INNOVATION TO IMPLEMENTATION PATHWAYS:

APPROACHES TO INFORMING ADOPTION AND IMPLEMENTATION OF HEALTH TECHNOLOGY

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Executive Summary

- This report provides an overview of evaluation tools and the main theories, models, and frameworks that have been applied to non-drug health technology selection and implementation.
- Canada does not have a national standardized process for decisions on non-drug health technology.
  - Health Canada, provincial and territorial government branches, and independent organizations such as the Canada's Drug Agency – L'Agence des médicaments du Canada, all have roles in evaluation and/or technology selection.
- Health Technology Assessment (HTA) is the primary evaluation tool. It uses evidence synthesis and economic evaluation as the primary approach for evaluating innovations before implementation.
  - HTA use may be limited by lengthy completion times, human and financial resource requirements, lack of familiarity with HTA among decision-makers, negative perception of evaluation approaches or goals, and methodological obstacles, such as difficulty capturing required data.
  - Several approaches have been proposed for addressing HTA limitations, such as using multi-criteria decision analysis, using more advanced HTA techniques, or increasing collaboration between HTA organizations and policymakers.
- Many implementation theories, models and frameworks (TMFs) have been developed but few are used frequently for understanding health technology implementation.
  - Several TMFs have been applied to support policy or practice decision-making related to health technology implementation, but there is too little data to evaluate what contributions they make toward implementation success.
- TMFs can potentially be used to strengthen HTA evaluation criteria, such as technology usability, contextual factors, and implementability.

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Introduction

There is a growing range of non-drug technologies that could be adopted for use in Canada's health system. These include medical devices, assistive devices, diagnostics and screening, health information systems, and potentially other technology-based innovations[1]. Due to limited budgets and human resources, Canada's health care policymakers and organization leaders are under pressure to ensure that health technologies they select for implementation or coverage within publicly funded programs will provide value. This report aims to support decision making by providing an overview of evaluation tools and prominent theories, models, and frameworks that have been applied to health technology adoption and implementation.

Regulatory controls vary for different types of health technology. Some that are perceived as having low risk of patient harm, for example some digital apps, are not included under health technology regulations and require little or no pre-implementation evaluation[2], while others, ranging from bandages to blood glucose monitors[3], are regulated more strictly. Regulatory requirements also differ between countries, and sometimes between jurisdictions within countries[2].

Canada does not have a national standardized process for making decisions about non-drug health technology adoption or coverage[4-7]. Because health service delivery in Canada falls mainly under provincial and territorial authority, the federal government's role is limited to the regulation of health technologies that require approvals under national health standards legislation. Health Canada's responsibilities include regulatory approval for drugs, medical devices, and natural health products[3]. Within Health Canada, the Medical Devices Directorate, "approves a new health technology for which reimbursement policies need to be formulated at the provincial/territorial levels"[8].

At the provincial and territorial level, each of the thirteen provinces and territories has formal processes for decisions around coverage of health technologies[5]. Four provinces have agencies for evaluating new technologies: Health Quality Ontario[9], now part of Ontario Health; Québec's Institut national d'excellence en santé et en services sociaux (INESSS); British

Columbia's Ministry of Health Technology Assessment Office (BC-HTAO); and Alberta's Institute of Health Economics (IHE)[6]. Other provinces and territories draw on reports from Health Canada or from independent health technology assessment organizations.

The primary pan-Canadian independent assessment organization is Canada's Drug Agency – L'Agence des médicaments du Canada (CDA-AMC), previously known as the Canadian Agency for Drugs and Technologies in Health (CADTH)[4,6,10,11], whose mandate is to provide Canada's health system leaders with independent evidence and advice so they can make informed drug, health technology, and health system decisions[12]. CDA-AMC provides assessment for both drug and non-drug health technologies, and includes a Health Technology Expert Review Panel to provide guidance on medical devices and other non-pharmaceutical interventions[10]. At least two other nationwide, sixteen provincial and territorial, and multiple academic and hospital-based organizations also evaluate health technologies[6].

Although collaboration between Canadian regulatory agencies and independent assessment organizations has been growing[6], administrative and organizational divisions can contribute to communication siloes around people working on similar topics, and to lack of coordination in the assessment and dissemination of information[7]. In addition, innovation departments and health departments within governments often develop separately from each other and sometimes have contradictory goals[5-7]. Fragmented communication can be improved by using shared terms of reference and/or approaches to examine related topics or problems. A range of evaluation techniques and implementation theories, models, and frameworks are discussed below that have been developed and applied to support decision making around adoption of health technology.

Evaluation Tools to Aid Health Technology Decision Making

Evidence-informed policy making in healthcare, "involves the use of research evidence along with expertise, existing public health resources, knowledge about community health issues, the local context and community, and the political climate"[13]. Health technology assessment (HTA) is a tool for evidence-informed decision making and has become the primary approach for evaluating innovations prior to their implementation at scale[14]. HTAs use evidence synthesis and economic evaluation techniques to support recommendations about the adoption of health technologies[15]. HTA approaches have become increasingly integrated into technology adoption decision making[14].

Health Technology Assessment

Although there is no single authoritative definition of, or guidance for, HTAs[14-18], the International Network of Agencies for Health Technology Assessment, a network of fifty-three HTA agencies in countries around the world, defines it as, "a multidisciplinary process that uses explicit methods to determine the value of a health technology at different points in its lifecycle. The purpose is to inform decision-making in order to promote an equitable, efficient, and high-quality health system"[19]. The ways HTAs are integrated into decision making processes vary, with several general modes: (1) HTA preceding and guiding procurement; (2) procurement referring cases to HTA for evaluation; (3) systematic processes combining HTA and procurement; or (4) non-coordination where HTA and procurement agencies operate as distinct niches with minimal reference to each other[7].

Despite variations, there are many points of general agreement about what constitutes HTA and how evaluations should be carried out. World Health Organization (WHO) guidance outlines the types of interventions or technologies that HTAs should be applied to, including medical devices, assistive devices, medicines, medical services, procedures, diagnostics, screening, vaccinations, and other relevant health programs[1]. HTAs are done to inform procurement or policy decisions and it is essential that they are performed in ways that align with decision makers' questions related to a technology's capacities, its applicability for the organization or agency's purposes, and its suitability for coverage or reimbursement[14,17]. It is important that HTA processes involve relevant stakeholders and use effective engagement and communications to disseminate its findings[14,17]. Finally, credibility of HTA processes is essential.

There is wide agreement that HTAs should use adequate and fair methods that are transparent and minimize biases wherever possible[1,14,17,20-22].

A central element of HTA is selecting suitable criteria to use for evaluating technologies. HTA evaluation criteria consistently include data on health outcomes, such as impact on public health[1] and the clinical effectiveness and/ or safety of interventions[4,5,8,11,16,23,24]. HTAs also collect data on budget impacts or costs associated with technologies. This is often framed in terms of cost-effectiveness[1,4,5,8,11,15,17,18,24,25], but may also be captured as direct costs[23], or overall resource use[1]. As *Table 1*, shows, HTAs may consider a range of additional criteria, including patient preferences[4], stakeholder or political preferences[4,23], implementation feasibility[4,5,11,24,26], and legal, ethical or equitability implications[11,17,23,27], among others.

TABLE 1: Criteria considered* in HTA processes

- Resource use
- Cost – comparison to other treatment or effectiveness
- Budget impact
- Risk
- Results of clinical trials
- Clinical efficacy, effectiveness, safety
- Unmet need (for new treatment)
- Clinical benefit compared to standard of care
- Appropriate and relevance compared with other technologies
- Social values - impact on equity, vulnerability of patient groups
- Severity of disease/Disease specific criteria

*These criteria are summarized from the literature reviewed and not a comprehensive list or standard practice in HTAs conducted in Canada

Canada's HTA processes within provincial and territorial health authorities and in hospitals are formal and health technology evaluations follow common patterns: request initiation; filling information requirements; making recommendations; and arriving at decisions[4]. Stages in CDA-AMC's process are similar and include topic identification and refinement; assessment protocol development; evidence retrieval; evidence synthesis; report writing; peer reviewing[11]. Approximately 66% of health authority and hospital HTAs in Canada also include post-implementation follow-up evaluations, but few organizations have processes for reviewing existing technologies[4]. De-implementation of obsolete or outdated technology is usually considered informally, with evaluations conducted on an as needed basis[4]. HTAs by provincial and territorial agencies and health service delivery organizations use similar criteria, such as clinical effectiveness and safety, and budget impacts[4,5,8,16]. Some also consider ethical implications[16], and how technologies will fit with care pathways once they are implemented[4,5,16]. HTAs carried out by CDA-AMC use clinical review and economic analysis to evaluate cost-effectiveness[11], and may also consider ethical implications, societal perspectives, cultural appropriateness and equity[10].

Limitations of Health Technology Assessment

Application of evidence-informed decision-making models is limited by a range of factors, including time, staff capacity, budgetary resources, complicated or difficult to interpret instruments, and unclear organizational expectations or values[13,28]. HTAs face similar limitations and barriers:

- Lengthy completion times[1,6,8,11,18,27,29], with the WHO reporting up to 2 years for HTA evaluations[1];
- Human and financial resource requirements[1,4,18], with the WHO estimating costs from $US 3000 to $US 650,000 [1], depending on scope and complexity;
- Limited technical understanding among decision-makers about HTA approaches[18];
- Resistance and negative perceptions about HTA approaches or goals, such as using cost as a criterion for decisions about care[1,18,20,29].

Even when HTA evaluation findings related to a health technology are favourable, recommendations do not necessarily result in health technology approval or adoption at the decision-making level[7]. Non-approval or non-adoption can occur when administrative responsibility for the implementation decision is not clear, or when people or departments involved in HTA are not directly involved in approving technologies for implementation[5,7,29].

While there is general agreement about the need to capture data on clinical effectiveness and costs, HTA approaches face several methodological obstacles. These include:

- Lack of consensus about some variables, such as using Quality Adjusted Life Years to measure outcomes[21], delineation between organizational impacts and economic factors in analyses[25], or use of value-based pricing[5,16,27] versus risk-based pricing[15];
- Practical challenges stemming from the need to capture comprehensive data on a wide range of variables[20,21];
- Evaluation recommendations becoming obsolete if the systematic evidence reviews, cost analyses, and syntheses they are based on are not updated[30].

In Canada, methodological differences between provincial HTA agencies and independent organizations can make collaboration challenging[6], particularly for the validation of analytical models[11].

HTAs also have drawbacks for application to some types of technology or areas of healthcare. The time required to conduct rigorous HTA evaluations makes them poorly suited to assessment of innovations in rapidly developing fields, such as digital health technologies and the application of artificial intelligence in health care[8]. HTA methods are also difficult to apply when making decisions that involve a significant degree of uncertainty around variables[15]. For example, HTAs are rarely used for evaluating public health initiatives, as it is methodologically difficult to define the impacts of those interventions[20]. Delimiting impacts may also be an obstacle to using HTA to evaluate technologies that impact several outcomes for patients or for the health system.

Options for Addressing HTA Limitations

Four approaches have been proposed to address limitations of HTA evaluation. Options include several expanded HTA methods and increasing collaboration between HTA organizations.

1. Multi-Criteria Decision Analysis (MCDA): offers structured ways to provide outcome measurements beyond cost and clinical outcomes, and evaluate wider societal impacts[22].

- Application of MCDA is well established[1,11,16,22,31-36], is part of HTA processes in Ontario[11,16], and has been used in Alberta[31];
- MCDA criteria are open and depend on the decision/ problem being considered[33,34,36], can be expanded as long as criteria are unambiguous, comprehensively cover range of consequences, direct, operational, and understandable[35,36];
- Suggested practices include: (1) the inclusion of a deliberative process; (2) using qualitative and quantitative approaches and decision rules; and (3) ensuring the specification of MCDA is appropriate and reflects societal preference[22].

2. Life-Cycle HTA: developed to address challenges standard HTAs face related to health system sustainability, changing evidence, and uncertainty[15].

- Uses risk-based pricing and research-oriented managed access to generate additional data about sustained performance following a technology's adoption[15];
- Supports recommendations about adjusting use or de-implementing technology in response to evolving evidence[15].

3. Living HTA: based on the concept of treating HTAs as a form of "living" document.

- Evaluation is updated periodically in response to technology developments, changing evidence, and the introduction of competing technologies[30];
- Updating HTAs and revising recommendations is especially important for rapidly developing digital health technologies and artificial intelligence[8].

4. Increased collaboration across HTA organizations and with policymakers: to promote sharing results more efficiently and help reduce duplicating HTA evaluations.

- Could be facilitated through development of standardized methods for HTAs[6,37];
- Could also be encouraged by establishing an online platform housing a regularly updated directory of HTA agencies and expertise, and for sharing information, such as ongoing and completed HTAs, and topics under consideration for future analyses[6].

While options for addressing limitations of HTAs hold promise, they may also compound barriers that conventional HTAs already face, such as time needed to conduct analyses, budgetary constraints, and limited human resources[30,35]. Partial automation of data collection and analysis has been suggested as a way to reduce additional labour and time requirements but automated processes would depend on achieving data standardization and interoperability between data systems used by organizations[30]. In addition, Life-cycle HTA would require that contracts with health technology companies grant HTA or health service organizations ongoing access to performance data for re-evaluation, and include options to de-implement the technology when it no longer meets requirements[15]. Changes in HTA processes will also be subject to organizational expectations and values. Stakeholders may have different interests and disagree about what values should be used for criteria[22], which could hinder collaboration. Even when stakeholders agree about goals, increased collaboration would involve establishing collaborative networks with formal organizational structures, defined vision and objectives, and terms of reference[6].

Implementation Theories, Models and Frameworks

While evaluation tools like HTA are valuable for selecting which innovations to adopt, theory-informed implementation can help integrate new health technology so that it delivers benefits for patients and the health system. There are over 100 theories, models, and frameworks (TMFs) designed to help better understand implementation and the factors that support or hinder the adoption of new policies, practices, or technologies in organizations[38-40].

Implementation TMFs in Health Technology Research

Despite the wealth of approaches available, literature reviews show that only a small number of implementation TMFs are used frequently in research examining health technology implementation[41-45]. To identify which TMFs have been used most often for evaluating health technology implementation initiatives, an analysis was conducted comparing the number of evaluation articles indexed in PubMed Central that use a specific TMF with the number of years since that TMF was first published (*Table 2*).

TABLE 2: TMF Application Frequencies in PubMed Central Indexed Publications

Theory/ Model/ Framework	Published Evaluations per Year
CFIR	4.93 (74 since 2009)
NASSS framework	3.86 (27 since 2017)
Theoretical Domains Framework/ Behaviour Change Wheel	1.89 (36 since 2005)
RE-AIM framework	1.48 (37 since 1999)
UTAUT	1.14 (24 since 2003)
Normalization Process Theory	1.12 (19 since 2007)
TAM	0.65 (21 since 1992)
Diffusion of Innovations Theory	0.48 (10 since first health sector article in 2003)
EPIS model	0.31 (4 since 2011)

These commonly used TMFs vary in their approaches and in the theoretical constructs they recommend for analyzing health technology implementation. Nilsen's typology of five implementation theory categories helps make sense of the variations[46].

1. Process Models: intended to describe or guide translation of research into practice[46].

- *Exploration, adoption/ Preparation, Implementation, Sustainment (EPIS)* is a multi-level process model. It proposes that implementation progresses through four phases: exploration, adoption/preparation, implementation, and sustainment. Actions during each phase are influenced by aspects of the outer context surrounding an implementing organization, such as the sociopolitical environment and funding availability, and the inner context, such as organizational characteristics[47].

2. Determinant Frameworks: designed for identifying barriers and facilitators that influence implementation outcomes[46].

- *Technology Acceptance Model's (TAM)* premise is that acceptance is determined by a technology's perceived usefulness and perceived ease of use. Specific constructs focus on individual-level user characteristics[48-50].
- *Unified Theory on Acceptance and Use of Technology (UTAUT)* identifies individual-level determinants of intention and usage: performance expectancy; effort expectancy; social influence; facilitating conditions. It treats a user's gender, age, experience, and voluntariness of use as moderators influencing relationships between key determinant variables[51].
- *Consolidated Framework for Implementation Research (CFIR)* classifies determinants according to 5 domains: intervention characteristics; outer setting; inner setting; characteristics of the individuals involved; process of implementation. Each domain has a detailed set of associated constructs[52,53].

3. Classic Theories: are developed outside implementation science but can help understand and/or explain aspects of implementation processes[46].

- *Diffusion of Innovations* theory was developed for use in sociology and social psychology[54,55]. It proposes that people adopt an innovation at different rates and that a potential adopter's orientation toward an innovation is based on multiple individual and contextual factors, such as their experience and their economic and social position[54-56].

4. Implementation Theories: are developed specifically to help understand and/or explain aspects of implementation[46].

- *Normalization Process Theory* treats implementation as a complex process in which innovations become normalized through routine actions. Analysis of initiatives considers four main components: coherence; cognitive participation; collective action; reflexive monitoring[57-59].

- *Theoretical Domains Framework* and *Behavior Change Wheel* are closely affiliated approaches that aim to explain behaviour change during implementation[60,61]. The Theoretical Domains Framework classifies constructs in twelve domains related to behavior change: knowledge, skills, social/professional role and identity, beliefs about capabilities, beliefs about consequences, motivation and goals, memory, attention and decision processes, environmental context and resources, social influences, emotion regulation, behavioral regulation, and nature of the behavior[60]. The Behavior Change Wheel framework describes implementation in terms of a behavior system, based on individuals' capability, opportunity, and motivation, at the center of nine implementation functions[61].
- The *Non-adoption, Abandonment, and challenges to the Scale-Up, Spread, and Sustainability (NASSS)* framework is intended to help describe multiple influences on complex implementation initiatives. It analyzes implementation in terms of seven domains: problem the initiative addresses, technology/solution, value proposition, adopter system (comprising professional staff, patient, and lay caregivers), organization(s), wider context (institutional and societal), and interaction and mutual adaptation between all these domains over time[62].

5. Evaluation Theories: are meant to help systematically evaluate implementation activities[46].

- The *Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM)* framework evaluates interventions in terms of dimensions that create intervention impact: reach, effectiveness, adoption, implementation, and maintenance[63]. Reach, effectiveness, and maintenance operate mainly at individual levels, while adoption and implementation operate mainly at organizational levels[64].

TMFs used for studying organization-level implementation decisions

Several of the TMFs above focus on factors contributing to adoption by end-users, such as clinicians or patients, and have not been applied to evaluations concerned with decision-making by organization leaders or managers. The TAM and UTAUT models are examples.

Although both were identified as prominent TMFs in multiple literature reviews[41-45] and both were used often in evaluation articles indexed in PubMed Central, none of the articles applied them to investigating policy or management-level decisions about whether to implement technologies or described their use by organizational leaders to help decision-making.

Among twenty-one articles that applied TMFs to look at leadership or management (*Table 3*), CFIR was used most frequently. It was applied in five articles by itself and used in two articles in combination with another TMF. The NASSS framework and Normalization Process Theory were used in four articles each, and other TMFs were each used in one or two articles.

Seventeen of the twenty-one articles that used TMFs to examine leadership or management-level decisions relied exclusively on qualitative methods. Interviewing was the main method of data generation, used by itself in ten articles[65-74], and in combination with other qualitative methods in five others[75-79]. Two articles that used qualitative approaches did not use interviewing; one used data generated during workshops[80], and one analyzed statements provided in open-ended questions in a survey[81]. Three articles used mixed qualitative and quantitative methods. Two combined interviewing with quantitative surveys[82,83], and one used a survey alongside direct observation of people in service delivery settings[84]. Only one article applied purely quantitative research methods, a survey based on CFIR constructs[85].

TABLE 3: TMF Application to decisions by Organizational leaders or Managers

Theory/ Model/ Framework	Articles
CFIR	5 [68-70,81,85]
• CFIR with Theoretical Domains Framework	1 [78]
• CFIR with RE-AIM	1 [79]
NASSS	4 [66,67,77,80]
Normalization Process Theory	4 [65,75,76,82]
RE-AIM	2 [72,83]
Diffusion of Innovations	2 [74,84]
Theoretical Domains Framework/ Behavior Change Wheel	1 [71]
EPIS model	1 [73]

Implementation TMFs at Work

The ways implementation TMFs were used varied in articles examining leadership or management decision-making in health technology initiatives. Sixteen of the twenty-one articles used TMFs only to guide development of research questions or as an aid in data analysis[65-

[74,77,79,81,83-85]. Five articles applied TMFs as some form of aid for policy or practice decision-making[75,76,78,80,82]. Of those, three used Normalization Process Theory[75,76,82], one used NASSS[80], and one used CFIR alongside the Theoretical Domains Framework[78]. All five articles relied on qualitative research methods, with one also using a quantitative survey tool[82].

Two articles that applied Normalization Process Theory examined the "delivering assisted living lifestyles at scale" (dallas) program in the United Kingdom[75,76]. The dallas UK program was a multi-year initiative from 2012 to 2015 that delivered multiple digital health promotion services to a wide range of recipients across both urban and rural areas. Normalization Process Theory was applied throughout the initiative to analyze implementation processes, with findings communicated to decision-makers as they were generated to help adjust the program[75,76]. The other article describing the application of Normalization Process Theory used it in British Columbia to evaluate potential future adoption of a shared decision-making e-personal health record system[82]. The TMF was used to design the evaluation, which applied the quantitative Normalization MeAsure Development (NoMAD) tool based on Normalization Process Theory concepts[86]. The study found support for the idea of applying the technology, and identified a need for systematic efforts if it was to be successfully implemented[82].

The NASSS framework was applied in one study, which was conducted in Sweden[80]. It used a pilot version of the NASSS Complexity Assessment Tool (NASSS-CAT)[87] during development of a potential initiative to implement a point-of-care dashboard supporting schizophrenia treatment. The study found that use of the NASSS framework and the NASSS-CAT tool helped provide stakeholders with a better understanding of the complexities they would face during implementation and identified aspects that they might otherwise have overlooked[80].

The remaining example applied CFIR with the Theoretical Domains Framework[78] in a US hospital prior to implementation to identify likely determinants of success of a telehealth-enhanced cardiac rehabilitation program. Insights from the evaluation identified potential barriers which then were considered during user-centred program design[78]. Outcomes from the subsequent program implementation study have not been published yet[78].

All the articles where implementation TMFs were used to inform decision making reported that people working on health technology initiatives found them useful[75,76,78,80,82]. However, with so few studies, and with the studies using data that are difficult to compare across cases, it is not currently possible to conclude precisely what contributions TMFs make to implementation success when they are applied to assist decision makers.

These findings echo observations made by others examining the use of implementation TMFs. Literature reviews have identified many TMFs[41-43], but most are not used in ways that provide insights into how organization leaders decide which technologies to adopt, or to assist decision makers during implementation processes. Some of the TMFs, such as TAM and UTAUT, focus on acceptance by end-users[42,43,45] and are not easily adapted to decision making by organizational leaders. Other implementation TMFs, including some that are widely used, have not been rigorously applied or tested in evaluation studies[38,88]. Reviewers also noted that implementation TMFs tend to be used for post-implementation research, rather than to guide implementation activities, and typically rely heavily on qualitative research methods[41,89,90].

Potential Future Steps

Healthcare practitioners are interested in theory mainly when it can help design and implement interventions more effectively[91], and, as mentioned in the introduction, Canadian healthcare policymakers and managers are under pressure to show that health technologies selected for implementation produce results. There is too little published evidence to show whether applying TMFs will improve implementation outcomes, but HTA is well established in Canada and insights from TMFs could potentially contribute to improved HTA practices.

Use of suitable evaluation criteria is essential for HTA assessments. Clinical effectiveness and cost are central to all HTA evaluations, with some variations in approaches[1,4,5,8,11,15-18,23-25], but other criteria are more varied and implementation TMFs could strengthen how those variables are framed. For example, some HTAs consider patient preferences as part of the evaluation process[4]. TAM[48-50], UTAUT[51] and Diffusion of Innovations[54-56] all focus on understanding why end users adopt or reject new technologies. Using concepts from those TMFs in assessments could provide insight into the usability or acceptability of health technologies. Similarly, several implementation TMFs provide structured ways of looking at contexts where implementation takes place. The EPIS framework includes impacts from sociopolitical factors[47], CFIR examines the outer context and inner organizational settings shaping implementation processes[52,53], and NASSS looks at adopter systems, organizations and wider context[62]. Any of these TMFs could be used to inform HTA evaluations.

Implementation feasibility is already a criterion in some HTA evaluation approaches[4,5,11,24,26] and an important contribution TMFs can make is through providing insights into how implementation occurs. CFIR would be suitable in that role, as it examines intervention characteristics and processes of implementation[52,53]. Normalization Process Theory's attention to the coherence, cognitive participation and collective action of people in the implementing organization, and implementation monitoring[57-59] could help inform HTA evaluation of health technology implementation feasibility. Several domains in the NASSS framework could also be adapted to HTA evaluation, including adopter systems, organizations, wider context, and interaction[62]. Although often considered an evaluation tool to be applied after implementation, the RE-AIM framework is also intended for use in planning[92]. It has been applied prospectively in health technology implementation[79], and the framework's adoption and implementation measures[64] could be adapted for use in HTA processes. Although they were not specifically HTA evaluations, the projects described above using the Normalization Process Theory, NASSS, CFIR (with TDF) TMFs demonstrate that they can be applied as part of decision making or implementation planning processes[75,76,78,80,82].

Like using Multi-Criteria Decision Analysis[35], Lifecyle HTA[15] or Living HTA[30], using TMFs to strengthen pre-implementation evaluations could face obstacles due to the need for additional resources. Applying TMFs as part of HTA processes would involve generating and analyzing new data, as was done in BC[82], Sweden[80], the UK[75,76], and the US[78] when TMFs were used prospectively to support decision making, adding to the cost and personnel required to conduct the evaluation.

A practical way forward would be for HTA agencies in government and independent HTA organizations to recommend conditional adoption of health technologies, similar to the approach proposed for Life-Cycle HTA evaluation[15]. Conditionally accepted technologies could be implemented but would require an initial period of monitoring and data generation informed by HTA and TMF requirements. That data would enable evaluation of specific variables, such as clinical outcomes, population health impacts, and actual costs, as well as the feasibility and integration of the technology adoption. Depending on results from the new data, a health technology would then be granted full approval or phased out if it proved unsuitable for wider use.

Another way to incorporate TMFs into HTA processes would be for HTA evaluators, and policy and decision makers using HTA reports, to refer to the TMFs as reminders about where implementation obstacles are likely to occur. That approach aligns with how formal theories are already used in decision making; they are rarely the primary basis for taking action and are considered alongside informal theories and the local experience and judgement of practitioners[91]. While not as rigorous as full theory and evidence-based evaluation, informal use of TMFs would be a low-cost way to use their insights to supplement HTA evaluation findings during implementation.

Conclusion

Opportunities in Canada differ across government agencies and HTA organizations for application of new approaches to HTA, or incorporating TMFs in HTA evaluations, to evaluate and implement health technologies. Health Canada could use expanded HTA processes within the Medical Devices Directorate, and the independent HTA organizations across Canada, such as Canada's Drug Agency, could expand HTA evaluations to consider a wider set of variables, especially those related to technology implementation feasibility. Insights from Health Canada and independent reports would help provinces and territories across the country select implementable technologies. The areas where such changes in HTA approaches may make the greatest impact are where they can be used directly in health technology selection and implementation. Alberta, British Columbia, Ontario and Québec could apply expanded approaches in their respective HTA agencies to help select technologies that are effective and compatible with service delivery. Expanded HTA approaches and use of TMFs could also be applied at the health organization level to help select and successfully implement health technologies that provide the high returns on the money and effort invested in them.

APPENDIX: Methods

The information provided in this report was compiled using scoping review methods[93,94]. Literature on evaluation tools was identified using Google Scholar searches designed to find articles and grey literature about tools and approaches that have been used to support policy decisions around health technology adoption in Canada, and in other countries with highly resourced health systems. The search and screening procedure found twenty-seven articles and five grey literature reports about health technology assessment and supplementary approaches, such as multi-criteria decision making, lifecycle HTA, and living HTA.

Literature on implementation theories, models and frameworks that have been applied to health technology decisions was identified in three stages. The first stage used searches in PubMed Central to find literature review articles published in the past 10 years that identify prominent TMFs used in studies of health technology implementation. The second stage consisted of a scoping review to find key theoretical articles describing the prominent TMFs that have been applied to research on health technology implementation. Searches were carried out in MEDLINE, Google Scholar, Embase, and Scopus, and the bibliographies of the five review articles were searched for relevant articles. Five hundred thirty-seven articles were captured, and eighteen articles were kept for analysis. Finally, PubMed Central searches were conducted to find studies that applied implementation TMFs to research on policy or management decision-making. Those searches identified twenty-one articles.

This report received feedback from and was validated by members of APPTA's policy stakeholder network.

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