in Canada (2019). Older adults and caregivers outlined a societal benefit which could be accrued if a home monitoring technology decreased the need for long-term care beds, which would benefit government. This broad set of societal benefits has been outlined as specifically challenging to measure (Menon, 2009).

Older adults also allude to the tension between a technology they purchase individually in an assisted-living facility which decreases the need for staff, but increases the demands on local services. Questions of ethics and equity may arise, if private care homes download care responsibilities to opt-in technologies which implicate responses from local health care systems.

5.5 Strengths and Limitations

I worked with an older adult to design a focus group to discuss issues related to technology adoption for older adults. This work sits in a niche among work on patient engagement in health care (Andrews et al, 2012); McNeil et al, 2016), citizen engagement in

health policy (Abelson et al., 2013; Li et al., 2015; Menon & Stafinski, 2008) and end-user involvement in technology development (Viswanathan et al., 2017; MacGillivray et al., 2019). There are not best practices for engaging older adults and caregivers on policy research about health technology innovation and adoption.

The strength of this work is having older adult and caregiver perspectives on policy issues presented along with those of industry, innovators, policymakers and researchers. Ideally, older adults and caregivers work with researchers to define the scope, research questions, methodology, and knowledge translation at the outset of a project (McNeil et.al, 2016). This research engaged older people and caregivers near the conclusion of the research project. This might be viewed as tokenistic, but it also gave prominence to the perspectives of older adults and caregivers.

More resources would be required to recruit, prepare, and engage older adults and caregivers at the project's outset than were available to this project. Game simulation is a resource-intense method to structure a deliberative session, which is seen as non-threatening, and can prompt deeper thinking about health policy issues (Li et al., 2015).

The case example described a technology to support living independently in the home, as did the language used in the recruitment materials. Although this terminology was recommended by an older adult stakeholder, it may have limited the discussion to similar types of technologies which support older adults in their homes, as opposed to the full range of health technologies (devices, medications, processes, vaccines and systems).

5.6 Conclusion

An older adult helped to design a focus group session to discuss key policy issues in health technology innovation and adoption for older adults. The discussion was anchored by a case example technology to which older adults and caregivers were able to relate well. Older adults and caregivers desired technologies which are integrated with health system actors, and see technology as a way to bridge silos between care settings for example, primary care and acute care. Participants brought up questions about who has the responsibility to respond to information generated by a home monitoring system, and how those responses should be conducted. They emphasized the heterogeneity of older adults and range of interest and capacity for technology use. Governments were seen as a hub to coordinate access to, and information about, technologies which could work well for older people and caregivers. Older adults and caregivers were attuned to the challenges of accounting for all the costs and benefits a home monitoring system could offer.

CHAPTER SIX: SUMMARY AND GENERAL DISCUSSION

6.1 Thesis Summary

This study sought to document and understand facilitators and barriers to health technology adoption in Canada across all stages of innovation; understand how these facilitators and barriers might impact technologies for older adults and caregivers, (such as those being developed inside the AGE-WELL research network); and to engage diverse stakeholders to create an evidence-informed policy agenda for health technology innovation for older adults. To achieve these aims, a scoping review; 46 qualitative interviews; a group Concept Mapping exercise; and a focus group interview were conducted.

The scoping review found that supporting health technology innovation requires attention across all phases of innovation: development, assessment and implementation. Silos between health and innovation policies impact how scarce resources are allocated, what partnerships get formed (and those that do not), what technologies get developed (Lehoux et al., 2014), how they are evaluated and which populations they target (Lehoux et al, 2000). Innovation ecosystems were proposed as a mechanism to engage stakeholders across silos in health and innovation policy (Etzkowitz & Leyesdorff, 2000). This review highlighted the value of evaluation across all stages of a health technology's life cycle to increase health system sustainability (Scotland & Bryan, 2016; Bryan, Mitton & Donaldson, 2014).

To provide illustrative examples of findings from the scoping review, a series of qualitative interviews were conducted with policymakers, innovators, industry representatives and researchers. Elements from the graphic depiction in the scoping review (development, assessment, implementation, partnerships, resources, Canadian policy context) guided data

analysis using Ritchie and Spencer's Framework analysis method (2003) to identify multiple

perspectives on facilitators and barriers across each stakeholder type.

In line with Kingdon's work (1984), this study highlighted a complex interplay between

ideas, institutions and interests in health technology policy in Canada. Our findings highlighted

challenges associated with innovating in a fragmented health care system. In such a system,

health care actors lack capacity to consider, adopt and integrate technologies, even those with the

potential to improve health outcomes for older adults. Again, partnerships were identified as a

way to integrate promising innovations into Canadian health care systems. Mechanisms are

required to support meaningful, sustained partnerships between patients and end-users,

caregivers, health care providers, policy-makers, decision-makers, and industry representatives

to ensure technologies meet health system needs. These are especially important when

considering that technologies, unlike medications, implicate a whole host of actors: health

technologies for older adults may be used, administered, prescribed, regulated, evaluated,

purchased, invested in, and developed, all by different interests (Lehoux et al, 2012).

Findings from the first two stages of this study reinforced the need for a 'whole systems'

approach to health technology innovation (Greenhalgh et al., 2004). Stakeholder perspectives

were gathered on which of the 95 policy options identified in earlier stages of the research were

likely to be the most relevant and feasible policy options to enable the innovation and adoption

of health technologies for older adults. Participants sorted options into clusters and rated policy

options as part of a six stage Concept Mapping process. As part of the process, a workshop to

discuss how to implement the most relevant and most feasible options was conducted.

Stakeholders perceived policy options related to end-user and patient engagement to be both the most relevant and feasible options to support technology innovation for older adults. Legislative and regulatory policy options were deemed very relevant but less feasible to implement, reflecting the complex institutional arrangements and 'lock-in' effects of large social programs which only change incrementally (Pierson, 2000; Béland, 2016). These institutional arrangements include multiple decision nodes in health care, contributing to a complex disordered technology adoption process, which does not respond well to efforts to control it (Scott, 2015). The single highest rated policy option was: *"encourage innovators to think ahead to implementation, where their technology will fit and who will pay"*. This policy action statement can be considered advice to new innovators to consider the whole system which affects the adoption of the technology.

Orienting health technologies for older adults towards a consumer purchase 'pathway' may appear to be a solution to bypass the complexities of the Canadian health care system (AGE-WELL, 2019). Alternatively, there may be problems of equity, access and waste if health technologies are oriented solely for consumer purchase (Lehoux et al, 2012, Lehoux 2014b). A move towards responsible innovation in health would suggest a move away from technologies for consumer purchase, and that a variety of factors be considered in the development of any new health technology: inclusivity; responsiveness to health system needs; ethical, social and legal issues; environmental value; and economic value or frugality (Silva et al., 2018).

A focus group interview with older adults and caregivers was conducted to discuss key issues in health technology innovation and adoption. This interview generated findings in five themes: integration, reporting relationships, varied abilities, government as a hub, and cost vs. benefit.

Older adults and caregivers contrasted technologies operating independently from the health care system with those which are integrated, and preferred the latter. This group alluded to the challenges of consumer technologies which operate independently from the health care system, but implicate a system response, and which can strain emergency services.

Although the older adults outlined challenges with demonstrating benefits of a technology which operates in a home and prevents (as opposed to treats) poor outcomes, they felt that the data generated would be very valuable to aid in care decisions. They felt that the data would be worth it to care providers to merit the investment by governments. Focus group participants felt that governments were a focal point in the relationship between older adults, caregivers, the health care system and technologies. They felt governments should play a role leveling the playing field for disadvantaged groups, coordinating access to health technologies, through the creation of cost-sharing programs, and spreading information and awareness about technologies which work well.

6.2 Implications

6.2.1 Federal Policy Implications

Pan Canadian Health Organizations
Health care and innovation were relatively absent from party platforms in the recent federal election. Under the previous federal government, three ministers were mandated to look individually at innovation, home care services, and access to digital health. It is not clear if new mandates for these ministers will prioritize these topics.

Information from this study may be relevant to policy actions prioritized in light of the findings of the External Review of Federally Funded Pan-Canadian Health Organizations. This

report creates four scenarios for change in how the federal government funds agencies with mandates relevant to health technology innovation such as the Canadian Agency for Drugs and Technology in Health (CADTH), the Canadian Foundation for Healthcare Improvement (CFHI), Canada Health Infoway and the Canadian Institute for Health Information (CIHI). Scenario two identifies innovation as a catalyst for change in health care financing and delivery, which is aligned with calls in the scoping review for bundled payments, value-based procurement, and pay for performance schemes characteristic of the Triple Aim (Verma & Bhatia, 2016; Forest & Martin, 2018). Scenario three relies on fostering engagement across clinicians, researchers, provincial and territorial stakeholders, policy makers, and the public to create transformative health care change in Canada (Forest & Martin, 2018). The need for diverse partnerships and co-designed strategies to health care service and delivery echo findings from this research. It may be of interest that a group of relevant stakeholders rated policy options promoting engagement of patients and end-users as both the most relevant and most feasible to implement of seven distinct policy clusters.

Forest and Martin view the federal government as possessing the necessary legal and financial tools to play a central role in catalyzing innovation in health care (Forest & Martin, 2018). Findings from this research support federal policy intervention to enable health technology innovation and adoption for older adults, but encourage the alignment of health innovation efforts with innovation policy efforts (MacNeil et al, 2019; Lehoux et al, 2017).

This report encouraged governments to consider revising the basket of health care services that are publicly funded in Canada to include mental health and home care services (Forest & Martin, 2018). Findings from this research indicate challenges specific to innovation in the home

and community care sector, which should be considered if federal policy action in home and community care is prioritized.

AGE-WELL Network Centre of Excellence

This study is part of a project affiliated with AGE-WELL, a federally funded research network on technology and aging. Findings from this research are relevant to members of AGE-WELL including innovators, researchers, industry representatives, policymakers, older adults, caregivers, and students. The findings of this study can be instructive for new grantees of the AGE-WELL network. This work has supported the creation of websites, process maps, or consultations for innovators, to help innovators navigate policies and regulations relevant to their technologies for older adults.

There is an ongoing tension between what constitutes meaningful evidence for decision-makers, and the resources (time and money) required to produce high-quality evaluations of promising health technologies. Our findings are supportive of ongoing partnerships between those with expertise in evaluation of technologies, and technology innovators, such as CADTH's recent mandate to broaden its assessment capacities and re-evaluate technologies to ensure they are being used appropriately in a way that creates value for healthcare systems (CADTH, 2018).

6.2.2. Provincial Policy Implications

Stakeholders we interviewed mentioned investment programs such as Alberta Innovates, and technology incubators such as MaRS in Ontario, as exemplary in supporting health technology innovation in Canada. Both of these programs saw their funding frozen or withdrawn with recent government changes in these provinces (CBC, 2019). Findings from this study which were seen as highly feasible, may be of interest to governments who wish to support health technology innovation through smaller investments than tax credits.

6.2.3. International Policy Implications

Health technology assessment international (HTAi) is the global scientific and professional society for users and producers of HTA. HTAi sponsors an interest group on patient engagement in HTA, which is focused on standardizing methodologies of involvement. Findings of this research related to measuring impact of technologies for older people may be of interest to this group. This study has informed recent collaborations in the HTA community among international policymakers, reflecting on special considerations for aging-related technologies and how to best incorporate older adults' perspectives in HTA processes (Juzwishin et al., 2018).

6.2.3. Targeted Areas for Next Steps

The conceptual framework developed in Chapter Three will be used to structure policy recommendations for different institutional levels. At the interpersonal/intrapersonal level, these findings suggest that older adults and caregivers should define problems for technology developers to address. Resources are required to help recruit patients to co-design innovations, and sustain their involvement across the innovation pathway. Efforts to bring older people and caregivers into the co-design of innovation should acknowledge the varied abilities and levels of interest in using technology. Early and late adopters of technology exist among any age group (Rogers, 1995) and perhaps this continuum could be used to typify technology users in a way that acknowledges differences, but does not attribute differences among them solely to age.

At the micro-level, where regional health organizations sit, this research supports the empowering of the home care sector to fund, test and implement new technologies. This may require dedicated resources so that home care agencies do not have to allocate funds designed for care delivery to technology activities. This may also necessitate new expertise or human resources designed to support these activities, as there may be a shortage of economic evaluation

expertise in evaluating integrated care interventions which span home and community care and acute care (Knai et a., 2013).

This research supports regional collaboration of academic, industry, citizen, clinical, and government stakeholders. The innovation ecosystem model (Etzkowitz & Leyesdorff, 2000). was presented throughout the work as a mechanism to support collaboration, and noted a transdisciplinary working style is required to ensure stakeholders with different backgrounds and interests work productively with one another. Extending the model of innovation ecosystems means installing and sustaining mechanisms for resource-sharing, communication and information-sharing to build trust. In talking with older adults and caregivers, their perception of governments as a hub between health care, citizens and researchers was clear. Governments can play an important role in convening stakeholders, ensuring access to technology for underprivileged older people, and building awareness about technologies which are working well in community settings.

Many of the policy recommendations are focused at the meso or provincial level which corresponds with provincial jurisdiction over health care delivery. This research supports changes to funding models so that health care budgets are integrated across years, departments and health care settings, such as those which fund a continuum of care as opposed to an episode of care. These funding changes would have impacts on how the health care system procures new technologies and would be responsive to technologies which offer benefits in terms of prevention, or decreased health care costs. Province-specific materials should be designed for innovators to aid them in participating in traditional models of procurement (competitive bidding models).

At the meso-level, resources are required to build the evidence base for new technologies such as: real world trials, trials which have health care provider participation, assessments of decision-makers' willingness to pay for a new technology, and studies which capture user experience/user acceptance.

The federal government plays an important role in raising awareness, and many of the policy recommendations to come out of this project have to do with building awareness among innovators. The federal government is in a unique position to demand that health technology innovations respond to demonstrated health system needs, given that their innovation program supports tens of millions of dollars in innovation granting programs. This includes building awareness among innovators of: health system priorities; how their technology fits with existing systems, workflows and scopes of practice; and what types of studies they need to conduct to ensure their technology can produce clinical and cost-effectiveness data for HTA. At the macro-level, the federal government can support programs which help to build expertise in health economics, which is in high demand (Kaambwa & Frew, 2013). This expertise can help to answer questions of willingness to pay, cost as opposed to value, and how to generate meaningful evidence for health technologies for older adults. New trainees in health economics can support innovators and health care systems from development through to sustainability and disinvestment of promising technology.

6.3 Future Research Directions

Future directions for this work include sharing results through traditional academic means including journal publications, conference posters and presentations. The older adults in the focus group interview were interested to see how the focus group information would be used in

this study. One of the first steps will be to re-engage this group to discern what format the follow-up should take.

Many of the stakeholders who were engaged in the interview process expressed interest in being re-contacted with results of the study. Briefing notes will be created summarizing the results of the interview process to share with stakeholders. The findings of the Concept Mapping process are specifically relevant for policy stakeholders and briefing notes summarizing the policy options in the Go Zone will be created and shared with stakeholders.

The findings of the Concept Mapping process will be shared through a workshop with policy actors within the AGE-WELL network who have a mandate to promote policy action in health technology innovation.

6.4 Conclusions

Jurisdictional issues lead to a complex network of institutions and stakeholders in the health technology and innovation policy arena in Canada. Policymakers, innovators, industry representatives, older adults and caregivers contributed to an understanding of policy and regulatory facilitators and barriers. Multiple stakeholders were engaged to rank policy options, forming the basis for an evidence-based health technology innovation policy agenda with special attention to health technologies for older adults.

REFERENCES

Abelson, J., Bombard, Y., Gauvin, F. P., Simeonov, D., & Boesveld, S. (2013). Assessing the
impacts of citizen deliberations on the health technology process. *International Journal
of Technology Assessment in Health Care, 29*(3), 282-289. doi:
10.1017/S0266462313000299

Abelson, J., Wagner, F., DeJean, D., Boesveld, S., Gauvin, F. P., Bean, S., … & Lavis, J. (2016).
Public and patient involvement in health technology assessment: A framework for action.
International Journal of Technology Assessment in Health Care, 32(4), 256-64. doi:
10.1017/S0266462316000362

Agency for Healthcare Research and Quality. (n.d.). *About the AHRQ health care innovations
exchange*. Retrieved from: https://innovations.ahrq.gov/about-us

AGEWELL (2019) AGE-WELL teams up with Best Buy Canada. Retrieved from:
https://agewell-nce.ca/archives/8572

AGEWELL (2018) *Solutions for Healthy Aging: Annual Report 2018-2019*. Retrieved from:
https://agewell-nce.ca/wp-content/uploads/2017/10/AGEWELL_ENG_AR2019_web-
pages.pdf

Agrawal, A. (2006). Engaging the inventor: Exploring licensing strategies for university
inventions and the role of latent knowledge. *Strategic Management Journal*, 27(1), 63-79.
doi: 10.1002/smj.508

Akpinar, I., Jacobs, P., & Husereau, D. (2015). Medical device prices in economic evaluations. *International Journal of Technology Assessment in Health Care*, 31(1-2), 86-89. doi: 10.1017/S026646231500015X

Andrews, J. O., Newman, S. D., Meadows, O., Cox, M. J., & Bunting, S. (2010). Partnership readiness for community-based participatory research. *Health Education Research*, 27(4), 555-571. doi: 10.1093/her/cyq050

Arksey, H., & O'Malley, L. (2005). Scoping studies: towards a methodological framework. *International Journal of Social Research Methodology*, 8(1), 19-32. doi: 10.1080/1364557032000119616

Arnkil, R., Järvensivu, A., Koski, P., Piirainen, T. (2010). *Exploring the Quadruple Helix. Outlining user-oriented innovation models.* Retrieved from https://trepo.tuni.fi/bitstream/handle/10024/65758/978-951-44-8209-0.pdf?sequence=1

Arshoff, L., Henshall, C., Juzwishin, D., & Racette, R. (2012). Procurement change in Canada: An opportunity for improving system performance. *Healthcare Management Forum*, 25(2), 66-9. doi: 10.1016/j.hcmf.2012.03.002

Assasi, N., Schwartz, L., Tarride, J. -., Campbell, K., & Goeree, R. (2014). Methodological guidance documents for evaluation of ethical considerations in health technology assessment: A systematic review. *Expert Review of Pharmacoeconomics and Outcomes Research*, 14(2), 203-220. doi: 10.1586/14737167.2014.894464

Balas, E. & Boren, S. (2000). Managing Clinical Knowledge for Health Care Improvement. In J. Bemmel & A. McCray (Eds). *Yearbook of Medical Informatics 2000: Patient-Centered Systems* (pp. 65–70). Stuttgart, Germany: Schattauer Verlagsgesellschaft mbH.

Baltussen, R., & Niessen, L. (2006). Priority setting of health interventions: the need for multi-criteria decision analysis. *Cost Effectiveness and Resource Allocation*, 4(1), 1. doi: 10.1186/1478-7547-4-14

Batalden, M., Batalden, P., Margolid, P., Seid, M., Armstrong, G., Opipari-Arrigan, L., & Hartung, H. (2016). Coproduction of healthcare service. *BMJ Quality & Safety, 25*(7), 509-17. doi: 10.1136/bmjqs-2015-004315

Battista, R. (2006). Expanding the scientific basis of health technology assessment: A research agenda for the next decade. *International Journal of Technology Assessment in Health Care*, 22(3), 275-280. doi: 10.1017/s0266462306051130

Bégin, M., Eggertson, L., & Macdonald, N. (2009). A country of perpetual pilot projects. *Canadian Medical Association Journal*, 180(12), 1185. doi: 10.1503/cmaj.090808

Behrens, L., McGhan, G., Abbott, K., Fick, D., Kolanowski, A., Liu, Y., … Haitsma, K.(2019). Mapping core concepts of person-centered care in long-term services and supports. *Journal of Gerontological Nursing*, 45(2), 7-13. doi: 10.3928/00989134-20190111-02

Béland, D. (2016). Kingdon reconsidered: Ideas, interests and institutions in comparative policy analysis. *Journal of Comparative Policy Analysis*, 18(3), 228-42. doi: 10.1080/13876988.2015.1029770

Bercovitz, J., & Feldman, M. (2007). Academic entrepreneurs and technology transfer: Who participates and why? Retrieved from http://irpublicpolicy.ir/wp-content/uploads/2016/11/Perspectives_on_Innovation.pdf#page=399

Blomqvist, Å., & Busby, C. (2016). *The Naylor Report and Health Policy: Canada needs a new model.* The C.D. Howe Institute. Retrieved from https://www. cdhowe.org/sites/default/files/attachments/research papers/mixed/E-brief 240.pdf.

Bombard, Y., Abelson, J., Simeonov, D., & Gauvin, F. (2011). Eliciting ethical and social values in health technology assessment: A participatory approach. *Social Science & Medicine*, 73(1), 135-144. doi: 10.1016/j.socscimed.2011.04.017

Brehaut, J., & Juzwishin, D. (2005). *Bridging the gap: The use of research evidence in policy development*. Alberta Heritage Foundation for Medical Research. Retrieved from http://www.ihe.ca/advanced-search/bridging-the-gap-the-use-of-research-evidence-in-policy-development

Bronfenbrenner, U. (1992). *Ecological systems theory*. London, England: Jessica Kingsley

Bryan, S., Mitton, C., & Donaldson, C. (2014). Breaking the addiction to technology adoption. *Health Economics*, 23(4), 379-83. doi: 10.1002/hec.3034

Braun, V., Clarke, V. (2008) Using thematic analysis in psychology. *Qualitative Research in Psychology*. 3(2): 77-101. doi: 10.1191/1478088706qp063oa

Burke, J. G., O'Campo, P., Peak, G. L., Gielen, A. C., McDonnell, K. A., & Trochim, W. M. (2005). An introduction to concept mapping as a participatory public health research method. *Qualitative health research*, 15(10), 1392-1410. doi: 10.1177/1049732305278876

Bubela, T., & Caulfield, T. (2010). Role and reality: technology transfer at Canadian universities. *Trends in Biotechnology*, 28(9), 447-451. doi: 10.1016/j.tibtech.2010.06.002

Burls, A., Caron, L., Cleret De Langavant, G., Dondorp, W., Harstall, C., Pathak-Sen, E., &

    Hofmann, B. (2011). Tackling ethical issues in health technology assessment: A proposed

    framework. *International Journal of Technology Assessment in Health Care*, 27(3), 230-

    237. doi: 10.1017/S0266462311000250

Canadian Association for Drugs and Technology in Health. (2019). *Aging in place. Health*

    Technology Update, 24, 1-15. Retrieved from https://www.cadth.ca/health-technology-

    update-issue-24

Canadian Association for Drugs and Technology in Health. (2014). *Grey matters: A practical*

    deep-web search tool for evidence-based medicine. Retrieved from

    https://www.cadth.ca/resources/finding-evidence/grey-matters

Canadian Institute for Health Information. (2011). *Seniors and the health care system: What is*

    the impact of multiple chronic conditions? Retrieved from

    https://secure.cihi.ca/estore/productFamily.htm?locale=en&pf=PFC1575

Canada Health Infoway. (2019). *Summary corporate plan*. Retrieved from https://infoway-

    inforoute.ca/en/component/edocman/3654-summary-corporate-plan-2019-2020/view-

    document?Itemid=101

Canada Mortgage and Housing Corporation. (2015). *Housing for older Canadians: The*

    definitive guide to the over-55 market. Retrieved from

    http://publications.gc.ca/site/eng/9.696164/publication.html

Canadian Broadcasting Corporation. (2019, May 10). Ontario's funding cuts to tech could hit

    women and young people hardest, some warn. Retrieved from

https://www.cbc.ca/news/canada/toronto/ontario-job-numbers-tech-innovation-cuts-1.5131975

Canadian Home Care Association (2016) *Better Home Care in Canada: A National Action Plan*. Retrieved from http://www.cdnhomecare.ca/media.php?mid=4723

Carbonneil, C., Quentin, F., Lee-Robin, S., & European network for Health Technology Assessment (EUnetHTA). (2009). A common policy framework for evidence generation on promising health technologies. *International Journal of Technology Assessment in Health Care*, 25(2), 56-67. doi: 10.1017/S0266462309990699

Carroll, C., Booth, A., & Cooper, K. (2011). A worked example of "best fit" framework synthesis: A systematic review of views concerning the taking of some potential chemopreventative agents. *BMC Medicine*, 11(9). doi: 10.1186/1471-2288-11-29

Chafe, R., Merali, F., Laupacis, A., Levinson, W., & Martin, D. (2010). Does the public think it is reasonable to wait for more evidence before funding innovative health technologies? The case of PET scanning in Ontario. *International Journal of Technology Assessment in Health Care*, 26(2), 192-197. doi: 10.1017/S0266462310000024

Challinor, A. (2016). *Adopting our advantage: Supporting a thriving health science sector in Ontario*. Retrieved from http://www.occ.ca/portfolio/adopting- our-advantage-supporting-a-thriving-health-science-sector-in-ontario/

Chandra, A., & Skinner, J. (2012). Technology growth and expenditure growth in health care. *Journal of Economic Literature,* 50(30), 645-80. doi: 10.3386/w16953

Choi, B., Pang, T., Lin, V., Puska, P., Sherman, G., Goddard …, Clottey, C.(2005) Can scientists

    and policy makers work together? *Journal of Epidemiological Community Health*. 59.

    632-7. doi: 10.1136/jech.2004.031765

Cornwall, A. & Jewkes, R. (1995) What is participatory research? S*ocial Science & Medicine*.

    41(12): 1667-1676. doi: 10.1016-0277-9536(95)00127-S

Culyer, A. (2014). Where are the limits of cost-effectiveness analysis and health technology

    assessment? *Journal of the Medical Association of Thailand*, 97(5), 1-2. Retrieved from

    https://www.marsdd.com/wp-content/uploads/2014/07/Tony-Culyer.pdf

Devlin, N., Shah, K, & Buckingham, K. (2017). *What is the Normative Basis for Selecting the*

    Measure of 'Average' Preferences for Use in Social Choices? Office of Health

    Economics. Retrieved from https://ideas.repec.org/p/ohe/respap/001798.html

Dillman, D. (2000). *Mail and internet surveys: The tailored design method*. New York, NY:

    John Wiley & Sons Inc.

Dishman, E., Matthews, J., Dunbar-Jacob, J. (2004). Everyday health: Technology for adaptive

    aging. In R. Pew & S. Van Hemel(Eds.), *Technology for adaptive aging*. Retrieved from

    https://www.ncbi.nlm.nih.gov/books/NBK97346/pdf/Bookshelf_NBK97346.pdf

Dixon-Woods, M. (2011). Using framework-based synthesis for conducting reviews of

    qualitative studies. *BMC Medicine*, 9(39). doi: 10.1186/1741-7015-9-39.

Edmonton TEC. (2017). *Promoting Alberta health & business innovation.* Retrieved from

    http://www.tecedmonton.com/health-accelerator/

Etzkowitz, H., & Leydesdorff, L. (2000). The dynamics of innovation: From National Systems and "Mode 2" to a Triple Helix of university-industry-government relations. *Research Policy,* 29(2), 109-23. doi: 10.1016/S0048-7333(99)00055-4

Fleiss, J. (1971). Measuring nominal scale agreement among many raters. *Psychological Bulletin*, 76(5), 378-382. doi: 10.1037/h0031619

Fransman, J. (2018) Charting a course to an emerging field of 'research engagement studies': A conceptual meta-analysis. *Research for All*. 2(2):185-229. doi: 10.18546/RFA.02.0.02

Forest, P.-G., & Martin, D. (2018). *Fit for purpose: Findings and recommendations of the external review of the Pan-Canadian Health Organizations*. Retrieved from https://www.canada.ca/content/dam/hc-sc/documents/services/health-care-system/reports-publications/health-care-system/findings-recommendations-external-review-pan-canadian-health-organization/findings-recommendations-external-review-pan-canadian-health-organization.pdf

Gale, N., Health, G., Cameron, E., Rashid, S., Redwood, S.(2013) Using the framework method for the analysis of qualitative data in multi-disciplinary health research. *BMC Medical Research Methodology*. 13(117). Retrieved from: http://www.biomedcentral.com/1471-2288/13/117

Gauvin, F. (2014). *Understanding policy developments and choices through the "3-i" framework: Interests, ideas, and institutions*. Retrieved from Institut National de Santé Publique Quebec: http://www.ncchpp.ca/165/Publications.ccnpps?id_article=1077

Golden, S. & Earp, J. (2012). Social ecological approaches to individuals and their contexts: twenty years of health education & behavior health promotion interventions. *Health Education & Behavior*, 39(3), 364-372. doi: 10.1177/1090198111418634

Government of Canada (2018) *Strategic Innovation Fund.* Retrieved from: https://www.ic.gc.ca/eic/site/125.nsf/eng/home

Government of New Brunswick. (2017). *We are all in this together: an aging strategy for New Brunswick.* Retrieved from https://www2.gnb.ca/content/dam/gnb/Departments/sd-ds/pdf/Seniors/AnAgingStrategyForNB.pdf

Greenhalgh, T., Robert, G., Bate, P., Kyriakidou, O. (2004). Diffusion of Innovations in Service Organizations: Systematic Review and Recommendations. *The Millbank Quarterly*. 82(4). 581-629. doi: 10.1111/j.0887-378X.2004.00325.x

Greenhalgh, T., Jackson, C., Shaw, S., & Janamian, T. (2016). Achieving research impact through co-creation in community-based health services: Literature review and case study. *The Milbank Quarterly*, 94(2), 392-429. doi: 10.1111/1468-0009.12197

Guerra-Júnior, A. A., de Lemos, L. L. P., Godman, B., Bennie, M., Osorio-de-Castro, C. G. S., Alvares, J., ... & Gutierrez-Ibarluzea, I. (2017). Health technology performance assessment: real-world evidence for public healthcare sustainability. *International Journal of Technology Assessment in Health Care*, 33(2), 279-287. doi: 10.1017/S0266462317000423

Gregson, J., Foerster, S., Orr, R., Jones, L., Benedict, J., Clarke, B., ... & Zotz, K. (2001). System, environmental, and policy changes: using the social-ecological model as a framework for evaluating nutrition education and social marketing programs with low-

income audiences. *Journal of nutrition education*, 33, S4-S15. doi: 10.1016/S1499-4046(06)60065-1

Grignon, M., & Spencer, B. (2018). The Funding of Long-Term Care in Canada: What Do We Know, What Should We Know? *Canadian Journal on Aging*. 37(2) doi:10.1017/S0714980818000028

Hailey, D., & Juzwishin, D. (2006). Managing external risks to health technology assessment programs. *International Journal of Technology Assessment in Health Care*, 22(4), 429-435. doi: 10.1017/S0266462306051348

Health Technology Assessment Task Group. (2004). *Health technology strategy 1.0: Final report.* Retrieved from https://www.cadth.ca/media/policy_forum_section/1_health_tech_strategy_1.0_nov-2004_e.pdf

Henshall, C., Schuller, T. (2013) Health technology assessment, value-based decision-making and innovation. *International Journal of Technology Assessment in Health Care*, 12(4). doi: 10.1017/SO266463211400026

Holliday, N., Magee, P., & Walker-Clarke, A. (2015). *Proceedings of the 3rd European Conference on Design4Health.* Retrieved from http://research.shu.ac.uk/design4health/wp-content/uploads/2015/07/D4H Holliday et al.pdf

Holmes, K. (2012). *A national medical devices strategy for Canada: Results of a stakeholder driven consultation process.* Retrieved from http://www.bme.ubc.ca/2012/05/18/national-medical-devices-strategy-of-canada/

Hsieh, H., & Shannon, S. (2005). Three approaches to qualitative content analysis. *Qualitative Health Research,* 15(9), 1277-88. doi: 10.1177/1049732305276687

Husereau, D. (2015). *Medical device and diagnostic pricing and reimbursement in Canada*. Edmonton, Alberta: The Institute of Health Economics.

Husereau, D., & Cameron, C. (2011). *The use of health technology assessment to inform the value of provider fees: Current challenges and future opportunities*. Retrieved from Canadian Health Services Research Foundation. Retrieved from https://www.cfhi-fcass.ca/SearchResultsNews/11-10-18/6e0a8d6f-2b35-4d4b-96c3-b3af4050d0e4.aspx

Innovation, Science, and Economic Development Canada. (2019) *Minister Ng announced investments to scale up Canadian companies*. Retrieved from https://www.newswire.ca/news-releases/minister-ng-announces-investments-to-scale-up-canadian-companies-822957328.html

International Network of Agencies for Health Technology Assessment. (2006). *HTA glossary*. Retrieved from http://htaglossary.net/HomePage

International Trade Administration. (2016). *Top markets report: Medical devices 2016*. Retrieved from https://www.trade.gov/topmarkets/pdf/Medical Devices Executive Summary.pdf.

International Trade Administration. (2019). *Canada healthcare and medical equipment*. Retrieved from https://www.export.gov/article?id=Canada-Healthcare-andMedical-Equipment

Juzwishin, D., McNeil, H., Ahn, J., Chen, Y., Cicchetti, A., Kume, N., Brooks, L., & Stolee, P.

    (2018) Aging and Health Technology Assessment: An Idea Whose Time Has Come.

    International Journal of Technology Assessment in Health Care, 34(5), 442-446. doi:

    10.1017/S02664623180006000

Kaambwa, B., & Frew, E. (2013). Health economics in the UK: Capacity, constraints and

    comparisons to the US health economists. *International Reviews of Economics Education*

    2013, 12, 1–11. doi: 10.1016/j.iree.2013.04.004

Kane, M., Trochim, W. (2007). *Concept mapping for planning and evaluation*. California, Sage

    Publications Inc.

Keown, O., Partson, G., Patel, H., Rennie, F., Saoud, F., Kuwari, H., & Darzi, A. (2014).

    Lessons from eight countries on diffusing innovation in health care. *Health Affairs*, 33(9).

    doi: 10.1377/hlthaff.2014.0382.

Khayat, Z. (2015). Emerging health technologies can enhance Canada's prosperity. *Canadian*

    Business Journal, 15, 107. Retrieved from https://www.marsdd.com/news/emerging-

    health-technologies-can-enhance-canadas-prosperity/

Kingdon, J. (1984). *Agenda's, alternatives and public policies*. 2nd ed. New York: Longman.

Klenk, N., Hickey, G. (2011). A virtual and anonymous deliberative and analytic participation

    process for planning and evaluation: The concept mapping policy Delphi. *International*

    Journal of Forecasting. 27, 153-165. doi: 10.1016/j.ijforecast.20110.05.002

Knai, C., Nolte, E., Brunn, M., Elissen, A., Conklin, A., Pedersen, J., ... & Fullerton, B. (2013). Reported barriers to evaluation in chronic care: experiences in six European countries. *Health Policy*, 110(2-3), 220-228. doi: 10.1016/j.healthpol.2013.01.019

Landis, J., & Koch, G. (1977). The measurement of observer agreement for categorical data. *Biometrics*, 33,159-174. doi: 10.2307/2529310

Lavis, J., Oxman, A., Moynihan, R., & Paulsen, E. (2008). Evidence-informed health policy 1 - Synthesis of findings from a multi-method study of organizations that support the use of research evidence. *Implementation Science*, 3(1), 1-7. doi: 10.1186/1748-5908-3-53.

Lavis, J., Ross, S., & Hurley, J. (2002). Examining the role of health services research in public policymaking. *The Milbank Quarterly*, 80(1), 125-154. doi: 10.1111/1468-0009.00005

Lavis, J., Wilson, M., Grimshaw, J., Haynes, R., Ouimet, M., Raina, P., . . . Graham, I. (2010). Supporting the use of health technology assessments in policy making about health systems. *International Journal of Technology Assessment in Health Care,* 26(4), 405-414. doi: 10.1017/S026646231000108X

Lee, R., Marshall, D., Waddell, C., Hailey, D., & Juzwishin, D. (2003). Health technology assessment, research, and implementation within a health region in Alberta, Canada. *International Journal of Technology Assessment in Health Care*, 19(3), 513-520. doi: 10.1017/s0266462303000448

Lehoux, P., & Blume, S. (2000). Technology assessment and the sociopolitics of health technologies. *Journal of Health Politics, Policy and Law*, 25(6), 1083-1120. doi: 10.1215/03616878-25-6-1083

Lehoux, P., Daudelin, G., Hivon, M., Miller, F., & Denis, J. (2014a). How do values shape

    technology design? An exploration of what makes the pursuit of health and wealth

    legitimate in academic spin-offs. *Sociology of Health & Illness*, 36(5), 738-755.

    doi:10.1111/1467-9566.12097

Lehoux, P., Denis, J., Tailliez, S., & Hivon, M. (2005). Dissemination of health technology

    assessments: Identifying the visions guiding an evolving policy innovation in Canada.

    Journal of Health Politics, Policy and Law, 30(4), 603-641. doi: 10.1215/03616878-30-4-

    603

Lehoux, P., Gauthier, P., Williams-Jones, B., Miller, F., Fishman, J., Hivon, M., & Vachon, P.

    (2014b). Examining the ethical and social issues of health technology design through the

    public appraisal of prospective scenarios: A study protocol describing a multimedia-based

    deliberative method. *Implementation Science*, 9(1) doi: 10.1186/1748-5908-9-81

Lehoux, P., Hivon, M., Denis, J., & Tailliez, S. (2008a). Health technology assessment in the

    Canadian Health Policy Arena: Examining relationships between evaluators and

    stakeholders. *Evaluation*, 14(3), 295-321. doi: 10.1177/1356389008090857

Lehoux, P., Hivon, M., Williams-Jones, B., Miller, F., & Urbach, D. (2012). How do medical

    device manufacturers' websites frame the value of health innovation? An empirical ethics

    analysis of five Canadian innovations. *Medicine, Health Care and Philosophy*, 15(1), 61-

    77. doi: 10.1007/s11019-011-9312-5

Lehoux, P., Miller, F., & Daudelin, G., & Denis, J. (2017). Providing value to new health

    technology: The early contribution of entrepreneurs, investors, and regulatory agencies.

International Journal of Health Policy and Management, 6(9), 1-15. doi:

10.15171/ijhpm.2017.11

Lehoux, P., Miller, F., & Daudelin, G. (2013a). Horizon 2020 and the need to reinvent health

technology development. *The Lancet*, 382(9902), 1402-1403. doi: 10.1016/S0140-

6736(13)62213-8

Lehoux, P., Miller, F., & Daudelin, G. (2016). How does venture capital operate in medical

innovation?. *BMJ Innovation,* 2(3), 111-7. doi: 10.1136/bmjinnov-2015-000079

Lehoux, P., Miller, F., Daudelin, G., & Urbach, D. R. (2015). How venture capitalists decide

which new medical technologies come to exist. *Science and Policy*, 43(3), 375-85. doi:

10.1093/scipol/scv051

Lehoux, P., Vachon, P., Daudelin, G., & Hivon, M. (2013b). How to summarize a 6,000-word

paper in a six-minute video clip. *Healthcare Policy*, 8(4), 19-26. Retrieved from

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3999530/

Lehoux, P., Williams-Jones, B., Miller, F., Urbach, D., & Tailliez, S. (2008b). What leads to

better health care innovation? Arguments for an integrated policy-oriented research

agenda. *Journal of Health Services Research and Policy*, 13(4), 251-254. doi:

10.1258/jhsrp.2008.007173

Levin, L. (2015). Early evaluation of new health technologies: The case for premarket studies

that harmonize regulatory and coverage perspectives. *International Journal of

Technology Assessment in Health Care*, 32(4), 207-9. doi: 10.1017/S0266462315000422

Lincoln, Y., & Guba, E. *Naturalistic Inquiry*. Vol 75. Sage, 1985

Luczak, J. (2012). Establishing a small company's medical device quality system. The TQM

    Journal, 24(4), 363-373. doi: 10.1108/17542731211247382

MacGillivray, M., Sadeghi, M., Mills, P., Adams, J., Sawatzky, B., & Mortenson, W. (2019).

    Implementing a self-management mobile app for spinal cord injury during inpatient

    rehabilitation and following community discharge: A feasibility study. The *Journal of*

    Spinal Cord Medicine, 1-9. doi: 10.1080/10790268.2019.1614343

MacNeil, M., Koch, M., Kuspinar, A., Juzwishin, D., Lehoux, P., & Stolee, P. (2019). Enabling

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

    processes. *Health Policy*, 123(2), 203-214.doi: 10.1016/j.healthpol.2018.09.018

MacQueen, K., McLellan, E., Kay, K., & Milstein, B. (1998) Codebook Development for Team-

    Based Qualitative Analysis. *Field Methods*. 10(2). 31-36. Doi:

    10.1177/1525822X980100020301

Marchildon, G. (2013). Canada: Health system review. *Health Systems in Transition, 15(1).*

    Retrieved from European Observatory on Health Systems and Policies.

    http://www.euro.who.int/__data/assets/pdf_file/0011/181955/e96759.pdf

Martin, J., Polisena, J., Dendukuri, N., Rhainds, M., & Sampietro-Colom, L. (2016). Local health

    technology assessment in Canada: Current state and next steps. *International Journal of*

    Technology Assessment in Health Care, 32(3), 175-80. doi:

    10.1017/S0266462316000210

Mattison, C., Wilson, M., Wang, R., & Waddell, K. (2019). Enhancing equitable access to

    assistive technologies in Canada: Insights from citizens and stakeholders. *Canadian*

    Journal on Aging, 1-20. doi: 10.1017/S0714980819000187

McDaid, D. (2003). Co-ordinating health technology assessment in Canada: a European

perspective. *Health Policy*, 63(2), 205-213. doi:S0168851002000672

McHugh, M. L. (2012). Interrater reliability: the kappa statistic. *Biochemia Medica*, 22(3), 276-

282. doi: 10.11613/BM.2012.031

McMillan LLP. (2010). *Health law in Canada*. Retrieved from http://www.

mcmillan.ca/files/Health Law in Canada.pdf

McNeil, H. (2017). *Engaging Canada's Older adults in health TECHnology innovation

ecosystems: the ECOTECH Project*. University of Waterloo, Canada. Retrieved from

https://uwspace.uwaterloo.ca/bitstream/handle/10012/11814/McNeil_Heather.pdf?sequen

ce=5&isAllowed=y

McNeil, H., Elliott, J., Huson, K., Ashbourne, J., Heckman, G., Walker, J., & Stolee, P. (2016).

Engaging older adults in healthcare research and planning: A realist synthesis. *Research

Involvement and Engagement*, 2(10). doi: 10.1186/s40900-016-0022-2

MEDEC Canada. (2011). *Business sector strategy: Medical technology*. Retrieved from

https://cdn.ymaws.com/medtechcanada.org/resource/resmgr/Government_Submissions/O

pen_for_Business_MEDEC_Repo.pdf

Medical Devices Innovation Institute (MDI2). (2011). *Medical devices challenges and

opportunities for enhancing the health and wealth of Canadians*. Retrieved from:

https://cdn.ymaws.com/medtechcanada.org/resource/resmgr/Government_Submissions/Fi

nal_Medical_Devices_Challe.pdf

Mezey, M., Capezuti, E., Fulmer, T. (2004). Care of older adults. *Nursing Clinics of North America*, 39 xiii-xx. doi:10.1016/j.cnur.2004.03.003

Menon, D., & Stafinski, T. (2009). Health Technology Assessment in Canada: 20 Years Strong? *International Society for Pharmacoeconomics and Outcomes Research*, 12(2), 514-519. doi:10.1111/j.1524-4733.2009.00554.x

Menon, D., & Stafinski, T. (2008). Engaging the public in priority-setting for health technology assessment: Findings from a citizens' jury. *Health Expectations*, 11(3), 282-293. doi: 10.1111/j.1369-7625.2008.00501.x

Menon, D., & Stafinski, T. (2011). Role of patient and public participation in health technology assessment and coverage decisions. *Expert Review of Pharmacoeconomics and Outcomes Research*, 11(1), 75-89. doi: 10.1586/erp.10.82

Miller, F., Lehoux, P., Peacock, S., Rac, V. E., Neukomm, J., Barg, C., ... & Krahn, M. (2019). How procurement judges the value of medical technologies: A review of healthcare tenders. *International Journal of Technology Assessment in Health Care*, 35(1), 50-55. doi: 10.1017/ S0266462318003756

Miller, F., Sanders, C., & Lehoux, P. (2009). Imagining value, imagining users: Academic technology transfer for health innovation. *Social Science and Medicine*, 68(8), 1481-1488. doi: 10.1016/j.socscimed.2009.01.043

Mitton, C., Dionne, F., & Donaldson, C. (2014). Managing healthcare budgets in times of austerity: the role of program budgeting and marginal analysis. *Applied Health Economics and Health Policy*, 12(2), 95-102. doi: 10.1007/s40258-013-0074-5

Morse, J. (1995). The significance of saturation. *Qualitative Health Research*, 5, 147-149. doi: 10.1177/104973239500500201

Mortenson, W., Clarke, L., & Best, K. (2013). Prescribers' experiences with powered mobility prescription among older adults. *American Journal of Occupational Therapy*, 67(1), 100-107. doi: 10.5014/ajot.2013.006122

Naylor, D., Fraser, N., Girard, F., Jenkins, T., Mintz, J., & Power, C. (2015). *Unleashing innovation: Excellent healthcare for Canada. Advisory Panel on Healthcare Innovation.* Retrieved from https://www.canada.ca/en/health-canada/services/publications/health-system-services/report-advisory-panel-healthcare-innovation.html

Newell, A., Amott, J., Carmicheal, A., & Morgan M. (2007). Methodologies for involving older adults in the design process. *International Conference on Universal Access in Human-Computer Interaction*, 4554, 982-9.

O'Brien, K. K., Colquhoun, H., Levac, D., Baxter, L., Tricco, A. C., Straus, S., … O'Malley. (2016). Advancing scoping study methodology: A web-based survey and consultation of perceptions on terminology, definition and methodological steps. *BMC Health Services Research,* 16, 305. doi: 10.1186/s12913-016-1579-z

Oliver, K., Kothari, A., & Mays, N. (2019). The dark side of coproduction: do the costs outweigh the benefits for health research?. *Health Research Policy and Systems*, 17(1), 33. doi: 10.1186/s12961-019-0432-3

Ontario Bioscience Innovation Organization. (2013). *Realizing the promise of healthcare innovation in Ontario*. Retrieved from

https://static1.squarespace.com/static/55bbf3f3e4b08b3622073685/t/55f1c672e4b03fe76

469e943/1441908338271/Innovation-Adoption-Report-for-Distribution.pdf.

Ontario Health Innovation Council. (2015). *The catalyst: Towards an Ontario health innovation*

strategy. Retrieved from http://health.gov.on.ca/en/pro/ programs/ochis/docs/OCHIS

strategy report.pdf.

Ontario Ministry of Health and Long-Term Care. (2018). *Bundled care (integrated funding*

model). Retrieved from http://www.health.gov.on.ca/en/pro/programs/ecfa/funding/ifm/

Ontario Ministry of Research and Innovation. (2015). *Seizing global opportunities: Ontario's*

innovation agenda. Retrieved from https://www.ontario.ca/ page/seizing-global-

opportunities-ontarios-innovation-agenda

Palinkas, L., Horwitz, A., Green, C., Wisdom, J., Duan, N., & Hoagwood, K. (2015) Purposeful

Sampling for Qualitative Data Collection and Analysis in Mixed Method Implementation

Research. *Administrative Policy in Mental Health.* 42(5). 533-44. doi: 10.1007/s10488-

013-0528-y

Patton, M. (2002) *Qualitative Research and evaluation methods*. Thousand Oaks, California:

Sage Publications.

Peek, S., Wouters, E., Luijkx, K., & Vrijhoef, H. (2016). What it takes to successfully implement

technology for aging in place: Focus groups with stakeholders. *Journal of medical*

Internet research, 18(5). doi:10.2196/jmir.5253

Point of Care Foundation. (2019). *Experience based co design toolkit*. Retrieved from

    https://www.pointofcarefoundation.org.uk/resource/experience-based-co-design-ebcd-

    toolkit/introduction/experience-based-co-design/

Padfield, S. (2017). Shifting paradigms in Canadian healthcare to support the scale and spread of

    innovation. *Healthcare Papers*, 16(3), 19. doi:10.12927/hcpap.2017.25084

Prada, G. (2011). *Innovation procurement in health care: A compelling opportunity for Canada.*

    The Retrieved from The Conference Board of Canada

    https://www.conferenceboard.ca/temp/e73050f7-109f-42c0-a249-30f00fab1be7/12-

    059_InnovationProcurement_ES.pdf

Prada, G. (2015). *Hot topics in health, health care and wellness: Value-based procurement: The*

    new health care system: The new health care imperative. Retrieved from The Conference

    Board of Canada http://www.conferenceboard.ca/commentaries/ healthcare/default/16-

    03-15/value-based procurement the new health care imperative-481875798.aspx.

Prada, G. (2016). Value-based procurement: Canada's healthcare imperative. *Healthcare*

    Management Forum, 29 (4), 162-164. doi: 10.1177/0840470416646119

Pratesi, A., Sixsmith, J., & Woolrych, R. (2013). Technological and methodological innovation:

    Working "with" and "for" older people to develop a smart activity monitoring system.

    Innovation Journal, 19(1), 1-17. Retrieved from

    https://pdfs.semanticscholar.org/a88e/7d55b1ec27b496ecc4635c479126c7ae5b2d.pdf?_g

    a=2.259184842.1719973948.1572544543-1925196102.1572544543

Public Health Agency of Canada. (2018, June 25). *Government of Canada investing $75 million in seniors' health* [News release]. Retrieved from https://www.canada.ca/en/public-health/news/2018/06/government-of-canada-investing-75-million-in-seniors-health.html

Quinn, W., O'Brien, E., Springan, G. (2018) Using Telehealth to Improve Home-Based Care for Older Adults and Family Caregivers. *AARP Public Policy Institute: Insight on the Issues*. 135. Retrieved from https://www.aarp.org/content/dam/aarp/ppi/2018/05/using-telehealth-to-improve-home-based-care-for-older-adults-and-family-caregivers.pdf

Ritchie, J., & Spencer, L. (2002). *Qualitative data analysis for applied policy research*. In Analyzing qualitative data (pp. 187-208). Thousand Oaks, California: SAGE Publications Inc.

Rogers, E.M. (1995) Diffusion of Innovations, 4th Edition. New York, NY: The Free Press.

Rosas, S.R. & Kane, M. (2012). Quality and rigor of the concept mapping methodology: A pooled study analysis. Evaluation and Program Planning, 35, 236-245. doi: 10.1016/j.evalprogplan.2011.10.003

Savage, R., Yon, Y., Campo, M., Wilson, A., Kahlon, R., & Sixsmith, A. (2009). *Market potential for ambient assisted living technology: the case of Canada*. Ambient Assistive Health and Wellness Management in the Heart of the City (pp. 57-65) Berlin, Heidelberg: Springer.

Schulz, R., Beach, S., Matthews, J., Courtney, K., De Vito Dabbs, A., & Mecca, L. (2015). Caregivers' willingness to pay for technologies to support caregiving. Th*e Gerontologist*, 56(5), 817-829. doi: 10.1093/geront/gnv033

Scotland, G., & Bryan, S. (2017). Why do health economists promote technology adoption rather than the search for efficiency? A proposal for a change in our approach to economic evaluation in health care. *Medical Decision Making*, 37(2), 139-47. doi 10.1177/0272989X16653397

Scott, A., Pasichnyk, D., Harstall, C., & Chojecki, D. (2015). *Optimizing adoption and diffusion of medical devices at the system level.* [Information Paper]. Retrieved from Institute of Health Economics https://www.ihe.ca/publications/optimizing-adoption-and-diffusion-of-medical-devices-at-the-system-level

Sebastianski, M., Juzwishin, D., Wolfaardt, U., Faulkner, G., Osiowy, K., Fenwick, P., & Ruptash, T. (2015). Innovation and commercialization in public health care systems: A review of challenges and opportunities in Canada. Innovation and Entrepreneurship in Health, 2, 69-80. doi: 10.2147/IEH.S60790

Shippee, N. D., Domecq Garces, J. P., Prutsky Lopez, G. J., Wang, Z., Elraiyah, T. A., Nabhan, M., … Murad, M. H. (2015). Patient and service user engagement in research: a systematic review and synthesized framework. Health Expectations, 18(5), 1151–1166. doi:10.1111/hex.12090

Silva, H., Lehoux, P., Miller, F., & Denis, J. (2018). Introducing responsible innovation in health: a policy-oriented framework. *Health Research Policy and Systems*, 16(1), 90. doi: 10.1186/s12961-018-0362-5

Simeon, R. (1976). Studying public policy. Canadian Journal of Political Science, 9 (4), 548-580. Retrieved from: http://www.jstor.org/stable/3231089

Sixsmith, A. (2013). *Technology and the challenge of aging*. In A. Sixsmith and G. Gutman

    (Eds.), Technologies for active aging, international perspectives on aging. Retrieved from

    http://www.springer.com/cda/content/document/cda_downloaddocument/9781441983473

    -c1.pdf?SGWID=0-0-45-1446008-p174086072.

Smith, N., Mitton, C., Davidson, A., & Williams, I. (2014). A politics of priority setting: Ideas,

    interests and institutions in healthcare resource allocation. *Public Policy and*

    Administration, 29(4), 331-347. doi: 10.1177/0952076714529141

Snowdon, A., Zur, R., & Shell, J. (2011). *Transforming Canada into a global centre for medical*

    device innovation and adoption. Centre for Health Innovation and Leadership. Retrieved

    from https://www.ivey.uwo.ca/cmsmedia/3468059/ichil-medical-devices-white-paper-

    final2.pdf

Snowdon, A. (2017). Health System Transformation through a Scalable, Actionable Innovation

    Strategy. *Healthcare Papers*, 16(3), 59. doi:10.12927/hcpap.2017.25078

Sorenson, C., Drummond M., & Bhuiyan-Khan, B. (2013). Medical technology as a key driver

    of rising health expenditure: Disentangling the relationship. *ClinicoEconomics and*

    Outcomes Research, 5, 223-34. doi: 10.2147/CEOR.S39634

Soril, L., MacKean, G., Noseworthy, T.M., Leggett, L., Clement, F. (2017). Achieving optimal

    technology use: A proposed model for health technology reassessment. *SAGE Open*

    Medicine, 5, 1-7. doi: 10.1177/2050312117704861

Tarride, J. -., McCarron, C., Lim, M., Bowen, J., Blackhouse, G., Hopkins, R., . . . Goeree, R.

    (2008). Economic evaluations conducted by Canadian health technology assessment

agencies: Where do we stand? *International Journal of Technology Assessment in Health Care*, 24(4), 437-444. doi: 10.1017/S0266462308080574

Tesfayohannes, M. (2007). The role of federal government funding on the outreach programs of independent industrial R&D establishments in Canada. *Journal of Manufacturing Technology Management*, 18(4), 461-478. doi: 10.1108/17410380710743815

The Change Foundation (2017) *Should money come into it? A tool for deciding whether to pay patient-engagement participants*. Retrieved from: https://www.changefoundation.ca/patient-compensation-report/Trochim, W. K. & Cabrera, D. (2005). The complexity of concept mapping for policy analysis. Emergence: Complexity & Organization, 7(11), 11-22. Retrieved from https://www.socialresearchmethods.net/research/The_Complexity_of_Concept_Mapping.pdf

Trochim, W., & Kane, M. (2005). Concept mapping: an introduction to structured conceptualization in health care. *International Journal for Quality in Health Care*, 17(3), 187-191. doi: 10.1093/intqhc/mzi038

Trudeau, J. (2017). Minister of Health mandate letter. Retrieved from https://pm.gc.ca/eng/minister-health-mandate-letter

Tsoi, B., Masucci, L., Campbell, K., Drummond, M., O'Reilly, D., & Goeree, R. (2013). Harmonization of reimbursement and regulatory approval processes: a systematic review of international experiences. *Expert Review of Pharmacoeconomics & Outcomes Research*, 13(4), 497-511. doi:10.1586/14737167.2013.814962

University of York Centre for Reviews and Dissemination. (2018). *HTA database Canadian search interface*. Retrieved form http://www.crd.york.ac.uk/PanHTA/ homepage.asp

Varabyova, Y., Blankart, C., Greer, A, Schreyögg, J. (2017) The determinants of medical technology adoption in different decisional systems: A systematic literature review. *Health Policy*. 121:230-242. doi: 10.1016/j.healthpol.2017.01.005

Verma, A., & Bhatia, S. (2016). A policy framework for health systems to promote triple aim innovation. *Health Care Papers*, 15(3), 9-23. Retrieved from https://www.semanticscholar.org/paper/A-Policy-Framework-for-Health-Systems-to-Promote-Verma-Bhatia/5b2d9393fa0802e781ce7d7be6402b0ddd0d54d6

Viswanathan, P., Zambalde, E. , Foley, G., Graham, J., Wang, R., Adhikari, B., ... & Mitchell, I. M. (2017). Intelligent wheelchair control strategies for older adults with cognitive impairment: user attitudes, needs, and preferences. *Autonomous Robots*, 41(3), 539-554. doi: 10.1007/s10514-016-9568-y

Watt, A., Hiller, J., Braunack-Mayer, A., Moss, J., Buchan, H., Wale, J., ... & Elshaug, A. (2012). The ASTUTE Health study protocol: deliberative stakeholder engagements to inform implementation approaches to healthcare disinvestment. *Implementation Science,* 7(1), 101. doi: 10.1186/1748-5908-7-101

Wilberforce, M., Batten, E., Challis, D., Davies, L., Kelly, M., & Roberts, C. (2018). The patient experience in community mental health services for older people: a concept mapping approach to support the development of a new quality measure. *BMC Health Services Research*, 18(1), 461. doi:10.1186/s12913-018-3231-6

World Health Organization. (2015). *Global age-friendly cities project*. Retrieved from

http://www.who.int/ageing/age-friendly-world/en/

Xie, F., Bowen, J., Sutherland, S., Burke, N., Blackhouse, G., Tarride, J. -., . . . Goeree, R.

(2011). Using health technology assessment to support evidence-based decision-making

in Canada: An academic perspective. *Expert Review of Pharmacoeconomics and*

Outcomes Research, 11(5), 513-521. doi: 10.1586/erp.11.60

APPENDICES

APPENDIX A: SEARCH TERMS FOR SCOPING REVIEW

Canad*[Title/Abstract] AND (technolog*[Title/Abstract] OR medical devic*[Title/Abstract])

AND (((governmen*[Title/Abstract] OR polic*[Title/Abstract] OR

regulat*[Title/Abstract] OR approval process*[Title/Abstract] OR

marketing[Title/Abstract] OR decision making[Title/Abstract] OR health technology

assessment[Title/Abstract])) OR health technology assessment[MeSH Terms]) NOT

(drug*[Title/Abstract] OR vaccin*[Title/Abstract] OR genetic*[Title/Abstract] OR

pharmaceutical*[Title/Abstract]) AND (("2000/01/01"[PDat] : "2015/09/18"[PData]))

APPENDIX B: INFORMED CONSENT- INTERVIEWEES

CONSENT FORM

By signing this consent form, you are not waiving your legal rights or releasing the investigator(s) or involved institution(s) from their legal and professional responsibilities.

_____

I have read the information presented in the information letter about a study being conducted by Dr. Paul Stolee, Melissa Koch and Maggie MacNeil from the School of Public Health and Health Systems at the University of Waterloo. I have had the opportunity to ask any questions related to this study, to receive satisfactory answers to my questions, and any additional details I wanted.

I am aware that I have the option of allowing my interview to be audio recorded to ensure an accurate recording of my responses.

I am also aware that excerpts from the interview may be included in the thesis and/or publications to come from this research, with the understanding that the quotations will be anonymous.

I was informed that I may withdraw my consent at any time without penalty by advising the researcher.

This project has been reviewed by, and received ethics clearance through a University of Waterloo Research Ethics Committee. I was informed that if I have any comments or concerns resulting from my participation in this study, I may contact the Director, Office of Research Ethics at 519-888-4567 ext. 36005.

With full knowledge of all foregoing, I agree, of my own free will, to participate in this study.

☐YES ☐NO

I agree to have my interview audio recorded.

☐YES ☐NO

I agree to the use of anonymous quotations in any thesis or publication that comes of this research.

☐YES ☐NO

Participant Name: _____ (Please print)

Participant Signature: _____

Only for consents obtained verbally:

Participant Name: _____ (Please print)

Interviewer Name: _____ (Please print)

Interviewer Signature: _____ Date: _____

_____
_____

When this study is completed, we will write a summary of the results. Would you be interested in receiving a copy?

☐YES, please e-mail me a summary of the results. My e-mail address is:

_____

☐YES, please mail me a summary of the results. My mailing address is:

☐NO, I do not wish to receive a summary of results

APPENDIX C: INFORMED CONSENT – OLDER ADULTS

CONSENT FORM FOR FOCUS GROUP

By signing this consent form, you are not waiving your legal rights or releasing the investigator(s) or involved institution(s) from their legal and professional responsibilities.

_____

I have read the information presented in the information letter about a focus group session being facilitated by Dr. Paul Stolee, Melissa Koch and Maggie MacNeil from the School of Public Health and Health Systems at the University of Waterloo. I have had the opportunity to ask any questions related to this focus group, to receive satisfactory answers to my questions, and any additional details I wanted.

I am aware that the focus group session will be audio recorded to ensure an accurate recording of my responses.

I am also aware that excerpts from the focus group may be included in the thesis and/or publications to come from this research, with the understanding that the quotations will be anonymous.

I was informed that I may withdraw my consent at any time without penalty by advising the facilitator of this decision.

This study has been reviewed and received ethics clearance through a University of Waterloo Research Ethics Committee (ORE# 30529). If you have questions for the Committee contact the Office of Research Ethics, at 1-519-888-4567 ext. 36005 or ore- ceo@uwaterloo.ca.

With full knowledge of all foregoing, I agree, of my own free will, to participate in this session and to keep in confidence information that could identify specific participants and/or information they provided.

☐YES ☐NO

I agree to the use of anonymous quotations in any thesis or publication that comes of this research.

☐YES ☐NO

Participant Name: _____ (Please print)

Participant Signature: _____

Witness Name (1): _____ (Please print)

Witness Signature (1): _____ Date: _____

Only for consents obtained verbally:

Participant Name: _____ (Please print)

Witness Name (1): _____ (Please print)

Witness Signature (1): _____ Date: _____

Witness Name (2): _____ (Please print)

Witness Signature (2): _____ Date: _____

_____
_____

When this focus group session is completed, we will write an executive summary of the results. Would you be interested in receiving a copy?

☐ YES, please e-mail me a summary of the results. My e-mail address is:

_____

☐ YES, please mail me a summary of the results. My mailing address is:

_____

☐ NO, I do not wish to receive a summary of results

APPENDIX D: SEMI-STRUCTURED INTERVIEW GUIDE

PRI-TECH: Policy and Regulatory Issues in Enabling Technological Innovation

Interview Guide Questions
Date:
1. Could you please describe your current role (in the federal/provincial/territorial ministry, department, or organization)?

2. What technologies do you look at and how do you decide which ones to consider?

3. What is your involvement in policy-making, planning or decision-making related to regulations and adoption of other health technologies?

4. Can you walk us through the process, from submission to approval, and do you have any guidelines or frameworks that guide this?

5. Do you have any policy, regulatory or reimbursement frameworks for technologies related to aging?

6. How does the reimbursement and adoption process for aging-related technologies differ from other health technologies?

7. In the medical device or health technology industry, what is working well in terms of: (Facilitators)

a. Regulatory processes
b. Approval/reimbursement?

8. What could be improved? (Barriers)
a. In the regulatory process?
b. In the approval/ reimbursement process?

9. Are you working on identifying potential policy or research priorities related to regulations, adoption and reimbursement in health technologies?

10. Are there any documents or summarized reports that you would be able to share with us?

11. Have you heard of _____ (AGE-WELL Technology)? What factors would influence the feasibility of this technology getting regulatory approval?
a. What factors could influence its adoption for reimbursement by the province?

12. Do you have any recommendations of other policy-makers, innovators, or industry representatives you think we should speak with?

APPENDIX E: FEEDBACK LETTER

FEEDBACK LETTER (for Focus Groups)
Seniors Helping as Research Partners (SHARP) Network
Principal Investigator: Paul Stolee, PhD
Co-investigators: Maggie MacNeil, Melissa Koch

Thank you for your participation in our project! The results of the focus groups will be used to inform the PRI-TECH project. The PRI-TECH (Policy and Regulatory Issues in Enabling Health Technology), is a project funded by AGE-WELL which explores current policy, regulatory, and health system issues relevant to the evaluation, approval, regulation and reimbursement of technologies to support healthy aging.

A. PURPOSE

The aims of the focus groups were to understand older adults and caregivers perspectives on areas of potential policy change including: building supportive partnerships for health technologies for older adults; patient and user involvement in technologies for older adults; and education and awareness about technologies for older adults.

B. SUMMARY OF FOCUS GROUP FINDINGS

C. CONFIDENTIALITY AND DATA SECRUITY

Your identity is considered completely confidential by the researchers. The results of the focus groups have been anonymized. Specific comments and statements are not directly identifiable in any reporting of the results. Your name and contact information will be remain confidential. Only the research team will have access to the data collected and all members of the research team have signed an agreement to maintain confidentiality. All paper documents are secured in a locked filing cabinet at all times and electronic files are maintained on a password-protected computer. All data will be retained for seven years; at this time, all electronic data files will be permanently deleted and any papers of the raw data will be destroyed.

D. QUESTIONS

If at any time you have questions about this research project, or wish to obtain a results summary of the findings, please contact the Principal Investigator:
Paul Stolee, PhD, School of Public Health and Health Systems, University of Waterloo, Waterloo, Ontario, 519-888-4567 ext.35879, stolee@uwaterloo.ca

Should you have any questions or concerns arising from your participation in this study, please contact Dr. Susan Sykes, Director, Office of Research Ethics, University of Waterloo, at (519) 888-4567 ext.36005, ssykes@uwaterloo.ca.

APPENDIX F: INTERVIEW CODE BOOK

Development: Research, device prototyping (include talk of finances for development, stakeholder engagement during development)

The innovation process generally begins with research and development of an innovation. Research should inform the innovator about the problem, existing solutions and the target population, or end-user. The initial research should show evidence in support of the clinical effectiveness of the innovation. This research may be necessary for obtaining regulatory licences and approval. The research and development phase continues throughout the entire innovation process to ensure that the product remains competitive with similar innovations, and maintains end-user interest.

Assessment: Regulatory approval, health technology assessment, other evaluation processes, data requirements/issues

It is important to determine whether or not the health technology will be considered a 'medical device' early in the innovation process. In Canada, health technologies that are considered 'medical devices' under the Food and Drugs Act, Medical Device Regulations, must be licensed by Health Canada. In order to obtain a medical device license, innovators must submit an application to Health Canada containing the evidence obtained from the research phase, along with application documentation. This manual will help innovators determine if their technology requires a medical device license in Canada.

Health Technology Assessment is a process in which the technology is evaluated for social, economic, organizational and ethical issues in order to inform policy decisions. Health Technology Assessment requires evidence on the therapeutic and cost effectiveness of the device. The outcome of the HTA process is used to inform hospitals, regional health authorities, provincial programs such as the Assistive Devices Program in Ontario, Alberta's Aids to Daily Living Program (AADL), BC's PharmaCare Prosthetic and Orthotic Program, or Quebec's Régie de l'assurance maladie du Québec (RAMQ) and third party payers about the technology, allowing them to determine whether or not the device will be reimbursed.

Implementation: Implementation plan, adoption, diffusion, reimbursement

If the device is reimbursed decisions around procurement and adoption can be made. In the procurement and adoption phase, group purchasing arrangements are made by Shared Service Organizations (SSOs) or provincial level Group Purchasing Organizations (GPOs). Alternatively, regional health authorities, government initiatives, research facilities, teaching hospitals and health care practitioners may provide smaller scale procurement initiatives.

Sustainability: Reinvest, disinvestment, reevaluating existing technology within the system, health technology management, evaluating if there is better technology to do the same job

(e.g. if grant-funds pay for initial hardware and software, will the partnership organization continue paying on-going upgrade and maintenance costs after the grant-funds are spent? This question extends to whether and how the organization aligns structure and processes to incorporate the new technology, sustainability depends on intelligent adoption of technologies that enable gains in population-based needs and outcomes)

Policy Context: Aspects/specifics of the policy context

- Federal
- Provincial
- Regional
- International

(e.g. multiple provincial/territorial jurisdictions, comparisons to international contexts, etc.)

Resources: Human, financial, considering the continuum of care (home/acute care resources)

(e.g. technology investment, venture capital, government expenditures), information resources

Partnerships: partnerships/communication between a variety of stakeholders, organizations or members of groups (e.g.. Experts and academics that partner within AGE-WELL)

clinicians/health care providers, patients, industry, policy makers, payers etc….

User or Consumer Co-Creation: Developers engaging the end-users throughout innovation processes, consulting about the design or development of the process

Aging/Older Adult Focus: Technology for older adults, technology not solving the aging problem, technology not specific to aging, misconceptions for technology for older adults

APPENDIX G: CHARTING FOR FRAMEWORK ANALYSIS

Older Adult		
Subtheme:	a) aging tech: same process	b) assumptions about older adults
Government	*"Generally... everybody I talk to no matter whether you're talking about or rapid diagnostic test or an assistive device or an app... they all seem to face some of the same barriers... so I don't think it will be that different"*	*"there is still a cultural barrier in terms of perceptions of what seniors can do in terms of technology adoption... I speak with some colleagues ...and they're like ... my grandma's not going to be able to use an iPhone... I'm like have you given an iPhone to your grandma? Because if a three-year-old can use it I'm pretty sure grandma can use it as long as she can see it and hear it... "*
Industry	*"So a lot of technologies that I have in mind, or that I am seeing, are not shaped to... especially focus on the old"*	*"You know, you also hear in terms of clinician resistance. ... They're passively telling you l... I'm not really there...."Well I'd like it, but I see mostly senior patients, and they'd never be able to use it."*
Innovator		*" this cohort of people who are in the baby boomer years and they're getting older except they don't want to think that they're older ... as a joke within some of our sales force that 80 is the new 60 because some of these people are still vibrant don't want to give up living in their own homes ..."*
Researcher	*"I do not know of any and I would be quite surprised if there was anything that is aging specific because even when you open it up to overall health we kind of lack those things at this point"*	*"how do you manage this patient, which may take into account age, because...patient preferences change when you age. A .02 increase or decrease in mortality isn't usually very important to somebody that is 75, being out of pain is hugely important to them. ... so I would argue if we were to think about preferences, properly and actually consider that in the equation you would probably look at technologies differently because we value them differently as we age "*

Partnerships		
Subtheme:	a) partnerships with health care stakeholders	c) strategies to connect partners	d) involving the right stakeholders at the right time
Government	*Reach out. Collaborate. We're all condemned to work together. … when you're with your little technology and you have an idea… you don't want this policy guy or the health research woman who will tell you, "This won't fly…"You have to tweak it because it won't fly."* *… It's better to have the cold shower right in the beginning and work together than to work five years, spend lots of money, make lots of proof of principle and at the end, say, "Nope. We don't want to."*	*"Part of what we're doing … is …trying to develop an ecosystem, talking to researchers, understand the early technologies… talking to [the hospital], talking to rehab, the innovation center …There are technologies… that could be focused on a long term care home, or could be used in the home… and we don't have a handle on all the challenges of deploying it at home."*	*"innovators, people that are coming out with these new technologies, …early engagement with regulatory authorities and asking the right questions to understand the obligations of an innovator who's entering into this space that's maybe uncharted territory for them … looking long-term about aspects related to regulations, uptake, and reimbursement. …having those early discussions and developing a regulatory strategy early on in the process is something that is very positive … playing catch-up after the fact is challenging."*
Industry	*"it seems to me that technologies that were identified should [have] the conversation with healthcare administrators and senior folks earlier…Otherwise it's kind of an old fashioned model to develop something and kind of hope for the best… I think the way forward is…having very early conversations about what do people need and how is this and is this actually going to enjoy uptake"*	*"So the SCNs in Alberta are these organizations that the government created that look at different sort of disease states or clinical areas, like diabetes, cardiovascular, that sort of thing…we've been working on an initiative with them to bring in medical technology companies, and um and then the Strategic Clinical Network…will talk to industry about what their health challenges are, and the companies can respond by presenting different technologies that will improve the health of that type of patient."*	*"The number one thing working well right now is that in the last five years, we have industry is at the table with governments - you know, this is sort of new to the industry. The medical technology industry historically hasn't had dialogue with government in the way that it has in the last few years"*
Innovator		*"there's a lot of different programs for entrepreneurs in Toronto specifically… on campus at UofT, there's 5 or 6 campus run accelerators that provide mentorship and advice and then we're also part of…. another Toronto based accelerator. … that's been, quite helpful too and. that's all been very helpful…. People willing to make introductions and provide feedback and mentorship and all those things are really*	

		critical for life sciences and health science start ups.”
Researcher		

CANADIAN POLICY CONTEXT	
Subtheme:	a) jurisdictional considerations	b) international comparisons
Government	*“one of the barriers is healthcare delivery is a provincial responsibility so there will then be a fair degree of diversity in what's covered across the country so any kind of standard that you might want to believe in…aids to daily living and that sort of thing will tend to be somewhat more fragmented.”*	*“I've heard this… "It's easier for me to sell into the US, than it is into my own province." …A lot of it is procurement rules, because …I can't provide any favoritism, or any weighting to say, "You're an Ontario-based company." Because that's against the North American Free Trade laws”.*
Industry	*“one of the last ones is probably scaling up good initiatives, right? … great pilots all over the place that are happening and then they just…stay happening in whatever area, or the pilot dies. I think one of the things we're trying to look at…is how do we bring that spread across a jurisdiction. How do you take a good thing happening in one community and … how do you take that spread across, but there is no formalized process for that in lots of different jurisdictions”*	*“in the United States or the European Union market…you can very quickly get approval and then start using your thing…we put substantive barriers especially around class II and class IV medical devices. Even ones that might just simply be the same idea in principle but using a different material but a material that's already been tested. You could theoretically see a much faster approval certain types of technologies in the states, because of their fast track process”*
Innovator	*“the Canadian model is really messed up because of the interprovincial trade barriers… we have a tiny market which we have shrunken even more with these interprovincial trade barriers… as a start-up company… I wind up having to pay 10, 20, 30 percent of my capital on travel to go to markets where people don't have enough critical mass that it makes sense for you to try and sell them something… there's no way that the Canadian market is remotely big enough to support what I'm doing.”*	*“some of the hard-core innovators were like "we don't care about getting our product adopted in Canada, tell us how to get it adopted in Germany”. So, there's definitely some countries that…have a single payer model that the innovators seem to be interested in…French, Germany are much better models”*
Researcher		*“the US is the market that has the gold standard for regulatory approval… they still have standards, they set meaningful standards around the regulation of medical devices that are higher than Canada's and they're infinitely higher than in Europe. … But Canada is… seen in some ways from the regulation of medical devices as the entry place to test out… on the way to… or at least can be a quicker entry to the North American market. The FDA has a higher standard, so we're kind of the intermediate, we're close to the US, but, but we're still easier… maybe it*

			needs to be closer to the FDA, but certainly id doesn't need to be closer to the EU."

Development			
Subtheme:	a) designing for health care	c) building capacity through human/financial resources in development	d) considerations for innovators in the development stage
Government	*"we don't have a full handle on all the challenges of deploying it at home…Simple things, if you've got a technology deployed in the long term care owners, and there's a power failure, A that the long term care home might have a generator, in a home, you don't have that. It's gone, who resets it? You don't have IT geeks running around an apartment that can reset technology, if that's required. Things have to be made entirely foolproof, entirely power failure proof, entirely suited for people that are not technically inclined to do what they need to do. That's a challenge in and of itself"* *"There's not a poll from the healthcare system right now saying, "Here's what we really need." On the one hand you have companies or academics working away on something that they think is cool. Then on the other end of the line you've got people who are like, "Well, it might be cool, but it doesn't actually help me solve the problems that I have right now." Then in the middle, you've got the regulator who's going, "Well, here's how I classify it and will approve it""*		*"And I try to remind people about how … the power of Excel now is amazing like you can do a Monte Carlo analysis on Excel… but the average person uses Excel to make tables …entrepreneurs have to be aware that in some cases only one third of the functionality of your tools will only ever be adopted fully"*

Industry	*"what happens is Health Quality Ontario…reported on what their areas of quality improvement are, what the strategic direction would be…and there's an annual report that's been generated out of that. … as an innovator, if I was to provide them with that tool and say "If your innovating, then innovate in the direction of where the health system is going. So they're improving these areas, and if they're looking at the strategic priorities of their hospital going in this direction, they're very likely you will have a buyer for technology if you're looking to address their problems. So this whole, looking at, look at the systems needs and then innovate in that direction would be an important thing"*	*one of the great things that we have going for us in our ecosystem is just, the R&D capacity that we have … there's a lot of support … in terms of funding, and just the regional innovation centres…many others that are there to facilitate, that are there to … take those ideation creation, … stage companies, through the continuum… we've got this really strong engine I think for R&D. I think that works very well for our system as a whole. Umm, I think we've got the talent… we've got lots of really focused monies and, and, and talent that are honing in to the kind of things that would be relevant as our population ages. … educationally, knowledge, we've got it all.*	*The other bottleneck we work on is, we deal with health solutions that are at the boundary between the consumer and the health system, where information right now doesn't really flow to the patient about their own data, their own body. It's kind of stuck in silos and prisons… we're trying to basically unlock that data and …its a flipping on it's head of data ownership in healthcare.*
Innovator	*…to work in the health industry personal information sharing is a challenge. You've got to comply to HIPAA or PHIPA … people interpret this in different ways in different organizations and often people will use this as a barrier to block changes … entrepreneurs like me … have great ideas that could make health care progress faster but because of this limitation or risk adverse type protocols it's very difficult to involve and to support those types of entrepreneurs …in Ontario or in Canada many, many systems exist to manage personal data … for caregivers or care professionals with ability to treat a patient and have access to all the data is extremely difficult …often I find good ideas will die because people are just not able to overcome those major barriers – Innovator 7*	*But I have noticed that many people from the healthcare sector do not appreciate how unwieldy the software can be….I hear, 'we will get a student to build this' and sometimes it is a small thing that can be built and sometimes it's not and the assumptions that are made about how the software behaves is completely unrealistic. …there is a gap on both sides and many times the failure of software… is because there was not enough resources allocated to it and there was not enough knowledge allocated to it to be developed properly.*	*Health Canada has ruled out that we are not a medical device…which I think is actually a positive in a sense because not having cumbersome regulatory oversight allows innovators and entrepreneurs to be more flexible especially in the development stages when you're still trying to understand, you know what is the feature set required to deliver value to residents… if Health Canada's more liberal with the way they look at kind of non-invasive devices that pose a low risk to residents… that's probably a positive.*

| Researcher | *from a policy perspective we need to do technologies differently...We need to create technologies which the RND is less costly...And that will be more affordable and that will tackle system level challenges, not just add, clinical value to what we do already. But to transform health care systems so they can better address today's needs and ageing is one... I don't know how people will tackle this* | *Uh in our research we've looked at uh one spinoff that created home monitoring And, and what really hit this spinoff very hard was that they could not articulate a business model, uh it was really hard for them, they, they had a great team they really worked closely with clinicians and, and the whole idea was to reduce unnecessary uh hospitalization and, emergency room visit* | |

Assessment					
Subtheme:	a) value of a national certificate	b) assessments don't decide/consider consequences	c) mismatch between the pace a tech develops and pace of assessment	d) many categories of evidence when assessing tech.	g) difficulty classifying complex devices
Government	*we would only review a device or technology that has been approved by Health Canada, so that's obviously one big consideration. It has to have Health Canada approval.*	*… while we might say that this appears to be very appropriate and the evidence supports inductiveness and the model seems to support that we might get a lot of savings from this, it is not up to us to make that decision. We might put it forward and say that this is a positive decision, but at the end of the day it is not up to us, or our process, or*	*one of the issues is timeliness, that's a very slow process both in collecting the evidence… the academic world operates at a standard and at a speed that just isn't practical from the delivery side. The types of things that turn their cranks, that motivate them, that they get motivated for doing*	*you talk to one person and they're like yeah you have to do randomized control trials you talk to another person no you don't need to do an RCT…there is a lot of variability…In what an HTA entails, so what we are trying to do is get to a minimum viable product … to the HTA… what is the minimum amount of data that you need as that healthcare*	*everything's innovative … it's new products and used in a way we've never used products before… the sheer challenges in terms of where devices fit right now... There's more and more things shoved into each submission, and you're trying to figure out what the different component parts are and what's approved and what's not approved... moving forward, it's a pharmaceutical, plus a natural health product, plus a device, plus it's actually three different types of device in the device …, and how*

		the advisory committee to make the decision that this is gonna happen.	*are not necessarily as relevant to those who are responsible for delivering care. …it's impossible to come up with recommendations that will apply to sites across the province or across the country.*	*setting to say 'ok I am ok with the decision lets purchase this' …And hopefully that evidence packages will be enough for the next.. healthcare setting*	*you manage that from a regulatory perspective.*
Industry		*Agencies … do a good job of health technology assessments .. But … there is no teeth to that recommendation…So the health system itself does not have to follow that recommendation. It's quite optional. And so linking those processes to the adoption of innovation … could be greatly improved to helping technologies through the system. on reimbursement and approval… we put all our eggs in the basket of a funding decision being the be-all and end-all, and its just not even close to the beginning. You know, if you've met the evidence threshold to make the decision "This should be*	*every jurisdiction, every country – so Canada, the US, Europe, Australia do their own thing… it means that if you do bring a product to market in Australia rather than launch it in Canada, you have to repeat the process … that is not encouraging innovators to come to certain markets*	*there's a lack of understanding of what is useful evidence generation, so a lot of things enter for the purpose of gaining experience, but is never really captured in a way that provides meaningful evidence on which we can make better decisions and I think that's a huge opportunity loss. And by the time its past the point of …we've kind of lost our ability to study it in a naïve sense in order to capture any of the signals from the noise so I think we need to work on that – it's one of the biggest barriers*	

		funded" … well that has nothing to do with adoption and ultimate value capture. So I mean that's a big problem…, we equate a reimbursement decision making with use and they're totally not! And so we have a terrible, terrible track record of access, and ultimate use by patients and clinicians of technologies that are frankly, standards of care in most countries			
Innovator	*the difficulty with going through health Canada …once you put them through the channel, if you package it into a hardware of some kind and then say it has, it's now health Canada approved, I suspect…decreases the accessibility of that product and now is maybe 10 times the cost and …it brings the competitive edge down because very few people can compete with that. -*			*we hypothesized that it would be great to work with research institutions and professors who are prominent in the field,… but we found I think there's been a lot of issues with that approach, … bridging the gap between academia and industry is …an ongoing issue… we don't wanna go run a $100 000, million dollar study …if at the end of the day, you know the design of the study is so academically focused and doesn't actually help us prove a case*	*we're getting into a realm where we could actually have individually produced medical devices. How on Earth do you figure out whether they are in spec?...From the regulator's point of view this was kind of mind blowing because wow, how cool is this, but at the same time … where would be the start, figuring out how to regulate it.*

			that then will result in driving adoption	
Researcher	*Health Canada certainly sees themselves on the med tech regulatory pathway ... The Health Canada regulatory approval process is pretty efficient... never mind small guys – for the small guys everything is impossible...*	*cost effectiveness tells you nothing about the actual, sticker shock that goes along with technology adoption... these technologies involve process changes and organizational changes and feasibility of adoption questions from an organizational perspective. Its really very poorly analyzed within an HTA process... often times there is a budget impact analysis that is done, but I think they're quite poorly done which effect to the real cost to the organizational level to adopt, certainly, any kind of meaningfully complex technology.*		*or a lot of technologies we've looked at they would not have the evidence base nor be likely to get it. So if you're looking at a medication or a certain type of medical procedure. Quite likely you will find or could do a systematic review of a number of regressively down randomized trials with straight forward outcome measures. That could you know cost effectiveness information that could then inform a decision. For many of the technologies that we're considering the you know the evidence base / is not there. And is less likely to get there because these are they may not be the kinds of intermission that would necessarily lead themselves to randomized trials for example. And maybe we need to look at different kinds of evidence. –*	

Implementation

Subtheme:	a) having the right evidence to make reimbursement decisions	b) bureaucratic complexities	d) value-based procurement	e) implementation considerations across HC settings
Government	*Unless you can show that these devices actually save money based on what you're already doing… It's actually sitting down with the innovators and saying…Is there any way we can save time here?" … they often don't think about that right off the bat. They're so into their little device and they already think it's wonderful … it's almost like it's your job to establish that dialogue and almost pull that information out of them … you go back to them and say "these are what I've come up with as potential benefits … I can see these as drawback. What am I missing?"*	*a lot of companies they think that that's the ultimate goal: to get reimbursement but I've been trying to impress upon them is that reimbursement is not the magic bullet that they think that it is… in some ways they're better off actually forgetting about reimbursement and actually building relationships with the healthcare organizations individually and working with the ones that are easiest to work with and then that might actually be faster pathway to reimbursement than it is trying to jump through bureaucratic hoops they're just not business friendly*	*we put…we're trying to do an outcome based RFP, here's the outcome: we want to reduce caregiver stress. …We tried to have a balance of being prescriptive, yet being open. Ultimately, I do think it worked out, I think we've got a good solution… We did debriefs with the other fourteen that didn't win, and they had different opinions as to the process, most liked it being open. … a lot of the respondents didn't understand what we were getting at when we said…"We want to see a reduction in caregiver stress." The typical response back, … "We can help you measure caregivers' stress in this fashion." Good, but that doesn't tell me how you're going to reduce it. … A few of them understood, "We can improve caregivers' stress through these features of our product." They were very explicit, that was one reason why they won the bid.*	*you have to change how you deliver the care and that's hard, that's really hard. It's really slow and costly in the sense of the amount of time and effort needed and a lot of people are just too busy or too focused on their immediate needs that they just can't free up enough mind share to work through how on earth are we going to change our workflow around this.*
Industry	*The other barrier is that we just don't know how to deal with the crowded nature of all these technologies dying for attention and all of them equally un-evidenced and unstudied, all of them looking equally fine but having nothing specific to make*	*first to get to the market in general like the Health Canada approval… and then the second step, which is the approval for reimbursement in the provinces that is even more complicated …you cannot say that health technology assessment that leads to*	*we have a unit …that works on outcome-based financing … the government is sort of tired of paying for things without really knowing if they get the value. So we pay for activities …to resolve that… called value-based healthcare, or outcomes based financing, or outcomes based*	*to kind of create a way for technology to be assessed and disseminated for homecare…there is no funding available from the ministry for research… for an organization like ours to do testing or to work with vendors, we don't actually get funding for that. And, it's really a big issue,*

	decisions upon. And patients and society being very ill informed of what they're demanding, generally wanting the new and shiny ...and so do clinicians. But our biggest barrier is that we just don't have information to advice which technologies should and should not be used... and it'll only get worse.	*purchasing decisions in Ontario would for the same product also qualify the product for being reimbursed in another province. ... one of the other barriers that might not seem as sort of apparent is, is within government, the lack of inter-ministerial sort of coordination and cooperation*	*payment. Also called pay for performance. In a technology room that's called risk sharing... the idea would be you don't pay the company ... a penny until you actually get the results of the value that they their clinical trial suggests should have happened in the real world*	*because – Because you're taking money away from other things you wanna do to invest in this and you've got lots of competing priorities. So, some way to tap into dedicated grants or funding that would enable homecare organizations to do the testing, do the evaluation and then support knowledge dissemination would be incredibly helpful. ...there's no mechanism to make it easy for us to do this.*
Innovator		*the health care professionals that we work with are really welcoming new ideas ... but health care is a very, very long process for changing things. Although they are very enthusiastic on a new project to come on board ... there's a lot of protocols to be changed to introduce a new product ... they can't actually just make a decision in one day ... there's protocols, processes, people ... that need to actually be made aware of it- it takes a long time.*		
Researcher	*I think that time to synthesize, or coordinate regulatory and reimbursement processes, um I think Health Canada should, should get more in line with um, CADTH and they need to be both at the table because I think um, especially for the device side they should be collecting um, the evidence*	*not just low tech versus high tech ...its not just the magnitude of the spend... Its also the power of the purchase...there are established players with a seat at various tables and their interests therefore, not necessarily in any nefarious way, are heard, and so physicians and surgeons, the*	*Places like Alberta, BC, with the big province-wide procurement agencies, and procurement organizations.... single province procurement and supply chain and, in BCs case shared service organizations that are serving health organizations ... they're serving health systems, ... that extend into the home and community care sector, even*	*if the technology is not costly and, small, residential or hospice organizations could buy it, then it's a matter of how do you convince this organization, that the device will pay off in, in one way or the other meaning... and this is where it's tricky...Because, if you make the argument that the technology will reduce the need for a, nurse, nursing staff or a*

that they need to get reimbursement um decisions	*tools that they use and their mechanism, to get them used. If they're home and community care, its just a total… So yes you're in the messiest space of all for technology adoption.*	*there I think its extremely hard for those procurement agencies to think about adoption in the home and community care sector because the, the ones that scream the loudest, The tyranny of the acute prevail. So the highest cost expenditures are still the Hips and Knees. The most influential interests are still the acute care hospitals, the doctors and the surgeons. So in their efforts, they get pulled. Now their doing two things, I think BCs initiative with value analysis teams, they've hooked procurement in some extent to the provincial wound care expert team in BC. Their capacity to bring some collective purchasing expertise to bear in aligning technology expenditure with clinical need*	*number of people taking care of the elderly think you are entering a very dangerous zone because what you do is put the technology against human delivered care… And you put this invention with how human resources are managed.. And…it will be tempting… to do what will save costs*

Sustainability	
Government	*…One other area of interest is health technology management…which is more of a life cycle approach to assessing technologies. It goes a little bit beyond an HTA… It would include disinvestment, while the technology is used to determine if it's still serving a real purpose or should it be disinvested… what are the best ways to use that technology. What should be the conditions for success to reap the most benefits from the technology throughout its life cycle."*

Industry	*"so the biggest one is the lack of organization and coordination. A lot of stuff just comes in and is never properly evaluated and by virtue of entering the hospital it is very difficult to get it back out again"*
	"the system I think just really needs to understand how to stop paying for a particular technology, de-listing these kind of items so that new things can come in.
	it's not the assessment, it's the health technology management. Because part of the problem with our system is that it never goes back to review the old stuff … So I think we need to take a look at how we're going to be exiting technologies that no longer meet our needs."
Innovator	
Researcher	

Co-creation	
Sub-theme:	a) end-user involvement throughout innovation process
Government	*"we have an element of co-design built into this program …(we) will be working with companies … and matching them with healthcare settings … to build evaluation projects. So the idea is that they have 6 -18 months to try out the technology in the in the actual clinical setting… and they form teams … the entrepreneurs… the clinicians…patients …whoever the end users are…the health procurement professionals- so the people …who would actually be filling out the paperwork to be actually buying this product"*
Industry	*the medical device sector has… some pretty big money in it…But the home health and wellbeing sector which a lot of those aging stuff … is really by far, [an] exponentially larger market and the only way that Canadian companies will be able to, position themselves and capitalize on that gross market is…if they can access the clinical and patient populations … at hospitals … Because the expertise and the capacities that exist in the hospitals can't be found any place else in the Canadian landscape*
Innovator	

Researcher	*"how patient preferences get in, it's a dog's breakfast of approaches. So you have a lot of, a lot of deliberative decision making processes, you'll have a lot of clinicians who will identify what patient preferences are…This is to my mind, quite an inadequate process in seeking input from patient organizations—typically only from patient organizations, and they do their best, or worst, …to gather some input, qualitative input, sometimes still too, quasi kind of research. Throw together a survey kind of questionnaire, hand it around to their membership. Umm, so it's not high quality evidence coming in, but some evidence is kind of brought to bear through those kind of patient input processes.*

Subtheme:	a) funding challenges: homecare	b) hidden costs of tech	c) siloed budgets in health care	d) need to coordinate health tech. with economic development and consider that adopting tech can save the health care system money
Government		*"… an eligible (program) expenditure includes any sort of training you might need to …get people in your office to be able to use this or even your patients to use it … any sort of culture and change management... any sort of supporting technologies so if you need software upgrades or … new computers or …a couple of smart phones to actually test out the app, that is also an eligible expense" – Government 9* *The cascading implications of changes in workflow is one of the things I think we need to get better at around the operational impact of the technologies…*	*the way the budgets are organized it's very, very difficult for folks to move resources or release resources now that you've included this transition cost and getting the new technology in place can be challenging…Depending on how it's implemented you may just increase your costs and may get the benefit. Like if it's done well you'll get the benefits but a lot of the times the benefits are obtained outside of that area…*	
Industry	*…our public delivery system, especially in home care is they sort of put their hands in [the air] and say "Oh I can't do innovation" and he challenged that and he set up an innovation center, the first one ever in a homecare agency in our province and they're out there to find the best of stuff that's gonna help people live well at home, that are older. And they have a rebuilt an entire home in their center and they have …different gadgets that are*	*"and there are products that would not fit into this pattern of use as it is traditionally developed in the health care system... the health care system is too rigid and has a problem to adapt... the benefit of a product sometimes requires a change in how the the care is being approached"* *There are a number of medical devices that would be useful for the elderly that*	*siloes in the health care system are another huge issue … health care is funded in this country based on primarily global budgets that are not reflective of the types of patients that are being treated and the volume of patients being treated and so hospitals are really disincentivized to really, to frankly want to have patients and all patients are looked at like a cost.*	*The system is being looked at as an economic driver and a way to prop up industry and as an industry in and of itself, because it is, it employs 2 million people in Canada and could lead to new industries that could drive Canada's economy. …so, that's a very, very big area*

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	being tested... when they validate it, that it works, then they help the company be around the table and the patients and their families and work out all the bugs in a safe environment. Then they make it available ...to any home care agency, so its scaled for the whole province.	*cannot be applied or used by the patient himself. So he needs help. And in the homecare setting, to provide this support by either a visiting nurse or something like that, it can be very, very difficult to do … certain products just need a second person to make this product work on the patient who needs the care.*		

| Innovator | *cumbersome policies when it comes to reimbursement, kind of demotivate innovators or companies from focusing on the latest innovations in this sector, and so then what ends up happening as a result of that… basically all the key stakeholders … are not as progressive … not as tech forward, because they just don't have the money. They're cash strapped and they're already overburdened and so the barrier…to adopting innovation is quite high…so for innovators … in this space, you might have a great product that could add a lot of value but there's no dollars and cents to pay for it and nursing staff and administrators… have like ten other priorities that they seem to be dealing with and, … there's lots of operators out there in the nursing home space who don't have the capacity to even look at innovations even if they wanted to because they're just so swamped with dealing with the day to day grind of running their business. It's very, very difficult, it's …disheartening.* | | *"you have now that gadget that everybody says that will save lives, so who's going to pay for it…How to tie in… the savings in the hospital in terms of getting people out of the hospital earlier. You can calculate that, but the hospital is not going to give you money because you got the person out. …."* | |

Researcher	*"this sector is significantly underfunded in every way shape and form, significantly under-resourced, massively complicated. No meaningful leadership, you know just a nightmare to organize, but deeply mission driven, hundreds of little organizations, mission driven, trying to do the best they can"-*			*So, I've, so in my advisory capacity then, I look at technologies with respect to, say, innovation procurement, where we're looking for, ummm, you know that sweet spot of— and that—those are specifically funded by the ministry government and social services to support umm, you know, pilot initiatives and experiments around the, I don't know, point 1 percent of—3% of med tech adoption. That is, that is the budget allocated to medical technologies in the health care system. So fairly small and narrow niche of focus that's the sweet spot there is to bring together health system needs with, um, the commercialization agenda or the innovation, um, the economic development agenda. So you're looking for made-in-Ontario technologies seem to have actual promise. And I'd say that's a niche from an HTA perspective.*

APPENDIX H: INFORMATION LETTER- CONCEPT MAPPING

Information Letter

Study Name: Policy and Regulatory Issues in Enabling Technical Innovation

Researchers:

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Introduction:

You are being invited to participate in a research study called "Policy and Regulatory Issues in Enabling Technical Innovation (PRI-TECH) conducted by Dr. Paul Stolee, Maggie MacNeil and Melissa Koch at University of Waterloo. This study is being conducted as part of the Aging Gracefully across Environments using Technology to Support Wellness, Engagement and Long Life Network Centre of Excellence (AGE-WELL NCE). AGE-WELL is a national research network in technology and aging whose aim is to help older Canadians to maintain their independence, health and quality of life through accessible technologies that increase their safety and security, support their independent living, and enhance their social participation.

Your participation in this study is entirely voluntary, so it is up to you to decide whether or not to take part in this study. Before you decide, it is important for you to understand what the research study involves. This letter will provide you with information about the study. It will explain the purpose of the research, your role in the research and potential benefits, risks and discomforts.

Please take the time to read the following information carefully.

Who is conducting the study?

This study is being conducted by: Dr. Paul Stolee, Maggie MacNeil and Melissa Koch from the School of Public Health and Health Systems at the University of Waterloo.

What is the purpose of the study?

This project will examine current policy and regulatory frameworks and processes that are relevant to the licensing, approval, regulation, reimbursement and evaluation of new technologies and innovations resulting from AGE-WELL and others involved in developing health technologies. Recommendations will be made 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 safe and timely adoption of promising and effective technologies. This understanding will be valuable in supporting the successful innovation and commercialization activities of AGE-WELL to the study aims to uncover the steps required for AGE-WELL and other technologies to be approved for licensing and marketing in different Canadian provinces.

What will happen?

You are being invited to participate in a workshop to learn from your knowledge/expertise in policy and regulatory issues related to new technologies and innovations. The workshop will be 3 hours in length. You will be asked to sort, rank and rate policy options, which have emerged through the earlier stages of the research project. The goal of this process is to create an actionable policy agenda for health technology innovation in Canada, specific to older adults.

Where will the study take place?

The workshop will take place in-person at a convenient location.

Will the study help you or others?

We hope to understand the regulatory and policy frameworks/processes that guide the implementation of new technologies. The knowledge gained through this study will directly help the commercialization and dissemination activities of AGE-WELL technologies that are being developed for older adults, and others involved in technology innovation. We hope to make recommendations for how innovation in health technologies for seniors can best be accommodated and stimulated within existing policy and regulatory frameworks which will help those within and beyond the network.

Will the study harm you?
There are no known risks to participating in this study.

What do you get for being in the study?

We are not providing any remuneration.

Is your participation voluntary?

Your participation in the study is completely voluntary and you may choose to withdraw from participating at any time. You can decline to participate in the study without penalty. If you agree to participate, you will be able to talk about whatever you are comfortable. If there is a question you do not want to answer, you may say, "I don't want to answer that question." Given the group format of this session we will ask you to keep in confidence information that identifies or could potentially identify a participant and/or his/her comments.

Can you change your mind or decide not to answer a question?

You can change your mind and stop being part of the study at any time. If you decide to leave the study, all of the data collected from you will be immediately destroyed.

What will happen to your information?

All personal information you give during the conversation will be held in confidence. Your information will be kept in a locked filing cabinet at the University of Waterloo, School of Public Health and Health Systems, and will be accessed only by members of the research team. *Your name will not* appear on any of the data. Only the project team will have access to entire focus group transcripts. With your permission, anonymous quotations may be used in the following way(s):

- in teaching and demonstration materials
- in scholarly papers, articles and other publications, and
- in presentations at academic, health care conferences

Electronic files containing study data will be password-protected, and will be destroyed after 7years. Data files will remain anonymous such that no names will be associated with the data. Each participant will be assigned an identification number, which will be used to organize the data. There are no conditions under which the confidentiality of data cannot be guaranteed.

Who can I contact if I have any questions?

If you have questions about the research or about your role in the study, please feel free to contact Dr. Paul Stolee by phone at (519) 888 4567 x 35879 or by e-mail (stolee@uwaterloo.ca) or Maggie MacNeil (Margaret.macneil@uwaterloo.ca). This study has been reviewed and received ethics clearance through a University of Waterloo Research Ethics Committee (ORE#30529). If you have questions for the Committee contact the Office of Research Ethics, at 1-519-888-4567 ext. 36005 or ore-ceo@uwaterloo.ca.

What will happen after the study is over?

The researchers will ask if you would like to be contacted in the future to go over the findings and give your opinions on the results. If you do not want to be contacted in the future, you may indicate this preference.

Conclusion

We are excited about this study and are looking forward to listening to your experiences and insights regarding policy and regulatory frameworks that impact the medical device and health technology industry. We sincerely hope that you will consider participating.

APPENDIX I: POINTS DIVIDED BY CLUSTER

Cluster 1: Legislative & regulatory

1. National policy to contain costs of telecommunication charges when used for health applications.
6. Make public (open data) generic and non identifiable data on costs, prices, quantity, utilization, quality, experience, etc of health care system consumption, production and outcomes available to industry, citizens, researchers and innovators.
7. Develop a procurement stream with tools and mechanisms that is independent of the day to day procurement processes that discourages innovative procurement. Innovate procurement within accountable and responsible limits agreed to all parties
25. Developing flexible agreements such as those that enable universities to hold Intellectual Property rights on publicly funded research
31. Develop national level standards and strategic priorities in health innovation, encourage better alignment between these two federal departments and their policy efforts
37. Health system need to be connected with economic development agenda with hospitals viewed as industrial development sites
38. Understanding how current competitive bidding processes can disadvantage small, local innovators (Ex. NAFTA)
44. Procurement reforms like risk-sharing, negotiation and value-based pricing
45. Moving to a value-based (as opposed to cost-focused) procurement process that is concerned with the life cycle of the technology
51. Reduce bureaucratic complexities within healthcare setting that slow implementation
55. More authority for local health care agencies to fund technologies
64. Strategies which address privacy issues working with health information
65. Procurement processes that do not create barriers for smaller innovation companies
91. Policy and regulatory processes align with the pace of technology development

Cluster 2: Funding & incentives

8. Develop a standardized template, structure and process with contracts or agreement for how organizations can carry out "trade offs" among budgets and departmental budgets in order to achieve improved outcomes for clients and health care delivery
14. Provide subsidies and/or funding support for technologies that have the potential to offset downstream healthcare costs
16. Payment reforms such as pay for performance schemes
17. Scale up and increase investment in existing successful funding programs (e.g. MaRS EXCITE and TECH Edmonton Health Accelerator)

21. Providing additional local/national seed funding or venture capital opportunities to spur innovation activities and decrease dependence on foreign investment

22. Federal or other resources to support innovation (e.g. developing a national medical devices partnership fund)

27. Payment reforms such as funding based on a patients continuum of care instead of episodic treatment

34. Programs that combine government funding with private pay to increase accessibility of technologies

39. Government funding structures that allow the transfer of funds between and among departments or across fiscal years.

42. Create incentives for health care providers to participate in innovation activities

46. A formal process for strategic resource allocation in health care setting

53. Create new innovation oriented tax credits

67. Allocation of funds to support the trialing of technologies in health care settings

75. Optimize existing innovation oriented tax credits

79. Health care funding that is flexible to transfer between years or departments

82. Government stimulus to offset the cost of a move to value-based procurement (ie which requires up-front costs in favor of long-term savings)

83. More resources during the early, high risk stages of technology development

90. Integrating health care budgets and incentives that support better patient outcomes

Cluster 3: Processes & pathways

2. Technologies are accessible in Canada (obtainable, affordable).

9. Be prepared to describe and explain the challenges and issues associated with failures in innovation so that mistakes are not repeated. Published literature has an aversion to negative results.

49. Develop strategies to help innovators scale technologies between different countries

54. Encourage development of technologies which respond to health care needs present in both publically funded and user-pay health care systems

62. Decision timelines around adoption are articulated between innovators and healthcare system payers

63. Support for collaborations between innovators and health care operators

72. Clear communication between decision-makers and innovators about willingness to pay

Cluster 4: System capacity

12. Develop and provide structure, processes and funding to encourage and expect usability analysis and human factor analysis to be used in supporting innovation with safe adoption of effective technologies. Results, whether + - or neutral to be public

13. Define clear pathways that lead from real world trials to adoption at the start of adoption consideration and deliberation
32. Products which allow for private and public sales
35. Resources to support patient recruitment for co-creation of technologies
50. Enable the home care sector to fund, test and implement new technologies
59. Tools that help health care systems consider the ways health technologies impact opportunity costs, organizational issues and budgets
70. Better understanding of health technology management and ways to disinvest
85. Encourage the development of affordable technology

Cluster 5: Evaluation

3. Ensure technologies are evidence-based.
5. Develop methods, processes, techniques, monitoring and reporting mechanisms to demonstrate the negative consequences to the health of the public of the opportunity cost and financial losses due to an inability to innovate from the path dependency
10. Emphasize the necessity for innovative technologies to demonstrate and report on the direct line of sight between the innovation and clinical, quality and or cost effectiveness of the innovation in the health care setting and as a benefit to the clients
15. Implementing user experience analysis and user acceptance testing during evaluation
18. Recognizing that technologies need to be adapted to various healthcare settings
30. Encourage innovators to think ahead to assessment (what data do they need)
43. Formalizing methods for patient involvement in health technology assessment
48. Health technology assessments are relevant and understandable for a particular context
57. Health technology assessment processes align with the timelines of decision-makers
66. Innovators understand the data they need to produce to participate in health technology assessment
84. Alternative approaches to assessment for promising technologies (e.g. allow for adoption and assessment to occur simultaneously)
86. Open access to, and contextualization of, existing evaluations of health technologies
88. Technology assessments are designed to incorporate a variety of metrics or evidence types (e.g outcomes, feasibility, cost effectiveness, budget and care pathway impacts)
93. Technology assessments are designed to incorporate a variety of perspectives (e.g. social, ethical, legal, patient preference)
95. Developing metrics for evaluating the effectiveness of technologies that consider societal impacts of health innovations as opposed to using metrics such as number of patents, licensing partnerships and intellectual property agreements

Cluster 6: Patient & end-user involvement

> 20. Build awareness and understanding among developers of unmet health system priorities (e.g. so technologies are driven by health system need)
>
> 23. Technology that has a useful interface for care providers that fit with existing technology and processes
>
> 29. Innovators/technology developers need to better understand the practical aspects of health delivery (e.g. resulting in more relevant technology)
>
> 33. Encourage the development of simple and easy to use technology for older adults
>
> 40. Increase awareness of implementation in health care settings besides acute care (e.g. home care and long-term care)
>
> 56. Involvement of patients across all stages of innovation
>
> 58. Create opportunities for innovators to consult with clients, health care professionals early (ie slow iterative development stage to understand target population)
>
> 60. Involvement of patients and caregivers in policy/process change
>
> 61. Encourage innovators to think ahead to implementation (where will their tech fit and who will pay)
>
> 80. Understanding health care provider perspectives about integrating technology in their work
>
> 81. Have patients define problems for developers to address
>
> 87. Bust myths about older adults and technology (e.g. their willingness and ability to use it)
>
> 92. Increase awareness that HTA recommendation does not guarantee widespread adoption

Cluster 7: Communication channels

> 4. Work with unions and associations representing health care workers in reviewing labour contracts with a view to identifying and amending clauses and serve as a disincentive or barrier to facilitating safe and effective diffusion of health care innovation
>
> 11. Develop and raise awareness and understanding of risk sharing agreement templates that could be adopted by health care delivery organizations, innovators and industry.
>
> 19. Strategies to bolster partnerships between stakeholders (tools to promote communication, information sharing and reduce duplication)
>
> 24. Earlier consideration and understanding by innovators of the regulatory process
>
> 26. Create opportunities for innovators to consult with regulators, reimbursers early
>
> 28. Developing materials for innovators, including a procurement how-to-handbook; standard bid templates and procurement best practices
>
> 36. Understanding professional college policies on scope of practice before introducing a new technology
>
> 41. Build the business skills of innovators

47. Acknowledging the time and cost associated with training staff to use a new technology

52. Policy makers need to better understand the practical aspects of health care delivery (e.g. resulting in the development of innovation policies that are reflective of the needs of the health care system)

68. Promote the development of innovation ecosystems (which can combine resources between partners, and link different regional partners)

69. Promote early engagement between medical device industry and regulators at Health Canada

71. Encourage better linkages between innovation departments, and their health policy directions in different provinces

73. Understanding how new technology engages with existing legislation (e.g. regulatory processes and software, multicomponent devices etc)

74. Support technology transfer offices in better understanding and responding to end-user needs to benefit the health care system

76. Acknowledge the role that arms-length agencies can play linking partners from different sectors (innovators, regional partners, institutions, governments, international partners)

77. Develop strategies to help innovators scale technologies between different jurisdictions (i.e. provinces)

78. Encourage transdisciplinary working within ecosystem partnerships

89. Promote partnerships between technology companies and venture capital firms

94. Strategic plans of health care organizations are externally accessible

APPENDIX J: GO ZONE STATEMENTS

3. Ensure technologies are evidence-based.

10. Emphasize the necessity for innovative technologies to demonstrate and report on the direct line of sight between the innovation and clinical, quality and or cost effectiveness of the innovation in the health care setting and as a benefit to the clients

13. Define clear pathways that lead from real world trials to adoption at the start of adoption consideration and deliberation

14. Provide subsidies and/or funding support for technologies that have the potential to offset downstream healthcare costs

15. Implementing user experience analysis and user acceptance testing during evaluation

20. Build awareness and understanding among developers of unmet health system priorities (e.g. so technologies are driven by health system need)

26. Create opportunities for innovators to consult with regulators, reimbursers early

28. Developing materials for innovators, including a procurement how-to-handbook; standard bid templates and procurement best practices

30. Encourage innovators to think ahead to assessment (what data do they need)

35. Resources to support patient recruitment for co-creation of technologies

38. Understanding how current competitive bidding processes can disadvantage small, local innovators (Ex. NAFTA)

40. Increase awareness of implementation in health care settings besides acute care (e.g. home care and long-term care)

47. Acknowledging the time and cost associated with training staff to use a new technology

50. Enable the home care sector to fund, test and implement new technologies

56. Involvement of patients across all stages of innovation

58. Create opportunities for innovators to consult with clients, health care professionals early (ie slow iterative development stage to understand target population)

60. Involvement of patients and caregivers in policy/process change

61. Encourage innovators to think ahead to implementation (where will their tech fit and who will pay)

63. Support for collaborations between innovators and health care operators

64. Strategies which address privacy issues working with health information

66. Innovators understand the data they need to produce to participate in health technology assessment

67. Allocation of funds to support the trialing of technologies in health care settings

80. Understanding health care provider perspectives about integrating technology in their work

81. Have patients define problems for developers to address

86. Open access to, and contextualization of, existing evaluations of health technologies

88. Technology assessments are designed to incorporate a variety of metrics or evidence types (e.g outcomes, feasibility, cost effectiveness, budget and care pathway impacts)

95. Developing metrics for evaluating the effectiveness of technologies that consider societal impacts of health innovations as opposed to using metrics such as number of patents, licensing partnerships and intellectual property agreements

APPENDIX K: CASE EXAMPLE

A group of proactive and community-minded Senior Citizens, Family & Caregivers, Home Care clinicians and Senior Administrators have become aware of a new home sensor system that may enable independent living for those with advancing age and increased health needs.

The sensor system has the ability to send alerts to caregivers by tracking and reporting older adults' temporal and spatial movement patterns. There is potential for these movement patterns to then be monitored and compiled as data.

Interventions could be established from this data to mitigate other health risks or declining health states. To make a well-informed decision, a multiplicity of issues needs to be considered.

APPENDIX L: PHASE 1 PARTICIPANTS' 9 CLUSTER CONCEPT MAP
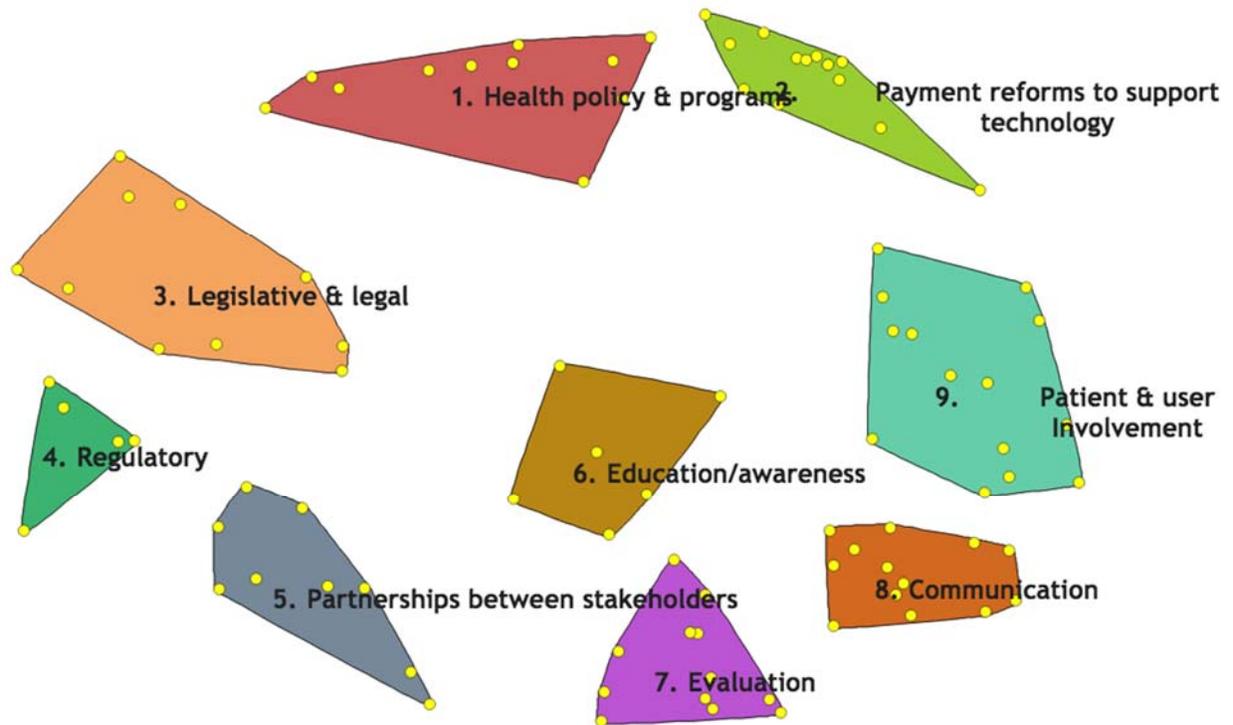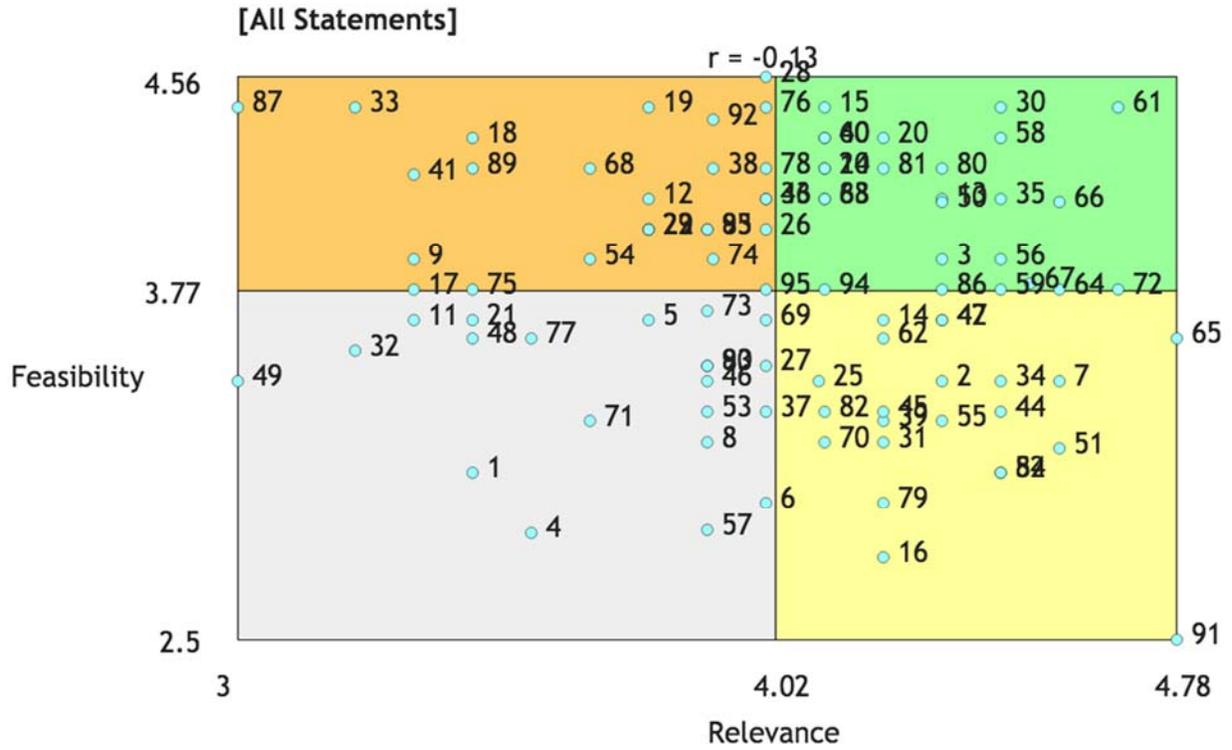
APPENDIX N: FINAL QUESTION LIST FOR FOCUS GROUP

1. What challenges exist to installing a technology in an older person's home as compared to a hospital or a retirement home?

2. Who should pay for health technologies such as the one identified in the case example?

3. Who should own older adults' health information?

4. What could be done to help companies developing technologies like the case example to understand our health care system?

5. How can we make technologies inclusive for disadvantaged groups of older adults?

(ex. low-income, visible minority groups, new immigrants, indigenous, sexual minorities)

6. How should we address negative assumptions about older adults' technology use?

7. How could we ensure the technological solutions that are developed are what our health care system needs?