POLICY SUPPORT IN GUIDELINE IMPLEMENTATION

HOW DOES POLICY SUPPORT GUIDELINE IMPLEMENTATION? THE ROLE OF POLICY, POLITICAL, AND HEALTH SYSTEMS CONSIDERATIONS IN CLINICAL PRACTICE GUIDELINE IMPLEMENTATION

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Lay abstract

Clinical practice guidelines (CPGs) help guide clinicians incorporate into their existing practice the best ways to treat patients, and they do so by providing recommendations based on the best available research evidence. There is research evidence about what factors are important and what approaches are effective in making sure CPGs are used, but there is a lack of understanding about how those factors and strategies are affected by the policy context. This thesis answers questions about the role of the policy context in CPG implementation to help fill this gap. It accomplishes this in three ways: 1) it enriches two existing implementation frameworks with policy context considerations; 2) it explores how these enriched frameworks could have helped with two past implementation efforts; and 3) it provides insights from guideline experts about how to improve upon and support the use of these enriched frameworks.

Abstract

Clinical practice guidelines (CPGs) provide recommendations based on the best available evidence to ensure that decisions about patient care are well-informed. Extensive research within implementation science has highlighted the factors and strategies that are most important in CPG implementation across a variety of settings. The uptake of evidence-based practice however, is quite complex, and there still exist gaps in knowledge about how those factors and strategies are affected by the policy context. In particular, we know little about how considerations about the role of policy, politics, and health systems affect whether and how CPGs are used. The objective of this dissertation is to advance the use of policy, political, and health systems considerations in the implementation of CPGs through three original scientific contributions. First, a critical interpretive synthesis of existing literature was used to enrich two existing implementation frameworks (the Knowledge-to-Action Framework and the Consolidated Framework for Implementation Research) from a policy context perspective. Second, a multiple explanatory case study of guideline implementation processes was used to investigate how the enriched frameworks could be used to identify policy context-related factors and strategies needed to support CPG implementation. Third, a formative evaluation study design was utilized to explore how to improve upon and support the use of these enriched frameworks from the perspective of expert guideline developers and guideline implementers across the six World Health Organization regions. Collectively, these studies contribute theoretical, substantive, and methodological insights toward understanding the policy context relevant factors and strategies that support effective implementation of CPGs. A better understanding of the policy, political, and health systems considerations that impact CPG implementation can translate into more fit-

for-purpose CPGs being developed and more tailored implementation strategies being employed, as well as more patients benefiting from clinical care informed by the best available evidence.

Acknowledgements

Pursuing a PhD is something I could not have fathomed growing up. Fleeing a civil war, I came to Canada as a child refugee with a single mother of three and grew up in one of Toronto's underprivileged communities. The reality of my conditions made pursuing a PhD not only a privilege but a dream beyond my wildest imagination. In Canada, however, I found a home that made me feel welcome. I was able to find my voice, my passion, and the opportunity to grow up in a place of safety. I am immensely grateful to all those that have supported, guided, and believed in me.

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List of abbreviations

3I+E – Institutions, interests, ideas and external factors

CFIR – Consolidated Framework for Implementation Research

CIS – Critical interpretive synthesis

CPG – Clinical practice guideline

GAB – Gait assessment battery

HSE – Health Systems Evidence

HKTP – Hispanic Kidney Transplant Program

KTA – Knowledge-to-Action Framework

MFB – Mary Free Bed Rehabilitation Hospital

WHO – World Health Organization

Declaration of academic achievement

Overall, this thesis presents an introductory chapter (chapter 1), three original research studies (chapters 2-4), and a concluding chapter (chapter 5). Each of the three original research studies were co-authored and I am the lead author on all three studies. I was responsible for conceptualizing and operationalizing all aspects of this thesis, including the design, data collection, extraction, and analysis. I was also responsible for drafting the chapters based on the analysis. My supervisor, Dr. John N. Lavis, provided guidance for the design thesis, contributed to the analysis and synthesis, and provided feedback on the chapters. My committee members, Dr. Melissa Brouwers and Dr. Michael G. Wilson, provided extensive feedback on various drafts and contributed to the analysis.

Chapter 1. Introduction

Overview

The policy context can profoundly shape clinical practice guideline (CPG) implementation efforts. Yet the policy context – specifically policy, political and systems considerations – are rarely given explicit attention in the implementation-science literature. This program of research will address this gap. First, this thesis will propose a set of enrichments to two widely used guideline-implementation frameworks, informed by a critical interpretive synthesis (chapter 2). Subsequent chapters further develop the framework, first using a multiple explanatory case study of two guideline-implementation initiatives that used both original frameworks (chapter 3) and second using a formative-evaluation design and interviews with guideline developers and implementers (chapter 4). The resulting framework can be used in future efforts to support CPG implementation in ways that are appropriately sensitive to and that strategically leverage local policy contexts.

This introductory chapter describes the current state of the literature on CPG implementation science. This will be followed with a discussion about the role played by the policy context in CPG implementation, and the opportunity that better engaging with the policy context poses. Subsequently, this will be followed by a brief overview of the aims of this thesis and how each aim was addressed. Lastly, a discussion of the anticipated theoretical, methodological, and substantive contributions of this work will be presented, along with the positionality of the author.

Background

Current state of literature on clinical practice guideline implementation

Implementation science has been defined as the "scientific study of methods to promote the systematic uptake of clinical research findings and other evidence-based practices into routine practice …".[1] Given its potential as a field, many advocates have been frustrated by the limited success in the transferring of evidence-based findings into routine practice through diffusion and dissemination strategies.[1-2] This has led to a considerable amount of focus within the literature on identifying, exploring, and understanding what factors influence (i.e., facilitate or hinder) implementation.[1-4] Of the various facilitators and barriers to implementation explored within the literature, the policy context within which implementation efforts take place has been inadequately studied. Clinical practice guidelines (CPGs) offer an opportunity for exploring how advancements in the field of implementation science can have better success in bridging the gap between evidence and practice, by examining how the policy context can better support implementation efforts.

CPGs are tools that aid in promoting the uptake of scientific findings into practice.[1,3,5,7,8] Within the field of healthcare, they provide healthcare professionals with decision-making support with the explicit goal of improving patient care using the best available evidence.[10] Providers, policymakers, and system leaders view CPGs as a means to the end of providing safe, effective and cost-effective care.[3-6] By providing explicit recommendations, CPGs provide clarity about which interventions are supported by the best available evidence, particularly in situations where there are multiple treatment options.[1,6-10]

Over the past two decades, researchers have sought to better understand implementation processes as a means of identifying and understanding what factors potentially influence implementation efforts.[1, 11] This led to theories, models, and frameworks being developed to better describe (e.g., definitions of variables and domains), organize (e.g., categorize key new

constructs), and engage with these potential factors.[1, 16] These theoretical approaches have three overarching aims: 1) to describe and/or guide the process of knowledge translation; 2) to understand and/or explain what factors influence implementation outcomes; and 3) to evaluate implementation as a whole.[16] Nilsen identified five approaches: process models, determinant frameworks, classic theories, implementation theories, and evaluation frameworks.[16] To understand and address the implementation challenges faced, there has been an increase in the use of theoretical approaches as a way of reducing the gap between evidence and practice.[16]

A significant and growing pool of literature is focused on the facilitators and barriers to implementation and that can lead to better clinical outcomes.[1] Although research findings have highlighted the potential of CPGs such as how their reliance on the best available evidence helps to avoid treatments and interventions that are ineffective, there is a significant pool of research highlighting that guidelines by themselves have a limited impact on clinical practice. [2, 4-6] In particular, their existence does not guarantee that optimal practices are taken up or that suboptimal or harmful practices are stopped.[1]

Overall, CPGs have three limitations that pose a challenge: 1) the evidence being used may be limited by the scope of what's available; 2) other factors may be prioritized over patient care within CPG recommendations; and 3) personal attributes may limit the implementation of recommendations.[1, 5, 7] The best available evidence informing CPG implementation may be limited in scope to specific patient populations, particular conditions for implementation, or narrowed priorities.[1,4, 6] CPG recommendations may also be limited by factors such as cost, stakeholder priorities (e.g., interest group demands), or social norms (e.g., cultural, religious), which may result in patient needs not being prioritized in how CPG recommendations are implemented by providers and organizations.[1, 5] Lastly, CPG recommendations may be

overlooked, minimized, or not followed as a result of the personal attributes of CPG implementers and providers.[1, 3] Their beliefs, opinions, and clinical experience may override evidence, resulting in skewed strategies in implementing CPGs.[1, 3, 4] The overarching challenge is the failure to consider the interventions that can be used to implement CPGs.

These limitations can collectively be better understood and engaged with through explicit focus being placed on the role of context within CPG implementation. Of the various factors related to implementation setting (i.e., the inner and outer context within which implementation unfolds), exploring the role of policy offers a great opportunity to examine and understand how these limitations can be overcome. The following section discusses what the policy context is, how it is relevant to implementation efforts, and how better understanding how it can be leveraged is lacking within the available literature.

The role of the policy context in clinical practice guideline implementation

Although the significance of the role that the policy context plays within implementation efforts seems obvious at face value, it is relatively neglected within the literature.[11-13] The policy context can be defined as the backdrop within which policy processes unfold, policy decisions are made, and relevant actors (i.e., stakeholders and/or institutions) engage with policy.[14] This context engages with and influences (i.e., facilitates or hinders) implementation efforts to varying degrees. In particular, policy, political, and systems considerations highlight some of the ways in which the policy context impacts the steps taken to accomplish a shared implementation goal (i.e., implementation plan). Policy considerations can help capture insights about implementation options that are available such as resource availability within a particular jurisdiction, and how that can influence what strategies are used to achieve implementation

priorities. Political considerations can provide insights into the various stakeholders and institutions that can directly or indirectly influence implementation processes. For example, advocacy groups and professional organizations may have a vested interest in the outcomes of the implementation of CPGs and can pose an active resistance to CPG implementation efforts. Lastly, health system considerations can help to outline the scope of implementation efforts by aiding in identifying any restrictions on procedures and drugs being used, as well as identifying any timelines within which implementation efforts must plan around.

This dissertation attempts to explore the role of policy within CPG implementation. It examines how the policy context offers insights and opportunities for refining implementation efforts to bridge the gap between implementation science pursuits and the available policy resources. In particular, this dissertation critically explores how policy can support the implementation of CPGs. The three studies of this thesis integrate insights from various discourses to highlight the multidisciplinary approach needed to better understand and incorporate policy within implementation efforts, but to also highlight salient connections from different areas that overlap between the two fields (i.e., policy and implementation science).

Aims and approach

The main goal of this dissertation is to advance the use of policy, political, and health systems considerations in the implementation of CPGs, and it does so by focusing on three aims: 1) to generate enriched versions of two existing guideline-implementation frameworks (chapter 2); 2) to use (and thereby further enrich) the frameworks in exploring how researchers incorporate policy, political, and health system considerations in two case studies of implementation processes (chapter 3); and 3) to use (and again further enrich) the frameworks in

determining what factors are important to expert guideline developers and implementers (chapter 4).

Chapter 2 presents a critical interpretive synthesis (CIS) of the available literature associated with how policy, political, and health systems considerations can be incorporated into two existing guideline-implementation frameworks (the Knowledge-to-Action Framework and the Consolidated Framework for Implementation Research), and thereby provide enriched versions of both frameworks. It draws on multiple sources of evidence from three areas of scholarship: implementation science, political science, and health-systems analysis. The enriched versions of both frameworks include new constructs, expanded relationships among existing processes, and new domains/stages. Later chapters use these enriched frameworks to explore and examine new areas to subsequently build upon the findings of this chapter.

Chapter 3 examines two case studies that used the same two existing frameworks (KTA and CFIR) to explore how researchers incorporated policy, political, and health system considerations in previous implementation efforts and whether and how enriched versions of the frameworks may have helped them in their work. Chapter 4 attempts to determine what factors are important to guideline developers and implementers, and how these factors can be better presented and described in the enriched frameworks to support guideline implementation. Both Chapter 3 and Chapter 4 seek to advance the use of policy, political, and health systems considerations in the implementation of CPGs by informing iterative improvements to the two enriched frameworks developed.

Anticipated contributions

The collection of studies in this dissertation contribute to theoretical, methodological, and substantive advances within the discourse on CPG implementation efforts. From a theoretical perspective, we expect this thesis to generate two enriched implementation frameworks reflecting new stages, concepts, and relationships that better integrate policy, political, and health systems considerations. The findings will fill a gap in our understanding of the role, influence, and potential of the policy context within implementation efforts.

Methodologically, we anticipate two contributions from this dissertation. First, this thesis will attempt novel applications of policy frameworks and analysis of their application will offer a unique opportunity to explore the potential and limits of these frameworks. This will also provide insights about how implementation concepts and approaches are perceived through a policy lens. Secondly, using an integrative approach that draws from implementation science, political science, and knowledge translation literature, will allow a unique lens with which to situate CPG implementation efforts and analyse the factors that influence (i.e., facilitate or hinder) CPG implementation in a more comprehensive manner.

Lastly, we anticipate two substantive contributions to emerge from this thesis. First, the enriched versions of the two existing implementation frameworks will provide insights into which facilitators and barriers are most salient. Second, the enriched versions of the frameworks will help to identify which strategies most need adaptation or incorporation, within CPG implementation.

Positionality of the author

I come to this research as someone who is not a clinician and has no experience with guideline implementation. I am however someone who sees how the neglect of policy, political,

and systems considerations are acting as a barrier to meaningful changes in clinical practice. I anticipate my training in health policy will act as a unique lens in how I analyze and interpret the studies. I see this as a strength that will enhance how I engage with the findings, but it is also something that I must critically interrogate throughout this thesis to ensure it does not disproportionally skew the findings.

References

1. Ogden, T., & Fixsen, D. L. (2014). Implementation science: A brief overview and a look ahead. *Zeitschrift für Psychologie*, *222*(1), 4.

2. Richter-Sundberg, L., Kardakis, T., Weinehall, L., Garvare, R., & Nyström, M. E. (2015). Addressing implementation challenges during guideline development–a case study of Swedish national guidelines for methods of preventing disease. *BMC health services research*, *15*(1), 1-13.

3. Fischer, F., Lange, K., Klose, K., Greiner, W., & Kraemer, A. (2016, June). Barriers and strategies in guideline implementation—a scoping review. In *Healthcare* (Vol. 4, No. 3, p. 36). MDPI.

4. Eccles, M. P., Grimshaw, J. M., Shekelle, P., Schünemann, H. J., & Woolf, S. (2012). Developing clinical practice guidelines: target audiences, identifying topics for guidelines, guideline group composition and functioning and conflicts of interest. *Implementation science*, *7*(1), 1-8.

5. Turner, T., Misso, M., Harris, C., & Green, S. (2008). Development of evidence-based clinical practice guidelines (CPGs): comparing approaches. *Implementation science*, *3*(1), 1-8.

6. Grimshaw, J., Thomas, R., MacLennan, G., Fraser, C. R. R. C., Ramsay, C. R., Vale, L. E. E. A., ... & Donaldson, C. (2004). Effectiveness and efficiency of guideline dissemination and implementation strategies.

7. Francke, A. L., Smit, M. C., de Veer, A. J., & Mistiaen, P. (2008). Factors influencing the implementation of clinical guidelines for health care professionals: a systematic meta-review. *BMC medical informatics and decision making*, *8*(1), 1-11.

8. Gagliardi, A. R., Brouwers, M. C., Palda, V. A., Lemieux-Charles, L., & Grimshaw, J. M. (2011). How can we improve guideline use? A conceptual framework of implementability. *Implementation Science*, *6*(1), 1-11.

9. Sarkies, M. N., Jones, L. K., Gidding, S. S., & Watts, G. F. (2022). Improving clinical practice guidelines with implementation science. *Nature Reviews Cardiology*, *19*(1), 3-4.

10. Nilsen, P., Ståhl, C., Roback, K., & Cairney, P. (2013). Never the twain shall meet?-a comparison of implementation science and policy implementation research. *Implementation Science*, *8*(1), 1-12.

11. Olswang, L. B., & Prelock, P. A. (2015). Bridging the gap between research and practice: Implementation science. *Journal of Speech, Language, and Hearing Research*, *58*(6), S1818-S1826.

12. Grimshaw, J., Eccles, M., & Tetroe, J. (2004). Implementing clinical guidelines: current evidence and future implications. *Journal of Continuing Education in the Health Professions*, *24*(S1), S31-S37.

13. Damschroder, L. J., Aron, D. C., Keith, R. E., Kirsh, S. R., Alexander, J. A., & Lowery, J. C. (2009). Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. *Implementation science*, *4*(1), 1-15.

14. Moat, K. A., Lavis, J. N., & Abelson, J. (2013). How contexts and issues influence the use of policy-relevant research syntheses: a critical interpretive synthesis. *The Milbank Quarterly*, *91*(3), 604-648.

15. Wensing, M. (2015). Implementation science in healthcare: Introduction and perspective. *Zeitschrift für Evidenz, Fortbildung und Qualität im Gesundheitswesen*, *109*(2), 97-102.

16. Nilsen, P. (2020). Making sense of implementation theories, models, and frameworks. In *Implementation Science 3.0* (pp. 53-79). Springer, Cham.

Chapter 2: Preface

A better understanding of the role that the policy context plays within implementation processes and outcomes can help guideline developers, guideline implementers, and those seeking to bridge the gap between evidence and practice. The clinical focus of much implementation science research, however, has led to very little research on the role of the policy context within implementation science, particularly within guideline implementation efforts. This makes it difficult for implementation science scholars to adequately draw from research that captures and explores the policy context. This first study addresses this gap by using a type of knowledge synthesis method to enrich two existing implementation frameworks to better capture and engage with the policy context. It also highlights the strengths of the critical interpretive synthesis as a method to synthesize and integrate diverse forms of evidence. Our findings offer a new way of engaging with the policy context within implementation processes and situating the observed outcomes from a policy perspective. I was responsible for developing the focus and design of the study with my supervisor (Dr. John N. Lavis), in addition to data collection, analysis, and interpretation. Dr. John N. Lavis also contributed to the analysis through an iterative process of interpretation and synthesis which produced the two enriched implementation frameworks. Dr. Elizabeth Alvarez aided me in refining the inclusion criteria and independently assessed a sub-sample of the documents for eligibility. I drafted the manuscript, and Dr. Lavis, Dr. Melissa Brouwers and Dr. Michael G. Wilson provided extensive feedback that were incorporated into the manuscript. All these individuals are co-authors on the manuscript.

Using a policy lens to focus supports for clinical practice guideline implementation: A critical interpretive synthesis

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Abstract

Background: Clinical practice guidelines (CPGs) aid in optimizing patient care using the best available evidence to promote best practices among clinicians. Extensive research has been conducted in the field of implementation science to understand why guideline recommendations are or are not implemented (i.e., facilitators and barriers) and what strategies can be used to support their implementation. The role of policy levers in guideline implementation, however, is one area that is the least understood despite its critical importance.

Methods: Using a critical interpretive synthesis, we systematically assessed how policy, political and system considerations are incorporated into two existing guideline-implementation frameworks (the Knowledge-to-Action Framework and the Consolidated Framework for Implementation Research), identified where there are gaps, and created enriched versions of the frameworks that optimized these features. We began with the compass question: How can policy, political, and systems analysis frameworks enrich two widely used frameworks – Knowledge-to-Action Framework and the Consolidated Framework for Implementation Research – that are used to support the implementation of clinical practice guidelines? We then searched eight databases in addition to grey literature and supplemented these documents to fill conceptual gaps with other sources.

Results: A total of 2,088 documents were retrieved and assessed for eligibility with an additional 30 documents being identified through other sources. Overall, 85 documents were ultimately included in the analysis. Our findings identified new concepts the frameworks did not include and existing concepts within the original frameworks that could be better contextualized for the policy context.

Discussion: Our analysis led to enriching both frameworks to better direct users to consider policy, political, and health systems considerations. Integrating empirical and conceptual research from both the implementation science and policy disciplines helps to bridge the divide between disciplines and highlight practical connections that can aid in collaboration.

Conclusions: The enriched frameworks allow for a better understanding of how policy, political, and health systems considerations can inform guideline implementation efforts.

Word count: 313 (max 350)

Background

Clinical practice guidelines (CPGs) are defined as "statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options".[8] Guidelines help to steer clinicians towards best practices and act as a standard against which evaluations of clinical practice can be made.[13, 24] The implementation of CPGs has been shown to provide several benefits, including a reduction in inappropriate care, increased technical efficiency (e.g., streamlined processes), and more cost-effective decisions.[15-17] Common challenges with the implementation of guidelines, however, thwart their potential.

A policy lens to guideline implementation

There is an extensive and growing pool of literature about factors that affect guideline implementation. These factors relate to defining features of the guidelines, the professionals that use them, the organizations or settings where professionals work, and the policy context that is in place. [1, 4, 13, 15, 17, 19]

In contrast to other factors, the ways in which the policy context affects guideline implementation is perhaps the least understood despite its critical importance.[50, 136, 137] Policy analysis, political analysis and systems analysis can inform how the policy context can be leveraged to improve guideline implementation. Policy analysis helps by 'unpacking' an issue (in this case the policy dimensions of a guideline-implementation opportunity), and specifically an existing problem and its causes (i.e., as they relate to risk factors, programs, health system arrangements, etc.), potential policy options, and policy implementation considerations. Thus, in analyzing the size of the problem one might consider the magnitude of the clinical problem the

CPG attempts to address (e.g., what portion of the population is at risk, are there issues of equity), any viable policy options available that may help or hinder guideline implementation (e.g., current investments in a common clinical area or a common population segment), and appropriate implementation considerations at the policy level (e.g., leveraging infrastructure previously used to implement a CPG recommendation to advance the implementation of a new CPG recommendation).[134] For example, Gagliardi and Alhabib (2015) highlight that guidelines are not often translated into viable policies and that this limited their use, leading to the ongoing use of ineffective (and sometimes harmful) therapies, suboptimal patient outcomes, and the mismanagement of scarce resources.[50]

Political analysis helps with considering the role of macro-level factors that guide decision-making about the implementation process for policies and for guidelines. It does this by helping us better understand how institutions (e.g., governmental structures), interests (e.g., stakeholder groups), ideas (e.g., the national mood), and other external factors can influence implementation processes, such as by highlighting factors influencing collaboration (i.e., acting as barriers and incentives).[41- 43] For example, Becker et al. (2017) pointed to how political considerations being overlooked can lead to the implementation of guidelines resulting in resistance among providers and inconsistent effects among patients.[136] As another example, attempts to increase the scope of practice of nurses as a means of supporting the implementation of one or more particular guidelines (e.g., nurses being able to see patients and prescribe medications without physician collaboration or supervision), can lead to physician associations (a key interest group) organizing against such a change to existing governance arrangements.

Lastly, systems analysis helps in capturing relevant supports to implementation processes for policies and guideline implementation by explicitly considering governance arrangements

(i.e., who can make what types of decisions), financial arrangements (i.e., how money flows in a health system) and delivery arrangements (i.e., how care is designed to reach those who need it).[44] Ploeg et al. (2017) discuss how overlooking system considerations can lead to limited integration of guideline recommendations within organizational structures and processes, which can act as a barrier to guideline implementation.[137] For instance, not adequately considering the level of administrative capacity required to be able to offer new clinical services may limit implementation efforts. It may also pose a threat to the proper execution of existing processes of clinical care that also depend on the same administrative services.

The Knowledge-to-Action Framework (KTA, a process model) and the Consolidated Framework for Implementation Research (CFIR, a determinant framework) were designed to support implementation.[5] The KTA framework is meant to guide the process of implementation and is comprised of two distinct, but related components: 1) knowledge creation; and 2) action cycle. It is based on the commonalities of over 60 planned-action theories, frameworks, and models which the action cycle is derived from.[22] Planned-action theories, frameworks, and models aide in controlling the variables that increase or decrease the likelihood for change in groups, which can vary in size and setting.[22] Overall, the KTA framework assumes a systems perspective that views the process of moving from evidence to action as an iterative and bi-directional process.

The CFIR framework on the other hand, aides in systematically considering which factors facilitate or hinder the uptake of evidence-based practices for effective implementation.[23] It is comprised of 39 constructs which are divided into five domains: 1) intervention characteristics; 2) inner setting; 3) outer setting; 4) characteristics of individuals involved; and 5) the process by which implementation is conducted.[23] It was developed from 19 implementation

theories within the available literature from theories that related to innovation, dissemination, implementation, organizational change, research uptake, and knowledge translation.[23] Although the CFIR framework lists constructs believed to influence (i.e., either positively or negatively), it does not specify how these constructs interact.[23] CFIR provides a more detailed strategy to operationalize the "barriers and facilitator assessment" step of the KTA.

Close examination of the KTA and CFIR however, highlights the failure to adequately describe, operationalize and guide policy, political, and systems considerations in the implementation process. A better understanding of policy, political, and health systems considerations can inform adaptations of these two frameworks.

Study objective

To systematically assess how policy, political and system considerations are incorporated into two existing implementation frameworks and to provide an enriched version that optimizes these features.

Research design

A critical interpretive synthesis (CIS) approach was used to achieve the objective. A CIS is a type of knowledge synthesis method.[14,18, 20] First described by Dixon-Woods and colleagues (2006), a CIS synthesizes and integrates diverse forms of evidence. A CIS has three distinct advantages compared to other knowledge synthesis methods. First, it is best suited for research questions that draw on literature that is neither well focused nor well developed. With this project, implementation science is an interdisciplinary field that historically draws and integrates insights from various social science disciplines (e.g., organization studies, psychology,

economics) that can influence and intersect with policy, political, and systems factors.[138] These factors, however, are more fulsomely addressed in other distinct literatures such as those relevant to the field of health policy and systems research which draws from and integrates insights from disciplines such as epidemiology, geography, history, medicine, nursing, and political science.[139, 140] Second, a CIS combines both systematic and purposive search strategies. For our inquiry, it will support explicit efforts to identify policy, political, and systems considerations by more systematically linking the various disciplines together. Third, a CIS offers flexibility and is driven by relevance. In our study, the very extensive literatures on each of policy, political and systems analyses can be purposively sampled to bring in considerations that are particularly germane to guideline implementation. [14,18, 20] Together, and operationalized for this project, it will mean exploring key junctures within and between various fields relevant to implementation science (e.g., knowledge translation, political science), with special attention to separate conceptual and methodological issues relevant to the study's objectives.

A CIS begins with a compass question that adapts throughout the span of the review in response to the literature encountered. [14,18, 20] The compass question for this study is:

How can policy, political, and systems analysis frameworks enrich two widely used frameworks – Knowledge-to-Action Framework and the Consolidated Framework for Implementation Research – that are used to support the implementation of clinical practice guidelines?

Methods

Identifying potentially relevant articles

Literature relevant to the compass questions was identified through database searches that were developed in consultation with a librarian, hand searching reference lists of included articles, and contacting experts and conducting purposive searches to fill gaps.

For the database searches, relevant text words or MESH terms were combined including clinical practice guidelines and either implementation or diffusion of innovation, evidence focused, theory, and policy context-level analysis (i.e., policy, political, and systems) (see Appendix 1). Articles were identified from the following eight databases: Canadian Public Policy Collection (for grey literature), EMBASE, Emcare, Health Systems Evidence (HSE), Medline, PsychINFO, Social Science abstract, and Web of Science (see Appendix 2).

Hand searches of reference lists were conducted from eligible publications, and of articles published in two peer-reviewed journals (Implementation Science and Health Research Policy and Systems). Implementation Science provides relevant literature on the uptake of research findings in clinical, organizational, and policy contexts that are aligned with the objectives and focus of this study. Health Research Policy and Systems, critically explores the organization and application of health research, providing a rich source to explore the factors relevant to policy, political, and systems considerations.

Experts from prominent organizations, authors of the peer-reviewed publications, and recommendations from other experts were identified and contacted to identify other seminal articles. We sought experts who were either: 1) guideline researchers and developers who were sensitive to the policy context (i.e., they have research experience or tacit knowledge relevant to the policy context); or 2) policy experts who are sensitive to the world of guidelines and implementation science (i.e., they have policy experience or tacit knowledge relevant to implementation science). Experts were sought across the six World Health Organization (WHO)

regions to ensure any major regional differences and perspectives were captured. Starting with this set of experts identified, additional experts with known expertise (vis a vis academic or professional dossiers) in the fields of policy, guidelines, and implementation were contacted.

In addition, to fill conceptual gaps, further articles were identified by the principal investigator through hand searches of the reference lists of relevant publications and authors. Upon completing these searches, an Endnote database was created to manage and store the results.

Selecting articles

Two reviewers (AA and EA) independently screened search results and included documents that addressed policy, political or system factors that influence guideline implementation. This included documents that had the potential to give insights into the role policy plays within implementation processes; described implementation efforts that fall within the policy, political, or systems level; and/or identified key junctures within implementation efforts where policy, political, and systems factors are most salient. Documents were excluded if they: 1) dealt with the development of guidelines or tools to support guideline implementation exclusively; 2) were not related to health or social systems; 3) focused solely on guideline training; 4) focused solely on provider-specific guidelines; and 5) focused solely on a single institution (i.e., creating a hospital-specific clinical policy or clinical pathway and no link to system level [i.e., outside single institution]). Differences in eligibility assessments were resolved by consensus and when that is not possible by a third reviewer, JNL. Any articles that did not meet at least one of the inclusion criteria were excluded. Language was not used as an exclusion criterion.

Using a random selection of two percent of the articles, a pilot screening was conducted to reach a consensus on the inclusion and exclusion criteria among reviewers (AA and EA). Reviewers classified each title and abstract as "include", "exclude", or "uncertain". Kappa values between 0.61-0.80 were classified as reflecting “substantial” agreement and values between 0.81-1.00 as reflecting “almost perfect” agreement.[45] Any values under 0.61 were classified as warranting a discussion among reviewers until consensus is reached, upon which formal screening commenced. While inter-rater reliability using the quantitative measure Kappa, is usually only used in quantitative systematic reviews, here it was used to support reflexivity as a way to enhance rigor and trustworthiness.[135] For example, the inclusion and exclusion criteria may change based on the findings from pilot screening and discussions among reviewers. Lastly, one reviewer (AA) assessed the remaining titles and abstracts. Articles classified as "include" or "uncertain" were kept for full-text review.

Full text of remaining articles was assessed by one reviewer (AA). Any articles excluded at this stage were deemed as not sufficiently providing new insight into the compass question. Remaining articles were sorted according to whether they focused on facilitators, barriers, or strategies within CPG implementation efforts across the various levels of focus for this study (i.e., policy, political, and systems).

Extracting data and information

Data were extracted by one of us (AA) and a sample of extracted data was checked by a second reviewer (EA) for consistency. A standardized data-extraction form (see Appendix 3) was used to capture descriptive characteristics of each article: title, author, year of publication, publication status country or region focus, study design (if applicable), and a summary of key

findings or insights from the document (i.e., relevant policy, political, and systems insights). Each article was then examined for information or knowledge pertaining to facilitators, barriers, and strategies to CPG implementation related to policy, political, and systems. Succinct narrative summaries were also developed. Three frameworks were used to structure and categorize this information: 1) a policy analysis framework that focuses on clarifying problems, framing options to address problems and identifying implementation considerations[134]; 2) the 3I+E framework which is used for political analysis to explain how a particular policy was developed (i.e., decided upon) at a specific time by exploring the role institutions, interests, ideas, and external factors play in a given policy's development and choices made by those in power[41, 42, 43]; and 3) the Health Systems Evidence (HSE) framework which is used as a taxonomy of health-system governance, financial and delivery arrangements for systems analysis.[44] NVivo software was used to sort, classify, and arrange emerging themes and categories. The facilitators, barriers, and strategies were identified either through deduction (i.e., when not explicitly mentioned) or as referenced within articles.

Synthesizing and integrating findings

To synthesize the information collected, an interpretive analytic approach was used. A constant comparative method was employed throughout the analysis until saturation was reached in the pursuit of identifying new concepts and themes, as well as new connections between previously identified items (i.e., concepts and themes).[39]

A matrix model was designed a priori as a foundation to how the KTA and CFIR could be enriched. Specifically, relevant articles were conceptually mapped to a 3 x 3 matrix to categorize findings, cross linking the three aspects relevant to CPG implementation that can

potentially be enriched (i.e., policy facilitators, policy barriers, and policy-related strategies), to the three areas of policy that can enrich them (i.e., policy, politics, and systems). This was accomplished using a three-pronged approach: 1) the literature was categorized into topics and domains to be further assessed, abstracted, and coded; 2) initial findings of the conceptual mapping were used to identify conceptual gaps; and 3) further purposive sampling was conducted to identify relevant literature until saturation was reached. The purposive searches and sampling were both dynamic and iterative, which required constant discussions amongst the research team.[20]

Using these data, the frameworks were refined and adapted to address the identified gaps until the research team felt further efforts would not produce new constructs or identify additional gaps, and no further insights gained to further build on the KTA or CFIR (and this resulted in what is called the 'synthesizing argument'). This process is similar to the approach described in grounded theory methodology as 'theoretical saturation'.[39,40]

Results

Search results and article selection

The search of electronic databases retrieved 3,034 documents, with 2,088 unique documents after removal of duplicates. A review of titles and abstracts was conducted independently by two reviewers (AA and EA) on a random sample of approximately two percent (n = 41) of the documents. A Kappa score of 0.76 was calculated. From the remaining titles and abstracts, 283 documents were included for full review. The full-text review resulted in an additional 223 documents being excluded, leaving 60 potentially relevant documents to be included. To fill conceptual gaps, 30 additional documents were identified from other sources

(e.g., from reference lists and suggestions from experts), of which 25 additional documents were included after full-text review. A total of 85 documents were included for analysis. Figure 1 outlines the full search strategy undertaken (see Figure 1).

Identified facilitators

Facilitators identified in CPG implementation relevant to policy, political, and systems considerations relate to the usability of the CPG, adaptability of the CPG, and the role of organizations in supporting implementation efforts (i.e., logistical, governance, etc.).[50-70, 112-115, 127-133] These facilitators ease the managing of competing priorities and demands within the implementation process. How these facilitators are reflected within the policy context is outlined in Table 1, with the unique additions that can enrich the KTA and CFIR frameworks identified in bold.

Identified barriers

Barriers identified in CPG implementation relevant to policy, political, and systems considerations include the lack of support from relevant stakeholders (e.g., organizational leadership, professional associations) for implementation efforts, minimizing policy-relevant stakeholder engagement, and resource scarcity.[71-93,102-111,118-123, 125] Using policy, political, and health systems frameworks, how these barriers would manifest within the policy context are captured in Table 1, with barriers that can bring insights to the KTA and CFIR frameworks if incorporated being in bold.

Identified strategies

Identified CPG implementation strategies relevant to policy, political, and systems considerations include cases where recommendations require the streamlining of logistical considerations, restructuring of organizational infrastructure (e.g., space, human resources, models of care), and ensuring adequate funding throughout the implementation process.[93-101,117, 124, 126] These strategies are relevant across all four levels (i.e., guideline, provider, organization, and policy) that influence guideline implementation efforts. Better understanding their implications is important to meaningfully address policy barriers (i.e., higher level factors at the meso- or macro-level). As such, policy, political, and health systems frameworks were used to identify how these strategies would manifest within the policy context and captured in Table 1 with the strategies that can bring insights to the KTA and CFIR frameworks if incorporated being in bold.

Emerging insights

From our analysis of facilitators, barriers, and strategies across the policy context, we identified several cross-cutting insights. At the policy analysis level, we found that it is important for policy-relevant stakeholders to understand the implementation issue (e.g., scope, priorities), actively participate in supporting efforts to address the implementation issue (e.g., aid in tailoring implementation), and have supports in place throughout the implementation process (e.g., educational programs). At the political analysis level, policy stakeholders need to understand the benefits and costs of implementing guideline recommendations. They need information about anticipated resistance by groups with vested interests in implementation efforts. For example, implementing guidance may result in demands to the organization or system that stakeholders feel are not financially manageable or conflict with other priorities that demand attention and

resources. Policy leaders need to be recruited to help guide the implementation of recommendations once the decision to act is made. Lastly, at the systems analysis level, policy stakeholders need appropriate supports relevant to implementation efforts to be comprehensively identified. For example, the training requirements and financial supports they need must be known. In addition, infrastructure barriers to implementation efforts such as issues with delivery of relevant services, need to be circumvented. Organizations need to leverage existing strategies to better support implementation efforts, such as better tailoring of educational supports for providers. Across all analytical levels, we found that there is a need to identify what policy-relevant factors influence (i.e., facilitate or hinder) the implementation process, which stakeholders are most relevant within implementation efforts, and what existing supports (e.g., programs, tools) are being overlooked or minimized within the policy context that can aid with implementation efforts.

Framework enrichments

To create enrichments in the KTA and CFIR frameworks, we juxtaposed the list of facilitators, barriers, and strategies that emerged from our CIS to the existing description and design of the KTA and CFIR models. We identified unique new concepts that the frameworks had not included; reframed existing concepts to contextualize them for a policy environment; and identified concepts that were already reflected in the models. We describe the enrichments to each framework below, which collectively help to achieve two goals: 1) anchor framework expansions to salient factors identified from the CIS; and 2) ensure that policy, political and systems considerations are made explicit to advance implementation efforts and future research activities.

Knowledge-to-Action Framework

<u>*Proposed enrichments*</u>

Policy, political, and health systems considerations are captured and considered at three stages within the action cycle: 1) adapt knowledge to local context; 2) assess barriers/facilitators to knowledge use; and 3) select, tailor, implement interventions (as highlighted in Figure 2). The language used to describe these stages, however, is often broad, and policy, political and health-system considerations are not explicitly labeled within the framework nor are they operationalized for the user. For instance, at the 'adapt knowledge to local context' stage, the framework focuses on the process by which individuals or groups make decisions regarding "value, usefulness, and appropriateness of particular knowledge to their setting and circumstances".[22] The goal is to better capture and contextualize the local priorities within the implementation process. From a policy analysis perspective, this is relevant for identifying the policy dimensions of the problem and its causes, policy options, and policy implementation considerations best suited at the local level (i.e., region, system). For example, if there is a large community of new immigrants within the local context, framing policy options intended to support the implementation of a new cancer screening guideline, may require consultation with stakeholders from this community to ensure their views and experiences (e.g., overcoming a language barrier) are being considered. From a political analysis perspective, understanding the value and usefulness of a given guideline requires understanding what interests and ideas are crucial to the local context. For example, if negative attitudes towards a new guideline for a new cancer treatment pose a barrier (e.g., seen as too rigid or reducing physician autonomy), it may be advantageous to identify how other priorities of relevant interest groups (e.g., physician

associations) could be addressed as a way to 'compensate' for such a concern.[121] Lastly, from a systems analysis perspective, understanding what is deemed appropriate at the local context requires consideration, not of what might be acceptable to patients or health professionals, but what are acceptable forms of new (or changes to existing) health system governance, financial, and delivery arrangements beyond what is directly proxy to a given implementation effort. For example, new cancer guidelines that promote patients receiving treatment options close to home may be in conflict with system arrangements that support a center-of-excellence model where care is concentrated in a very few centers, requiring patients to travel.

Three stages of the KTA are adaptable to the policy context. As illustrated in Figure 2, conceptual and operational enrichments that align with policy-relevant facilitators, barriers, and strategies can enhance these stages. Specifically, policy-relevant facilitators explicitly signal activities at each of the three KTA stages to explore how usability, adaptability, and the role of organizations in supporting implementation efforts (i.e., logistical, governance, etc.) are relevant in aiding efforts to achieve implementation objectives (i.e., priorities, timelines, etc.). For instance, for a guideline about cancer screening at the *adapt knowledge to local context stage*, the enrichments will signal what policy legacies (e.g., previously established regulations and mandates) best support organizational changes needed to adopt the guideline, but also what policy, political and systems factors can help to leverage end-user engagement to promote implementation. Policy, political, and system considerations can change evidence-informed knowledge regarding cancer screenings in several ways. Policy considerations can change how this knowledge is framed and shared within the media to increase screening uptake. For example, understanding how the problem of high rates of breast cancer is viewed and experienced by different segments of the population can assist with the social-media messaging used by public

health units. Political considerations can change how this knowledge is assessed to help leverage policy legacies that were able to garner better provider feedback and frame provider incentives more clearly. For example, identifying which stakeholder organizations (e.g., patient advocacy groups) have been most effective in the past, can help with the selection of groups to engage a public health campaign to increase cancer screening uptake. Lastly, health systems considerations can change how this knowledge can be better supported through existing financial arrangements, such as reducing out-of-pocket costs to patients. For example, exploring available financial arrangements within the healthcare system can help to identify any programs that can help to offset out-of-pocket costs (e.g., for parking and diagnostic breast imaging services) for low-income patients.

Policy-relevant barriers require implementation activities to account for the role support plays in implementation efforts, the extent to which stakeholder engagement is prioritized, and how resource scarcity impacts implementation efforts at a given stage, as a means of anticipating challenges stemming from the policy context. For instance, for a guideline about cancer screening at the *assess barriers/facilitators to knowledge use stage*, might require an analysis of the impact different screening option recommendations have on the scope of practice of differing health professionals. Colorectal cancer screening recommendations may cause tension between gastroenterologist specialists who provide colonoscopy services and advanced practice nurses who provide flexible sigmoidoscopy ("flexsig") services.

Policy considerations at this stage could mean in assessing the magnitude of the problem and available policy options, considering how care close to home is being prioritized if colonoscopy clinical experts are mostly in academic centres and not in community or rural centres. For political considerations, this could mean considering how patient advocacy groups

can help to raise awareness in difficult to reach communities about colorectal cancer screening and how such 'interest groups' can collaborate with relevant actors (e.g., cancer organizations, physicians, and policymakers) to leverage limited resources. Lastly, for health systems considerations this could mean considering how financial and delivery arrangements influence cancer screening by exploring whether the health system can adjust payments to colonoscopy services or ensure the laboratory capacity to ensure continuity of care.

Lastly, policy-relevant strategies explicitly require activities at any of the three stages to assess and evaluate how the streamlining of logistical considerations, restructuring of infrastructure, and adequate funding throughout the implementation process can aid the Action Cycle using effective strategies that leverage the policy context. For instance, for a guideline about cancer screening at the *select, tailor, implement interventions stage*, this will require exploring ways provider-targeted implementation strategies (e.g., use of educational outreach visits) and governance arrangements (e.g., management strategies used to ensure health care organizations are performing optimally), may align or conflict with implementation priorities and timelines. For health systems considerations, this could mean creating an integrated cancer screening recall system or extending existing breast screening systems to colorectal cancer screening.

Table 1 captures specific considerations stemming from policy, political, and health systems analysis at each of the policy context considerations stages. How these considerations could potentially be operationalized is outline in Table 2 and Appendix 4. Appendix 6 highlights how these enrichments map onto each relevant component of the KTA framework.

Consolidated Framework for Implementation Research

Proposed enrichments

The proposed enrichments to the CFIR framework are more complicated given it is a more deconstructed model with greater granularity within each domain. To some extent, the CFIR has domains and constructs that lend themselves to engaging with the policy context but with operational gaps.

This limitation to fully engage with policy, political, and health system considerations is evident within four domains: 1) outer setting; 2) inner setting; 3) process domain; and 4) characteristics of individuals (i.e., individuals involved). Beginning at the outer setting, the CFIR could be enhanced with more explicit consideration of political changes (e.g., elections resulting in change of leadership) or economic changes (e.g., recessions) that may impact whether specific health care options and programs informed by guidelines continue to be supported or funded. This helps to identify what potential facilitators and barriers (i.e., the consequences of a lack of support or funding) may have on implementation efforts, both present and future, and what strategies are most appropriate to circumvent challenges stemming from these policy decisions. At the inner setting, the CFIR could be enhanced with more explicit consideration of the vested interest of various actors (e.g., providers, hospital administration, etc.) in order to make salient connections between what is said and what is understood implicitly, which would allow for more tailored strategies to be devised to increase the chances of successful implementation. Although this domain takes into consideration networks and communications, implementation climate, and leadership engagement, those constructs and their application do not fully engage with the policy context. For example, under networks and communications, the importance of communication is stressed but factors that are policy-relevant, such as the impact of benefits and costs from the perspectives of various actors are overlooked. Similarly, for the process domain, although it

takes into consideration opinion leaders and champions, the CFIR could be enhanced with more explicit consideration of how these individuals exercise their influence from the policy context (e.g., active resistance of professional organizations). This would allow for not only relevant barriers and strategies to be identified, but strategies best suited to address potential conflicts, both real or perceived, can be better designed. Lastly, the characteristics of the individuals domain engages with factors that can influence individual perspectives, including knowledge and beliefs about the intervention and other personal attributes (i.e., values, motivations, etc.), but the CFIR could be enhanced with more explicit consideration of what sources and types of evidence influences knowledge or beliefs about the intervention. This would allow strategies to leverage sources perceived as more credible to be used to frame how implementation efforts are promoted, how supporting documents are structured, and how target populations are engaged with.

The proposed enrichments build upon previous constructs that indirectly or minimally considered policy, political, and health systems considerations by adding another layer that forces implementation efforts to engage with and be cognizant of the policy context. This new layer labelled policy context considerations allows the list of facilitators, barriers, and strategies identified in this CIS, to be explicitly considered, but also at the granular level, leveraging the constructs already present within these domains. For instance, in the inner setting norms and values of an organization will be complemented with national mood. Similarly, in the outer setting, peer pressure will be considered not just within a given organization but how various professional groups (e.g., physician associations) can influence implementation efforts. Figure 3 outlines where these enrichments would integrate with the CFIR, with the domains in blue the targets of the enrichments.

Similar to the KTA framework, the CFIR framework will expand to include policy context considerations consisting of three separate but related stages for taking into account policy context considerations by exploring policy-relevant facilitators, barriers and strategies. Unlike the KTA framework however, the expansion will be a new domain that interacts with four CFIR domains: 1) outer setting; 2) inner setting; 3) characteristics of individuals; and 4) process domain.

At these four domains, policy-relevant facilitators explicitly explore how the respective subconstructs are informed and influenced by factors related to usability, adaptability, and the role of organizations in supporting implementation efforts (i.e., logistical, governance, etc.). For instance, in the outer setting domain, the External Policies and Incentives subconstruct will be examined with attention to how external mandates are facilitated by the level of support within organizations involved throughout the implementation process. For a guideline about cancer screening, this could mean hiring a policy analyst to help the implementation team better understand how external mandates are relevant to implementation efforts. Policy-relevant barriers assess subconstructs in these domains to explore the role support for implementation efforts, stakeholder engagement, and resource scarcity impact implementation efforts at a given stage in the implementation process. For instance, in the inner setting domain, the subconstruct of Networks and Communications will be assessed with explicit consideration for how the quality of communication within an organization can act as a barrier in clarifying the scarcity of resources to policy-relevant stakeholders. For a guideline about cancer screening, this could be accomplished by having multiple versions of the CPG and a summary of recommendations to help policy-relevant stakeholders better understand the level of demand for available resources. Lastly, policy-relevant strategies will engage with the four domains to better capture and

evaluate how the streamlining of logistical considerations, restructuring of infrastructure, and adequate funding throughout the implementation process can aid implementation efforts. For instance, within the process domain, the subconstruct of Planning will explicitly consider how the strategies within the implementation process are informed and sensitive to logistical, structural, and financial factors stemming from the policy context. For a guideline about cancer screening, this could be accomplished by mapping new recommendations onto existing policies to see areas of overlap and distinction. Table 3 and Appendix 5 outline how these considerations could potentially be operationalized at each domain. Appendix 6 highlights how these enrichments map onto each relevant component of CFIR.

Discussion

Principal findings

The principal findings of this study are the policy, political, and health systems considerations now used to enhance the KTA and CFIR frameworks. The enrichment of the KTA framework is a modest departure from what is currently within the framework in the following ways: the Action Cycle is expanded to include a new stage that takes into account efforts to adapt, support, and amplify the policy context. This enrichment is a means of building upon the original structure to aid at specific stages to address the gap in how policy, political, and systems considerations are captured, prioritized, and acted upon. In contrast, the enrichment of the CFIR framework includes a new domain for policy context considerations and is therefore a more significant departure from the original framework. This is a significant change since these domains and their unique subconstructs are now given more continuity and guidance by explicitly using the same facilitators, barriers, and strategies as means of contextualizing the

various activities of each respective domain with policy-relevant insights and perspectives. This new domain helps to anchor the framework in such a manner that explicitly ensures policy, political, and systems considerations help guide implementation efforts.

Strengths and limitations

This study has two key strengths stemming from the overall research focus and the methodological approach employed. First, this study provides a unique systematic and comprehensive analysis of the policy, political and health systems literature in the context of CPG implementation. The result is two adapted frameworks that have been augmented to more explicitly integrate the policy lens. The enriched frameworks provide an opportunity to integrate empirical and conceptual research from both implementation science and policy discourse in a manner that highlights practical connections. Secondly, using a CIS as the synthesis design was a key strength of this study. The emergent enriched frameworks reflect the advantages of systematic reviews and the iterative nature of qualitative review methods. They also present a contribution to the literature that integrates implementation science and policy discourse in a manner that expands the scholarship and reflects the key existing literature.

This study had four challenges that warrant highlighting. First, the clinical nature of CPG implementation meant a significant pool of literature focused on clinical, provider-focused research that was explicitly technical in nature. Our approach may have excluded some relevant documents. Second, the search strategy may have resulted in the literature underrepresenting policy-relevant documents due to implementation science search terms being too narrow. Third, given that the principal investigator (AA) selected the bulk of the studies deemed relevant and those selected for inclusion, the principal investigator's perception of the study's aims may have

influenced the outcome. This challenge was addressed, however, through discussions with the research team. Lastly, although the study team's experiences and expertise covered both implementation science and health policy analysis, the analysis and interpretation of the results may have been influenced by the principal investigator's training in health policy. Although extensive discussions took place to overcome this, additional purposive sampling may have been shaped by this reality. Given the comprehensiveness of the search strategy and that a constant comparative method was employed throughout the analysis until saturation was reached in the pursuit of identifying new concepts and themes, these limitations do not pose a significant concern.

Implications for policy and practice

The research findings of this study have policy and practice implications for practitioners, guideline implementers, and policymakers looking for policy sensitive conceptual models to aid in CPG implementation. The enrichments to both the KTA and CFIR framework provide insights for those within the field of implementation that help to more critically explore and be mindful of policy, political, and health systems considerations. Implementation efforts will have new perspectives and expanded facets within each respective framework to allow more avenues towards successful CPG implementation. Policy, political, and health systems considerations also provide additional criteria to assess the success of implementation efforts spanning the entire implementation process (i.e., planning, executing, and evaluating). Furthermore, identifying areas of conflict, key junctures, and underlying motivations (i.e., interests, ideas, etc.) will help to proactively and iteratively address any potential challenges that may hinder implementation efforts. In turn, the application of the enriched frameworks can be used to help

mitigate barriers to recommendation use and to improve implementation efforts for better patient care and a more robust health system.

Implications for future research

Future research should focus on formally testing the enriched frameworks to evaluate if their application leads to CPGs that are more credible, of higher quality, and ultimately more implementable. In particular, further refinement of the identified list of facilitators, barriers, and strategies in light of testing in different contexts would be helpful. The enriched frameworks bring both insight and opportunity to implementation efforts through the explicit focus on policy variables missing within the implementation literature. The lack of attention and engagement with policy within implementation science both by those in the field and those from the policy context, also opens the door to research on unlikely topics and applications of the frameworks.

References

1. Bauer, M. S., Damschroder, L., Hagedorn, H., Smith, J., & Kilbourne, A. M. (2015). An introduction to implementation science for the non-specialist. *BMC psychology*, *3*(1), 32.

2. Damschroder, L. J. (2019). Clarity out of Chaos: Use of Theory in Implementation Research. *Psychiatry Research*.

3. Peters, D. H., Adam, T., Alonge, O., Agyepong, I. A., & Tran, N. (2013). Implementation research: what it is and how to do it. *Bmj*, *347*, f6753.

4. Bauer, M. S., & Kirchner, J. (2019). Implementation science: What is it and why should i care?. *Psychiatry research*.

5. Nilsen, P. (2015). Making sense of implementation theories, models and frameworks. *Implementation science*, *10*(1), 53.

6. Rycroft-Malone, J., Harvey, G., Seers, K., Kitson, A., McCormack, B., & Titchen, A. (2004). An exploration of the factors that influence the implementation of evidence into practice. *Journal of clinical nursing*, *13*(8), 913-924.

7. Fischer, F., Lange, K., Klose, K., Greiner, W., & Kraemer, A. (2016, June). Barriers and strategies in guideline implementation—a scoping review. In *Healthcare* (Vol. 4, No. 3, p. 36). Multidisciplinary Digital Publishing Institute.

8. Hayawi, L. M., Graham, I. D., Tugwell, P., & Yousef Abdelrazeq, S. (2018). Screening for osteoporosis: A systematic assessment of the quality and content of clinical practice guidelines, using the AGREE II instrument and the IOM Standards for Trustworthy Guidelines. *PloS one*, *13*(12), e0208251.

9. Turner, T., Misso, M., Harris, C., & Green, S. (2008). Development of evidence-based clinical practice guidelines (CPGs): comparing approaches. *Implementation science*, *3*(1), 45.

10. Prior, M., Guerin, M., & Grimmer-Somers, K. (2008). The effectiveness of clinical guideline implementation strategies–a synthesis of systematic review findings. *Journal of evaluation in clinical practice*, *14*(5), 888-897.

11. Gagliardi, A. R., Brouwers, M. C., Palda, V. A., Lemieux-Charles, L., & Grimshaw, J. M. (2011). How can we improve guideline use? A conceptual framework of implementability. *Implementation Science*, *6*(1), 26.

12. Davis, D. A., & Taylor-Vaisey, A. (1997). Translating guidelines into practice: A systematic review of theoretic concepts, practical experience and research evidence in the adoption of clinical practice guidelines. *Canadian Medical Journal Association*, *157*(4), 408-416.

13. Conroy, M., & Shannon, W. (1995). Clinical guidelines: Their implementation in general practice. *The British Journal of General Practice*, *45*(396), 371-375.

14. Dixon-Woods, M., Cavers, D., Agarwal, S., Annandale, E., Arthur, A., Harvey, J., ... & Riley, R. (2006). Conducting a critical interpretive synthesis of the literature on access to healthcare by vulnerable groups. *BMC medical research methodology*, *6*(1), 35.

15. Grimshaw, J., & Russell, I. T. (1993). Effect of clinical guidelines on medical practice: A systematic review of rigorous evaluations. *The Lancet*, *342*(8883), 1317-1322.

16. Halpern, J. (1995). Can the development of practice guidelines safeguard patient values? *Journal of Law, Medicine & Ethics*, *23*(1), 75-81.

17. Kane, R. L. (1995). Creating practice guidelines: The dangers of over-reliance on expert judgment. *Journal of Law, Medicine & Ethics*, *23*(1), 62-64.

18. Moat, K. A., Lavis, J. N., & Abelson, J. (2013). How Contexts and Issues Influence the Use of Policy-Relevant Research Syntheses: A Critical Interpretive Synthesis. *The Milbank Quarterly*, *91*(3), 604-648.

19. Pauly, M. V. (1995). Practice guidelines: Can they save money? Should they? *Journal of Law, Medicine & Ethics*, *23*(1), 65-74

20. Wilson, M. G., Ellen, M. E., Lavis, J. N., Grimshaw, J. M., Moat, K. A., Shemer, J., ... & Peffer, J. (2014). Processes, contexts, and rationale for disinvestment: a protocol for a critical interpretive synthesis. *Systematic reviews*, *3*(1), 143.

21. Michie, S., Atkins, L., & West, R. (2014). The behaviour change wheel. *A guide to designing interventions. 1st ed. Great Britain: Silverback Publishing*, 1003-1010.

22. Graham, I. D., Logan, J., Harrison, M. B., Straus, S. E., Tetroe, J., Caswell, W., & Robinson, N. (2006). Lost in knowledge translation: time for a map?. *Journal of continuing education in the health professions*, *26*(1), 13-24.

23. Damschroder, L. J., Aron, D. C., Keith, R. E., Kirsh, S. R., Alexander, J. A., & Lowery, J. C. (2009). Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. *Implementation science*, *4*(1), 50.

24. Woolf, S., Schünemann, H. J., Eccles, M. P., Grimshaw, J. M., & Shekelle, P. (2012). Developing clinical practice guidelines: types of evidence and outcomes; values and economics, synthesis, grading, and presentation and deriving recommendations. *Implementation Science*, *7*(1), 61.

25. Sackett, D. L., Rosenberg, W. M., Gray, J. M., Haynes, R. B., & Richardson, W. S. (1996). Evidence based medicine: what it is and what it isn't.

26. Gagne, M. E., & Boulet, L. P. (2018). Implementation of asthma clinical practice guidelines in primary care: A cross-sectional study based on the Knowledge-to-Action Cycle. *Journal of Asthma*, *55*(3), 310-317.

27. Munce, S., Kastner, M., Cramm, H., Lal, S., Deschêne, S. M., Auais, M., ... & Brouwers, M. (2013). Applying the knowledge to action framework to plan a strategy for implementing breast cancer screening guidelines: an interprofessional perspective. *Journal of Cancer Education*, *28*(3), 481-487.

28. Wallace, B., Pagan, F., & Pauly, B. B. (2019). The implementation of overdose prevention sites as a novel and nimble response during an illegal drug overdose public health emergency. *International Journal of Drug Policy*, *66*, 64-72.

29. Lambert-Kerzner, A. C., Aasen, D. M., Overbey, D. M., Damschroder, L. J., Henderson, W. G., Hammermeister, K. E., ... & Meguid, R. A. (2019). Use of the consolidated framework for implementation research to guide dissemination and implementation of new technologies in surgery. *Journal of thoracic disease*, *11*(Suppl 4), S487.

30. Hader, J. M., White, R., Lewis, S., Foreman, J. L., McDonald, P. W., & Thompson, L. G. (2007). Doctors' views of clinical practice guidelines: a qualitative exploration using innovation theory. *Journal of Evaluation in Clinical Practice*, *13*(4), 601-606.

31. Harting, J., Rutten, G. M., Rutten, S. T., & Kremers, S. P. (2009). A qualitative application of the diffusion of innovations theory to examine determinants of guideline adherence among physical therapists. *Physical Therapy*, *89*(3), 221-232.

32. Bamford, C., Heaven, B., May, C., & Moynihan, P. (2012). Implementing nutrition guidelines for older people in residential care homes: a qualitative study using normalization process theory. *Implementation Science*, *7*(1), 106.

33. May, C., Sibley, A., & Hunt, K. (2014). The nursing work of hospital-based clinical practice guideline implementation: an explanatory systematic review using Normalisation Process Theory. *International journal of nursing studies*, *51*(2), 289-299.

34. Lazenby, M., Ercolano, E., Tan, H., Ferrucci, L., Badger, T., Grant, M., ... & McCorkle, R. (2019). Using the RE-AIM framework for dissemination and implementation of psychosocial distress screening. *European journal of cancer care*, *28*(4), e13036.

35. Catherine, H. Y., Casey, C. G., Ke, C., Lebovic, G., & Straus, S. E. (2019). Process Evaluation of the Diabetes Canada Guidelines Dissemination Strategy Using the Reach Effectiveness Adoption Implementation Maintenance (RE-AIM) Framework. *Canadian Journal of Diabetes*, *43*(4), 263-270.

36. Field, B., Booth, A., Ilott, I., & Gerrish, K. (2014). Using the Knowledge to Action Framework in practice: a citation analysis and systematic review. *Implementation Science*, *9*(1), 172.

37. Safaeinili, N., Brown-Johnson, C., Shaw, J. G., Mahoney, M., & Winget, M. (2020). CFIR simplified: Pragmatic application of and adaptations to the Consolidated Framework for Implementation Research (CFIR) for evaluation of a patient-centered care transformation within a learning health system. *Learning Health Systems*, *4*(1), e10201.

38. Rycroft-Malone, J., & Bucknall, T. (Eds.). (2010). *Models and frameworks for implementing evidence-based practice: linking evidence to action*. John Wiley & Sons.

39. Glaser, B. G., & Strauss, A. L. (2017). *The discovery of grounded theory: Strategies for qualitative research*. Routledge.

40. Creswell, J. W., & Poth, C. N. (2016). *Qualitative inquiry and research design: Choosing among five approaches*. Sage publications.

41. Lavis J. N. Setting agendas and developing and implementing policies: Summary sheet. Hamilton, Canada: McMaster Health Forum, 2017. https://www.mcmasterforum.org/docs/default-source/resources/9_sdi_summary-sheet.pdf?sfvrsn=8

42. Lavis, J. N., Røttingen, J. A., Bosch-Capblanch, X., Atun, R., El-Jardali, F., Gilson, L., ... & Haines, A. (2012). Guidance for evidence-informed policies about health systems: linking guidance development to policy development. *PLoS Med*, *9*(3), e1001186.

43. Gauvin, F. P. (2014). *Understanding policy developments and choices through the" 3-i" framework: interests, ideas and institutions*. National Collaborating Centre for Healthy Public Policy.

44. Lavis J. N. Health systems evidence: Taxonomy of governance, financial and delivery arrangements and implementation strategies within health systems. Hamilton, Canada: McMaster Health Forum, 2017. https://www.mcmasterforum.org/docs/default-source/resources/16_hse_taxonomy.pdf?sfvrsn=6

45. McHugh, M. L. (2012). Interrater reliability: the kappa statistic. *Biochemia medica: Biochemia medica*, *22*(3), 276-282.

46. Rogers, E. M. (1995). Lessons for guidelines from the diffusion of innovations. *The Joint Commission journal on quality improvement*, *21*(7), 324-328.

47. McKinlay, J. B., Link, C. L., Freund, K. M., Marceau, L. D., O'Donnell, A. B., & Lutfey, K. L. (2007). Sources of variation in physician adherence with clinical guidelines: results from a factorial experiment. *Journal of General Internal Medicine*, *22*(3), 289-296.

48. Radwan, M., Sari, A. A., Rashidian, A., Takian, A., Elsous, A., & Abou-Dagga, S. (2018). Factors hindering the adherence to clinical practice guideline for diabetes mellitus in the Palestinian primary healthcare clinics: a qualitative study. *BMJ open*, *8*(9), e021195.

49. Cabana, M. D., Rand, C. S., Powe, N. R., Wu, A. W., Wilson, M. H., Abboud, P. A. C., & Rubin, H. R. (1999). Why don't physicians follow clinical practice guidelines?: A framework for improvement. *Jama*, *282*(15), 1458-1465.

50. Gagliardi, A. R., & Alhabib, S. (2015). Trends in guideline implementation: a scoping systematic review. *Implementation Science*, *10*(1), 1-11.

51. Brouwers, M. C., De Vito, C., Bahirathan, L., Carol, A., Carroll, J. C., Cotterchio, M., ... & Wathen, N. (2011). Effective interventions to facilitate the uptake of breast, cervical and colorectal cancer screening: an implementation guideline. *Implementation Science*, *6*(1), 1-8.

52. Kastner, M., Bhattacharyya, O., Hayden, L., Makarski, J., Estey, E., Durocher, L., ... & Brouwers, M. (2015). Guideline uptake is influenced by six implementability domains for creating and communicating guidelines: a realist review. *Journal of clinical epidemiology*, *68*(5), 498-509.

53. Gagliardi, A. R., & Brouwers, M. C. (2012). Integrating guideline development and implementation: analysis of guideline development manual instructions for generating implementation advice. *Implementation science*, *7*(1), 1-9.

54. Liang, L., Bernhardsson, S., Vernooij, R. W., Armstrong, M. J., Bussières, A., Brouwers, M. C., & Gagliardi, A. R. (2017). Use of theory to plan or evaluate guideline implementation among physicians: a scoping review. *Implementation Science*, *12*(1), 1-12.

55. Gagliardi, A. R., Marshall, C., Huckson, S., James, R., & Moore, V. (2015). Developing a checklist for guideline implementation planning: review and synthesis of guideline development and implementation advice. *Implementation Science*, *10*(1), 1-9.

56. Braithwaite, J., Hibbert, P. D., Jaffe, A., White, L., Cowell, C. T., Harris, M. F., ... & Muething, S. (2018). Quality of health care for children in Australia, 2012-2013. *Jama*, *319*(11), 1113-1124.

57. Stokes, T., Shaw, E. J., Camosso-Stefinovic, J., Imamura, M., Kanguru, L., & Hussein, J. (2016). Barriers and enablers to guideline implementation strategies to improve obstetric care practice in low-and middle-income countries: a systematic review of qualitative evidence. *Implementation Science*, *11*(1), 1-10.

58. Bäck, A., Ståhl, C., von Thiele Schwarz, U., Richter, A., & Hasson, H. (2016). Walking the tightrope-perspectives on local politicians' role in implementing a national social care policy on evidence-based practice. *International journal of mental health systems*, *10*(1), 1-9.

59. Abrahamson, K. A., Fox, R. L., & Doebbeling, B. N. (2012). Facilitators and barriers to clinical practice guideline use among nurses. *AJN The American Journal of Nursing*, *112*(7), 26-35.

60. Ahn, H. S., & Kim, H. J. (2012). Development and implementation of clinical practice guidelines: current status in Korea. *Journal of Korean medical science*, *27*(Suppl), S55-S60.

61. Beauchemin, M., Cohn, E., & Shelton, R. C. (2019). Implementation of clinical practice guidelines in the healthcare setting: A Concept Analysis. *ANS. Advances in nursing science*, *42*(4), 307.

62. Wang, Z., Bero, L., & Grundy, Q. (2021). Understanding professional stakeholders' active resistance to guideline implementation: The case of Canadian breast screening guidelines. *Social Science & Medicine*, *269*, 113586.

63. Zoubi, F. M. A., Menon, A., Mayo, N. E., & Bussières, A. E. (2018). The effectiveness of interventions designed to increase the uptake of clinical practice guidelines and best practices among musculoskeletal professionals: a systematic review. *BMC health services research*, *18*(1), 1-11.

64. Mazrou, S. H. A. (2013). Expected benefits of clinical practice guidelines: Factors affecting their adherence and methods of implementation and dissemination. *J Health Spec*, *1*(3), 141.

65. Markström, U. (2014). Staying the course? Challenges in implementing evidence-based programs in community mental health services. *International journal of environmental research and public health*, *11*(10), 10752-10769.

66. Jesse, D. E., Morrow, J., Herring, D., Dennis, T., & Laster, B. M. (2009). Translating research to prevent antepartum depression in a local health department prenatal clinic: A model approach. *Journal of Public Health Management and Practice*, *15*(2), 160-166.

67. Ishii, L. E. (2013). Closing the clinical gap: translating best practice knowledge to performance with guidelines implementation. *Otolaryngology–Head and Neck Surgery*, *148*(6), 898-901.

68. Hysong, S. J., Best, R. G., & Pugh, J. A. (2007). Clinical practice guideline implementation strategy patterns in Veterans Affairs primary care clinics. *Health services research*, *42*(1p1), 84-103.

69. Harrison, M. B., Légaré, F., Graham, I. D., & Fervers, B. (2010). Adapting clinical practice guidelines to local context and assessing barriers to their use. *Cmaj*, *182*(2), E78-E84.

70. Harrison, M. B., & Graham, I. D. (2012). Roadmap for a participatory research–practice partnership to implement evidence. *Worldviews on Evidence‐Based Nursing*, *9*(4), 210-220.

71. Grol, R. (2001). Successes and failures in the implementation of evidence-based guidelines for clinical practice. *Medical care*, II46-II54.

72. Grimshaw, J., Thomas, R., MacLennan, G., Fraser, C. R. R. C., Ramsay, C. R., Vale, L. E. E. A., ... & Donaldson, C. (2004). Effectiveness and efficiency of guideline dissemination and implementation strategies.

73. Gagliardi, A. R., Brouwers, M. C., Palda, V. A., Lemieux-Charles, L., & Grimshaw, J. M. (2011). How can we improve guideline use? A conceptual framework of implementability. *Implementation Science*, *6*(1), 1-11.

74. Brouwers, M. C., Kho, M. E., Browman, G. P., Burgers, J. S., Cluzeau, F., Feder, G., ... & Zitzelsberger, L. (2010). AGREE II: advancing guideline development, reporting and evaluation in health care. *Cmaj*, *182*(18), E839-E842.

75. Murad, M. H. (2017, March). Clinical practice guidelines: a primer on development and dissemination. In *Mayo Clinic Proceedings* (Vol. 92, No. 3, pp. 423-433). Elsevier.

76. van der Wees, P. J., Jamtvedt, G., Rebbeck, T., de Bie, R. A., Dekker, J., & Hendriks, E. J. (2008). Multifaceted strategies may increase implementation of physiotherapy clinical guidelines: a systematic review. *Australian Journal of Physiotherapy*, *54*(4), 233-241.

77. Unverzagt, S., Oemler, M., Braun, K., & Klement, A. (2014). Strategies for guideline implementation in primary care focusing on patients with cardiovascular disease: a systematic review. *Family practice*, *31*(3), 247-266.

78. Thompson, D. S., Estabrooks, C. A., Scott-Findlay, S., Moore, K., & Wallin, L. (2007). Interventions aimed at increasing research use in nursing: a systematic review. *Implementation Science*, *2*(1), 1-16.

79. Smith, G., & Kenneally, J. (2013). Development and implementation of Victorian prehospital Clinical Practice Guidelines: The supraventricular tachycardia example. *Australasian Journal of Paramedicine*, *10*(4).

80. Shiffman, R. N., Michel, G., Essaihi, A., & Thornquist, E. (2004). Bridging the guideline implementation gap: a systematic, document-centered approach to guideline implementation. *Journal of the American Medical Informatics Association*, *11*(5), 418-426.

81. Weller, C. D., Richards, C., Turnour, L., Patey, A. M., Russell, G., & Team, V. (2020). Barriers and enablers to the use of venous leg ulcer clinical practice guidelines in Australian primary care: A qualitative study using the theoretical domains framework. *International journal of nursing studies*, *103*, 103503.

82. Jun, J., Kovner, C. T., & Stimpfel, A. W. (2016). Barriers and facilitators of nurses' use of clinical practice guidelines: an integrative review. *International journal of nursing studies*, *60*, 54-68.

83. Watkins, K., Wood, H., Schneider, C. R., & Clifford, R. (2015). Effectiveness of implementation strategies for clinical guidelines to community pharmacy: a systematic review. *Implementation Science*, *10*(1), 1-23.

84. Jin, Y., Li, Z., Han, F., Huang, D., Huang, Q., Cao, Y., ... & Shang, H. C. (2019). Barriers and enablers for the implementation of clinical practice guidelines in China: a mixed-method study. *BMJ open*, *9*(9), e026328.

85. Dizon, J. M., Grimmer, K., Louw, Q., Machingaidze, S., Parker, H., & Pillen, H. (2017). Barriers and enablers for the development and implementation of allied health clinical practice guidelines in South African primary healthcare settings: a qualitative study. *Health Research Policy and Systems*, *15*(1), 1-13.

86. Oliveira, C. D. F., Ribeiro, A. Â. V., Luquine Jr, C. D., de Bortoli, M. C., Toma, T. S., Chapman, E. M. G., & Barreto, E. J. O. M. (2020). Barriers to implementing guideline recommendations to improve childbirth care: rapid review of evidenceObstáculos a la aplicación de las recomendaciones para la atención del parto normal: revisión rápida de evidencia. *Revista Panamericana de Salud Publica= Pan American Journal of Public Health*, *44*, e132-e132.

87. Fischer, F., Lange, K., Klose, K., Greiner, W., & Kraemer, A. (2016, September). Barriers and strategies in guideline implementation—a scoping review. In *Healthcare* (Vol. 4, No. 3, p. 36). Multidisciplinary Digital Publishing Institute.

88. Graham, I. D., Harrison, M. B., Brouwers, M., Davies, B. L., & Dunn, S. (2002). Facilitating the use of evidence in practice: evaluating and adapting clinical practice guidelines for local use by health care organizations. *Journal of Obstetric, Gynecologic, & Neonatal Nursing*, *31*(5), 599-611.

89. Hakkennes, S., & Dodd, K. (2008). Guideline implementation in allied health professions: a systematic review of the literature. *BMJ Quality & Safety*, *17*(4), 296-300.

90. Alnaim, L., & Almazrou, S. (2018). A study of barriers and facilitators of clinical practice guidelines implementation among physicians. *Indian Journal of Pharmaceutical Sciences*, *79*(6), 923-929.

91. Bahtsevani, C., Willman, A., Stoltz, P., & Östman, M. (2010). Experiences of the implementation of clinical practice guidelines–interviews with nurse managers and nurses in hospital care. *Scandinavian journal of caring sciences*, *24*(3), 514-522.

92. Baradaran-Seyed, Z., Nedjat, S., Yazdizadeh, B., Nedjat, S., & Majdzadeh, R. (2013). Barriers of clinical practice guidelines development and implementation in developing countries: a case study in iran. *International journal of preventive medicine*, *4*(3), 340.

93. Barreto, J. O. M., Bortoli, M. C., Luquine Jr, C. D., Oliveira, C. F., Toma, T. S., Ribeiro, A. A., ... & Chapman, E. (2020). Implementation of national childbirth guidelines in Brazil: barriers and strategies. *Revista Panamericana de Salud Pública*, *44*.

94. Baskerville, N. B., Liddy, C., & Hogg, W. (2012). Systematic review and meta-analysis of practice facilitation within primary care settings. *The Annals of Family Medicine*, *10*(1), 63-74.

95. Restall, G., Diaz, F., & Wittmeier, K. (2020). Why Do Clinical Practice Guidelines Get Stuck during Implementation and What Can Be Done: A Case Study in Pediatric Rehabilitation. *Physical & occupational therapy in pediatrics*, *40*(2), 217-230.

96. Ozisik, L., Tanriover, M. D., Altınel, S., & Unal, S. (2017). Vaccinating healthcare workers: level of implementation, barriers and proposal for evidence-based policies in Turkey. *Human vaccines & immunotherapeutics*, *13*(5), 1198-1206.

97. Lin, I. B., Coffin, J., & O'Sullivan, P. B. (2016). Using theory to improve low back pain care in Australian Aboriginal primary care: a mixed method single cohort pilot study. *BMC family practice*, *17*(1), 1-14.

98. Higuchi, K. S., Downey, A., Davies, B., Bajnok, I., & Waggott, M. (2013). Using the NHS sustainability framework to understand the activities and resource implications of Canadian nursing guideline early adopters. *Journal of Clinical Nursing*, *22*(11-12), 1707-1716.

99. Sharma, S., Pandit, A., & Tabassum, F. (2017). Potential facilitators and barriers to adopting standard treatment guidelines in clinical practice: An Indian context. *International journal of health care quality assurance*.

100. Hoomans, T., Ament, A. J., Evers, S. M., & Severens, J. L. (2011). Implementing guidelines into clinical practice: what is the value?. *Journal of evaluation in clinical practice*, *17*(4), 606-614.

101. Kredo, T., Bernhardsson, S., Machingaidze, S., Young, T., Louw, Q., Ochodo, E., & Grimmer, K. (2016). Guide to clinical practice guidelines: the current state of play. *International Journal for Quality in Health Care*, *28*(1), 122-128.

102. Francke, A. L., Smit, M. C., de Veer, A. J., & Mistiaen, P. (2008). Factors influencing the implementation of clinical guidelines for health care professionals: a systematic meta-review. *BMC medical informatics and decision making*, *8*(1), 1-11.

103. Chakkalakal, R. J., Cherlin, E., Thompson, J., Lindfield, T., Lawson, R., & Bradley, E. H. (2013). Implementing clinical guidelines in low-income settings: a review of literature. *Global public health*, *8*(7), 784-795.

104. Parks, J. J. (2007). Implementing practice guidelines: Lessons from public mental health settings. *Journal of Clinical Psychiatry*, *68*(4), 45.

105. Gartlehner, G. (2004). Evidence-based medicine breaking the borders–A working model for the European Union to facilitate evidence-based health care. *Wiener Medizinische Wochenschrift*, *154*(5), 127-132.

106. Docherty, M., Shaw, K., Goulding, L., Parke, H., Eassom, E., Ali, F., & Thornicroft, G. (2017). Evidence-based guideline implementation in low and middle income countries: lessons for mental health care. *International journal of mental health systems*, *11*(1), 1-16.

107. Ploeg, J., Davies, B., Edwards, N., Gifford, W., & Miller, P. E. (2007). Factors influencing best-practice guideline implementation: Lessons learned from administrators, nursing staff, and project leaders. *Worldviews on Evidence-Based Nursing*, *4*(4), 210-219.

108. Correa, V. C., Lugo-Agudelo, L. H., Aguirre-Acevedo, D. C., Contreras, J. A. P., Borrero, A. M. P., Patiño-Lugo, D. F., & Valencia, D. A. C. (2020). Individual, health system, and contextual barriers and facilitators for the implementation of clinical practice guidelines: a systematic metareview. *Health research policy and systems*, *18*(1), 1-11.

109. Overington, J. D., Huang, Y. C., Abramson, M. J., Brown, J. L., Goddard, J. R., Bowman, R. V., ... & Yang, I. A. (2014). Implementing clinical guidelines for chronic obstructive pulmonary disease: barriers and solutions. *Journal of thoracic disease*, *6*(11), 1586.

110. Cortoos, P. J., Simoens, S., Peetermans, W., Willems, L., & Laekeman, G. (2007). Implementing a hospital guideline on pneumonia: a semi-quantitative review. *International Journal for Quality in Health Care*, *19*(6), 358-367.

111. Kallam, B., Pettitt-Schieber, C., Owen, M., Asante, R. A., Darko, E., & Ramaswamy, R. (2018). Implementation science in low-resource settings: using the interactive systems framework to improve hand hygiene in a tertiary hospital in Ghana. *International Journal for Quality in Health Care*, *30*(9), 724.

112. Marcial, E., & Graves, B. A. (2019). Implementation and evaluation of diabetes clinical practice guidelines in a primary care clinic serving a Hispanic community. *Worldviews on Evidence-Based Nursing*, *16*(2), 142-150.

113. Miller, M., & Kearney, N. (2004). Guidelines for clinical practice: development, dissemination and implementation. *International journal of nursing studies*, *41*(7), 813-821.

114. Padula, W. V., Gibbons, R. D., Valuck, R. J., Makic, M. B. F., Mishra, M. K., Pronovost, P. J., & Meltzer, D. O. (2016). Are evidence-based practices associated with effective prevention of hospital-acquired pressure ulcers in US academic medical centers?. *Medical care*, *54*(5), 512.

115. Borbas, C., Morris, N., McLaughlin, B., Asinger, R., & Gobel, F. (2000). The role of clinical opinion leaders in guideline implementation and quality improvement. *Chest*, *118*(2), 24S-32S.

116. Browman, G. P., Levine, M. N., Mohide, E. A., Hayward, R. S., Pritchard, K. I., Gafni, A., & Laupacis, A. (1995). The practice guidelines development cycle: a conceptual tool for practice guidelines development and implementation. *Journal of Clinical Oncology*, *13*(2), 502-512.

117. Chaillet, N., Dubé, E., Dugas, M., Audibert, F., Tourigny, C., Fraser, W. D., & Dumont, A. (2006). Evidence-based strategies for implementing guidelines in obstetrics: a systematic review. *Obstetrics & Gynecology*, *108*(5), 1234-1245.

118. Chan, W. V., Pearson, T. A., Bennett, G. C., Cushman, W. C., Gaziano, T. A., Gorman, P. N., ... & Vann, J. C. J. (2017). ACC/AHA special report: clinical practice guideline implementation strategies: a summary of systematic reviews by the NHLBI Implementation Science Work Group: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *Circulation*, *135*(9), e122-e137.

119. Bernhardsson, S., Lynch, E., Dizon, J. M., Fernandes, J., Gonzalez-Suarez, C., Lizarondo, L., ... & Grimmer, K. (2017). Advancing evidence-based practice in physical therapy settings: multinational perspectives on implementation strategies and interventions. *Physical therapy*, *97*(1), 51-60.

120. Bero, L. A., Grilli, R., Grimshaw, J. M., Harvey, E., Oxman, A. D., & Thomson, M. A. (1998). Closing the gap between research and practice: an overview of systematic reviews of interventions to promote the implementation of research findings. *Bmj*, *317*(7156), 465-468.

121. Bierbaum, M., Rapport, F., Arnolda, G., Nic Giolla Easpaig, B., Lamprell, K., Hutchinson, K., ... & Braithwaite, J. (2020). Clinicians' attitudes and perceived barriers and facilitators to cancer treatment clinical practice guideline adherence: a systematic review of qualitative and quantitative literature. *Implementation Science*, *15*, 1-24.

122. De Angelis, G., Davies, B., King, J., McEwan, J., Cavallo, S., Loew, L., ... & Brosseau, L. (2016). Information and communication technologies for the dissemination of clinical

practice guidelines to health professionals: a systematic review. *JMIR medical education*, *2*(2), e6288.

123. Lyssa Friedman, R. N., Constance Engelking, R. N., Catherine Harvey, R. N., & Martha Read, R. N. (2009). The EDUCATE study: a continuing education exemplar for clinical practice guideline implementation. *Clinical Journal of Oncology Nursing*, *13*(2), 219.

124. Garbutt, J. M., Dodd, S., Walling, E., Lee, A. A., Kulka, K., & Lobb, R. (2018). Theory-based development of an implementation intervention to increase HPV vaccination in pediatric primary care practices. *Implementation Science*, *13*(1), 1-8.

125. Phillips, J. L., Lovell, M., Luckett, T., Agar, M., Green, A., & Davidson, P. (2015). Australian survey of current practice and guideline use in adult cancer pain assessment and management: The community nurse perspective. *Collegian*, *22*(1), 33-41.

126. Prior, M., Guerin, M., & Grimmer-Somers, K. (2008). The effectiveness of clinical guideline implementation strategies–a synthesis of systematic review findings. *Journal of evaluation in clinical practice*, *14*(5), 888-897.

127. Sandström, B., Willman, A., Svensson, B., & Borglin, G. (2015). Perceptions of national guidelines and their (non) implementation in mental healthcare: a deductive and inductive content analysis. *Implementation Science*, *10*(1), 1-13.

128. Yawn, B. P., Akl, E. A., Qaseem, A., Black, P., & Campos-Outcalt, D. (2012). Identifying target audiences: who are the guidelines for? Article 1 in integrating and coordinating efforts in COPD guideline development. An official ATS/ERS Workshop Report. *Proceedings of the American Thoracic Society*, *9*(5), 219-224.

129. Shrubsole, K., Worrall, L., Power, E., & O'Connor, D. A. (2019). Barriers and facilitators to meeting aphasia guideline recommendations: What factors influence speech pathologists' practice?. *Disability and Rehabilitation*, *41*(13), 1596-1607.

130. Vega, R., Jackson, G. L., Henderson, B., Clancy, C., McPhail, J., Cutrona, S. L., ... & Bhatnagar, S. (2019). Diffusion of excellence: accelerating the spread of clinical innovation and best practices across the nation's largest health system. *The Permanente journal*, *23*.

131. Parmelli, E., Langendam, M., Piggott, T., Adolfsson, J., Akl, E. A., Armstrong, D., ... & Schünemann, H. J. (2021). Guideline-based quality assurance: a conceptual framework for the definition of key elements. *BMC Health Services Research*, *21*(1), 1-8.

132. Piggott, T., Langendam, M., Parmelli, E., Adolfsson, J., Akl, E. A., Armstrong, D., ... & Schünemann, H. J. (2021). Bringing two worlds closer together: a critical analysis of an integrated approach to guideline development and quality assurance schemes. *BMC Health Services Research*, *21*(1), 1-12.

133. Langendam, M. W., Piggott, T., Nothacker, M., Agarwal, A., Armstrong, D., Baldeh, T., ... & Schünemann, H. J. (2020). Approaches of integrating the development of guidelines and quality indicators: a systematic review. *BMC health services research*, *20*(1), 1-11.

134. Lavis JN. Finding and using research evidence: Summary sheet. Hamilton, Canada: McMaster Health Forum, 2019.

135. Patton, M. Q. (1999). Enhancing the quality and credibility of qualitative analysis. *Health services research*, *34*(5 Pt 2), 1189.

136. Becker, T., Kilian, R., & Koesters, M. (2017). Policies, guideline implementation and practice change–how can the process be understood?. *Epidemiology and Psychiatric Sciences*, *26*(2), 115-118.

137. Ploeg, J., Davies, B., Edwards, N., Gifford, W., & Miller, P. E. (2007). Factors influencing best-practice guideline implementation: lessons learned from administrators, nursing staff, and project leaders. *Worldviews on Evidence-Based Nursing*, *4*(4), 210-219.

138. Kislov, R., Pope, C., Martin, G. P., & Wilson, P. M. (2019). Harnessing the power of theorising in implementation science. *Implementation Science*, *14*(1), 1-8.

139. Sheikh, K., Gilson, L., Agyepong, I. A., Hanson, K., Ssengooba, F., & Bennett, S. (2011). Building the field of health policy and systems research: framing the questions. *PLoS medicine*, *8*(8), e1001073.

140. Mills, A. (2012). Health policy and systems research: defining the terrain; identifying the methods. *Health policy and planning*, *27*(1), 1-7.

Figure 1 – Literature search and study selection flow diagram

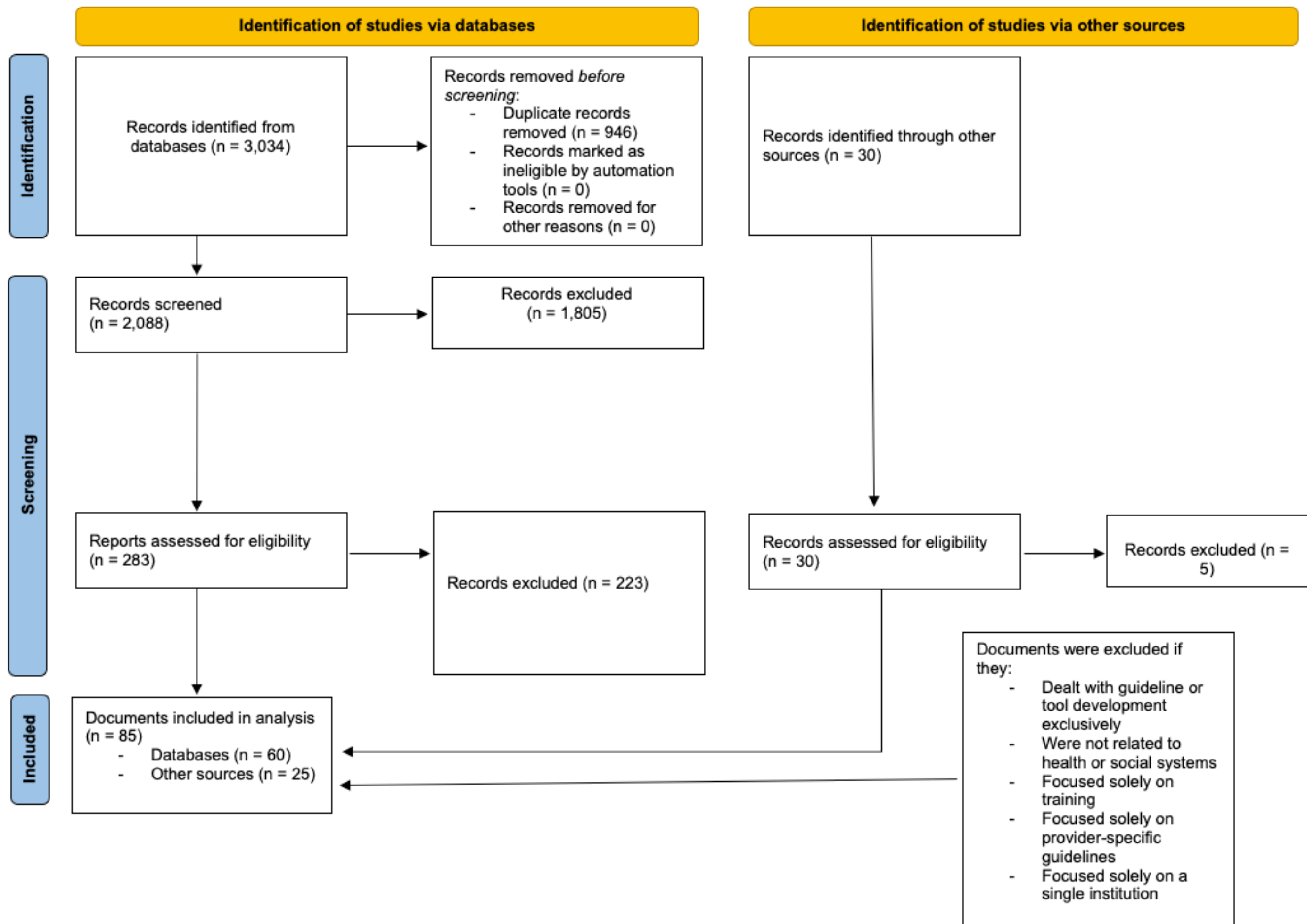


Table 1: Policy-relevant facilitators, barriers, and strategies for CPG implementation within the policy context

<table>
<tr><th>Level</th><th>Facilitators (in the language of the source literature)</th><th>Barriers (in the language of the source literature)</th><th>Strategies (in the language of the source literature)</th></tr>
<tr><td>Policy level</td><td>Alignment with frameworks
• Framing implementation efforts in a manner that motivates different groups (i.e., relevant stakeholders and users) to adhere to or participate in implementation efforts
• Tailored interventions that are multifaceted and provide tools, templates, or instructions for implementation
• Use of local consensus processes, educational outreach visits, and peer review to assess implementation efforts

Unique additions to frameworks
• Policy stakeholders' views and experiences explicitly made a priority in implementation efforts

Augmentation to frameworks
• Leveraging policy legacies:
○ Aligning implementation efforts with relevant past efforts (i.e., past policies, initiatives)</td><td>Alignment with frameworks
• Lack of adequate consideration of local applicability (i.e., options for adapting to local policies, regulations, etc.)
• Lack of awareness of implementation efforts by both users and relevant interest groups (e.g., clientele pluralist networks)
• Overlooking implementation considerations that require large organizational changes (i.e., investments of time and resources)

Unique additions to frameworks
• Benefits of options not made clear to those who will be affected (i.e., citizens/patients, providers, organizations, or system)

Augmentation to frameworks
• Recognizing limited organizational policy support:
○ Lack of policies to foster trust (i.e., options to contribute to decision-making process) within implementation hierarchy (e.g., opportunity to join a steering committee)</td><td>Alignment with frameworks
• Create strategic and operational plans that optimize implementation capacity (e.g., identifying and addressing local costs of each option)

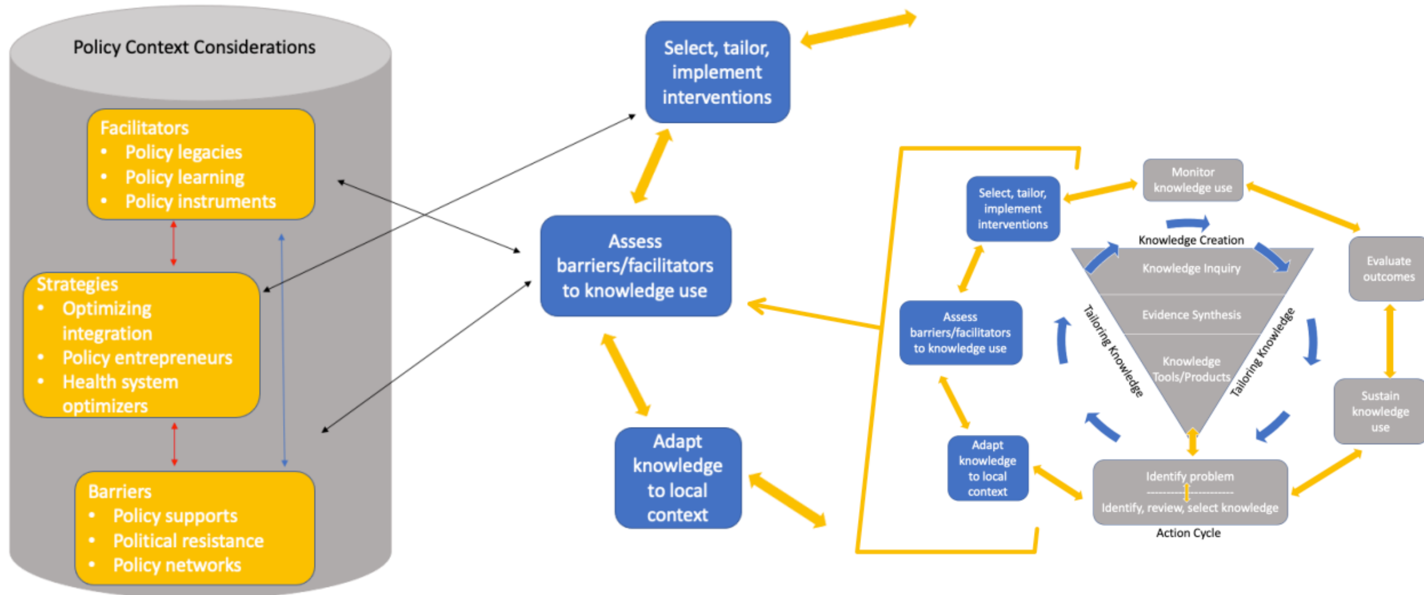
Unique additions to frameworks
• Establishing programs to support implementation efforts among policy-relevant stakeholders

Augmentation to frameworks
• Optimizing integration through policy:
○ Identifying existing programs or services that can aid in devising clear integration strategies for organizational structures/processes</td></tr>
</table>

Political level	*Alignment with frameworks* • Knowledge/beliefs about 'what is' is delivered by someone considered a trusted source of information • Implementation programs are informed by research evidence and tacit knowledge to ensure well-defined objectives and systematically applied methods • Elite opinions help to bring awareness to the negative consequences of inappropriate practices *Unique additions to frameworks* • **Framing implementation efforts as concentrated benefits for clientele pluralist networks and emphasize diffusion of cost to address potential resistance** *Augmentation to frameworks* • **Policy learning:** ○ **Using policy learning to support/leverage the success of implementation efforts**	*Alignment with frameworks* • Overlooking or minimizing the role of local authorities (i.e., entrepreneurs) within implementation efforts • Lack of endorsement from government elites • Contradictory or complex evidence underlying implementation efforts (e.g., external factors) *Unique additions to frameworks* • **Jurisdictional (i.e., institutional arrangements) and professional autonomy conflicts (i.e., set by past policies) that impact implementation efforts** • **Lack of administrative capacities to support implementation efforts** • **Issues related to conflict of interest between policy networks (i.e., clientele pluralist networks and pressure pluralist networks)** *Augmentation to frameworks* • **Political resistance:** ○ **Active resistance from interest groups (e.g., professional associations)**	*Alignment with frameworks* • Clearly defining target interest groups (i.e., patients, public, etc.) to ensure tailored implementation efforts reflect their views and preferences • Using clear and simple messaging to better capture ideas (e.g., knowledge/beliefs about 'what is'; values/mass opinion about 'what ought to be') ○ Justifying any deliberate vagueness • Tailoring language to specific groups (e.g., policymakers) *Unique additions to frameworks* • **Use of elite opinions (i.e., opinion leaders) and policy entrepreneurs to:** ○ **Advise on tailoring of implementation** ○ **Influence peers as champions** ○ **Assist with implementation** *Augmentation to frameworks* • **Partnerships with policy entrepreneurs:** ○ **Leveraging individuals who can exploit opportunities to influence policy outcomes so as to promote and facilitate implementation**
Health systems level	*Alignment with frameworks* • Access to appropriate delivery arrangements (i.e., clear procedures,	*Alignment with frameworks* • Lack of clarity of professional role (i.e., policy authority), required	*Alignment with frameworks* • Creating a better communication infrastructure between distant health professionals (i.e., delivery arrangement)

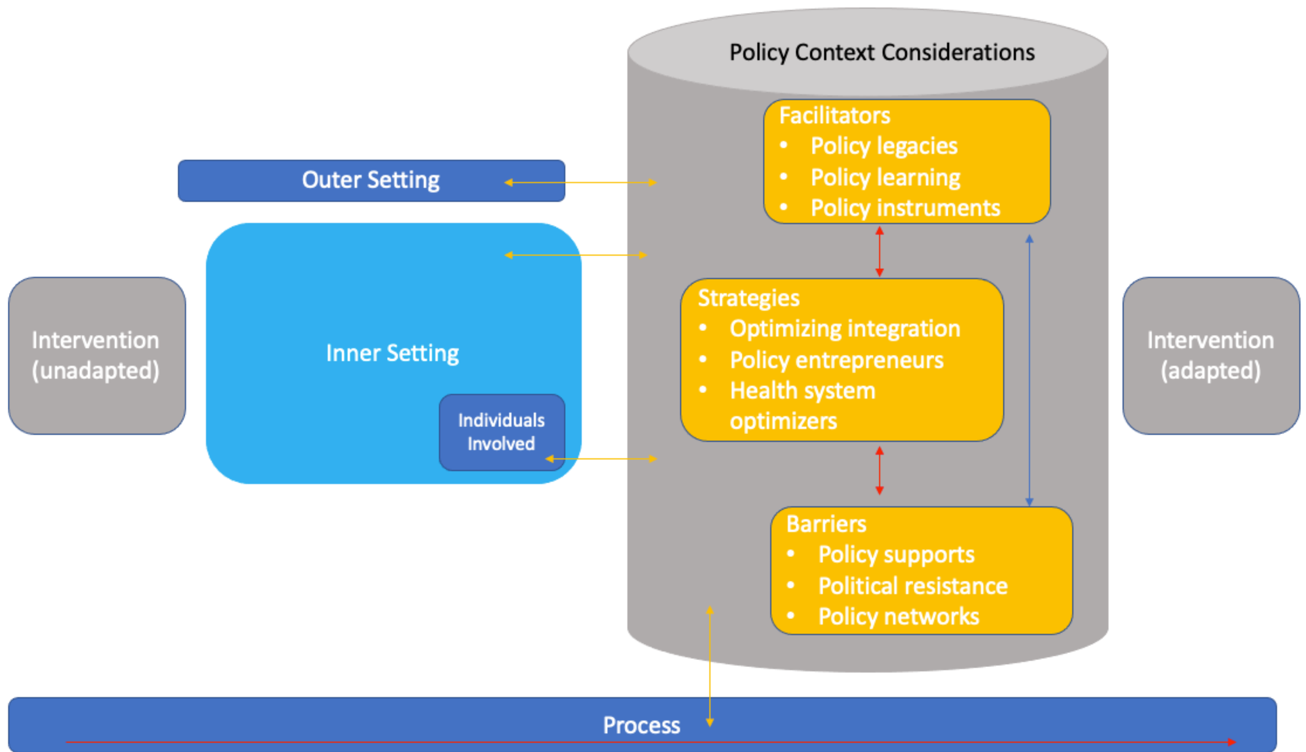
	protocols, and standardized resources) *Unique additions to frameworks* • **Governance (i.e., leadership supports), financial (i.e., align budgets), and delivery arrangements (i.e., integration of services) in place to support and guide diffusion of implementation efforts** • **Education provisions (i.e., delivery arrangements) in place to support all relevant stakeholders** *Augmentation to frameworks* • **Leveraging collaborative policy instruments:** ○ **Governance arrangements (i.e., clear mandates) to facilitate inter-organizational collaboration and networks**	skills/knowledge (i.e., professional authority), or available resources • Overlooking barriers for delivery arrangements (i.e., how care is designed, by whom is care provided, where care is provided, and with what supports is care provided) stemming from training, workforce availability, and scarce resources • Lack of adequate human resources (both number and type) • Inadequate organizational structure to support implementation efforts *Unique additions to frameworks* • **Underdeveloped infrastructure to support, compensate, and train all relevant stakeholders (i.e., recruitment, retention, and transitions)** • **Poor information/communication technology training and supports** *Augmentation to frameworks* • **Exclusion of policy networks:** ○ **Lack of adequate patient/stakeholder involvement (i.e., provider-targeted strategies) in implementation efforts and associated policies**	• Creating an implementation or multidisciplinary team *Unique additions to frameworks* • **Governance arrangements to support implementation strategies such as overcoming issues stemming from professional authority (e.g., liability protection)** • **Investing significantly in financial and delivery arrangements that support implementation efforts** • **Standardizing implementation approaches and strategies across organizations (i.e., provider- and organization-targeted strategies)** *Augmentation to frameworks* • **Health system optimizers:** ○ **Better tailoring policy instruments (i.e., legal, voluntary, education, etc.) to support implementation efforts**

Figure 2 - Enrichments to Knowledge-to-Action Framework



Note: Adapted from Graham et al.[22]

Figure 3 - Enrichments to the Consolidated Framework for Implementation Research



Note: Adapted from Damschroder et al.[23]

Table 2: Operationalizing the policy context considerations within the Action Cycle stages

Action Cycle Stage	Examples of ways to operationalize policy context considerations
Adapt knowledge to local context.	• Prioritize the views and experiences of policy networks by either: o Creating a review process that leverages local policy actors and networks to provide feedback related implementation recommendations and related activities. o Expanding the implementation team by adding local/national policymakers, policy analysts, or other policy-relevant actors. o Hiring policy consultants to assess policies, initiatives, and regulations at the local context, that may influence (i.e., hinder or facilitate) implementation efforts. • Conduct a scan of local policies (i.e., a jurisdictional scan) to ensure implementation efforts are aligned with relevant past efforts (i.e., past policies, initiatives) and use policy learning to support/leverage the success of implementation efforts. • Provide training for policy-relevant stakeholders to address gaps in knowledge pertaining to implementation concepts and activities.
Assess barriers/facilitators to knowledge use	• Identify health system optimizers such as what governance (i.e., leadership supports), financial (i.e., align budgets to objectives), and delivery arrangements are in place to support and guide diffusion of implementation efforts. • Assess what governance supports (e.g., clear mandates) exist that can influence (i.e., facilitate or hinder) inter-organizational collaboration and policy networks engagement with implementation efforts. • Consult with professional organizations involved in CPG implementation efforts to appropriately assess the existence of any political resistance, such as those that may stem from professional autonomy and jurisdictional conflicts, that may impact implementation efforts. • Identify policy supports that may cause any shortcomings in organizational infrastructure within participating organizations as they pertain to: o Administrative capacities to support implementation efforts. o Infrastructure to support, compensate, and train all policy-relevant stakeholders. o Information/communication technology training and supports.
Select, tailor, implement interventions	• Identify existing (or create) continuing education support programs to support policymakers involved in CPG implementation. • Consult with policy-relevant stakeholders (e.g., policy entrepreneurs) to devise clear integration strategies for organizational structures/processes. • Better tailoring of implementation efforts to policy instruments (i.e., legal, voluntary, education, etc.).

	• Expand recommendations to include a section for policymakers, outlining identified opportunities to invest significantly in financial and delivery arrangements that support implementation efforts.

Table 3: Operationalizing the policy context considerations within CFIR domains

Domain	Examples of ways to operationalize policy context considerations
Outer setting	• Reviewing how similar guideline recommendations were implemented in different jurisdictions (i.e., policy learning). • Creating macro-level reports (i.e., provincial or state-level) on the of level implementation success achieved. • Having local authorities and relevant policy networks provide feedback on implementation plans and policy-relevant recommendations. • Auditing organizational infrastructure to ensure sustainability, ease of access, and that organizational and user strengths are being matched to policy priorities.
Inner setting	• Having policy-relevant stakeholders (i.e., policy entrepreneurs and policy networks) provide feedback on implementability of proposed recommendations. • Create recommendation and guideline formats that appeal to policy-relevant stakeholders. • Use contextualized materials (i.e., procedures and protocols) and tailored implementation training to explicitly target relevant policy networks and users. • Add policy-relevant stakeholders (i.e., policymakers and policy analysts) to the implementation team, to aid in defining target end user populations and mitigating conflict of interest to help facilitate CPG implementation. • Explicitly stating anticipated time and resource constraints to integrate CPG recommendations within the CPG. • Inviting policy-relevant stakeholders to be part of the interdisciplinary implementation team to help in raising awareness about the facets of the implementation effort, the CPG involved, or relevant supports (i.e., tools, protocols, etc.). • Offering training to aid policy-relevant stakeholders in understanding implementation processes, concepts, and priorities.
Characteristics of individuals	• Creating a section within CPG recommendations specifically for policymakers to frame implementation benefits in a manner that aligns with the outcomes important for local policy initiatives and policies. • Consulting with policy analysts to identify best practices for managing contradictory or complex evidence for policy-relevant stakeholders. • Identifying and consulting with relevant organizations that can hinder CPG implementation by actively resisting actions and processes that threaten professional autonomy (e.g., scope of

	practice) and create conflict of interest, or involve cross-jurisdictional supports.

Process	• Using structured guideline implementation programs with clear objectives, priorities, and methods throughout the implementation process specifically for policy audiences (i.e., policy-relevant stakeholders).
	• Building new recommendation actions onto existing policy efforts.
	• Having policy-relevant stakeholders help to steer implementation efforts to better tailor priorities within specific contexts (i.e., patients, diseases, or locations).
	• Using prominent policy stakeholders (i.e., policymakers, policy analysts) as intermediates to help support implementation efforts by endorsing CPGs, supporting peers, and facilitating administration of the CPG implementation.
	• Selecting appropriate health systems relevant intermediates (i.e., based on experience, expertise, etc.) to aid in better identifying policy priorities, training barriers, and available policy supports important within the implementation process.
	• Adapt recommendations to local conditions and budgetary constraints and have a review process established to ensure policy changes at the local level are reflected in implementation efforts.
	• Create strategic and operational plans that are informed by policy priorities as they relate to:
	  ○ Human resources (both number and type)
	  ○ Multidisciplinary teams
	  ○ Communication infrastructure

Appendix

Appendix 1: Overview of search terms

Clinical Practice Guidelines	AND	(Implementation	OR	Diffusion of Innovation)	AND	Evidence Terms (with and without dashes)	AND	Theory	AND	Policy
• "clinical guideline" • "practice guideline" • guideline*		• implement* • adher* • uptake		• "knowledge translation" • "knowledge to action" • "knowledge mobili*" • "knowledge transfer"		• "evidence-based practice*" • "evidence-informed practice*" • "evidence-informed policy" • "evidence-based policy"		• "model" • "framework" • "theory"		• policy • politic* • system

Appendix 2: Details of search strategy

No.	Databases/Sources	Search Query
1	Medline (OVID)	1. "Practice Guideline"[Mesh] 2. "guideline*".ti, ab, kw 3. "Guidelines as Topic"[Mesh] 4. #1-#4 OR 5. "implement*".ti, ab, kw 6. "adher*".ti, ab, kw 7. "uptake*".ti, ab, kw 8. #5-#7 OR 9. "knowledge translation*".ti, ab, kw 10. "knowledge to action*".ti, ab, kw 11. "knowledge mobiliz*".ti, ab, kw 12. "knowledge transfer".ti, ab, kw 13. #9-#12 OR 14. "Implementation science"[Mesh] 15. #8 OR #14 16. #13 OR #15 17. #4 AND #16 18. "evidence-based practice*".ti, ab, kw 19. "evidence-informed practice*".ti, ab, kw 20. "evidence-informed policy*".ti, ab, kw 21. "evidence-based policy*".ti, ab, kw 22. #18 - #21 OR 23. #17 AND #22 24. "theor*".ti, ab, kw 25. "model*".ti, ab, kw 26. "framework*".ti, ab, kw 27. #24-#26 OR 28. #23 AND #27 29. "polic*".ti, ab, kw 30. "politic*".ti, ab, kw 31. "system*".ti, ab, kw 32. #29-#31 OR 33. #28 AND #32
	EMBASE	1. exp practice guideline/ 2. "practice guideline*".ti, ab, kw 3. "clinical practice guideline*".ti, ab, kw 4. "clinical guideline*.ti, ab, kw 5. "Guideline*". ti, ab, kw 6. #1-#5 OR 7. exp protocol compliance/ 8. "implement*.ti, ab, kw 9. "adher*.ti, ab, kw 10. "uptake*.ti, ab, kw 11. #7-#10 OR 12. " knowledge translation*.ti, ab, kw 13. " knowledge to action*.ti, ab, kw 14. " knowledge mobili*.ti, ab, kw 15. " knowledge transfer.ti, ab, kw

		16. #12-#15 OR 17. #11 OR #16 18. #6 AND #17 19. evidence based practice 20. "evidence-based practice*".ti, ab, kw 21. "evidence-informed practice*".ti, ab, kw 22. "evidence-informed policy".ti, ab, kw 23. "evidence-based policy".ti, ab, kw 24. #19 - #23 OR 25. #18 AND #24 26. "theory".ti, ab, kw 27. "model".ti, ab, kw 28. "framework".ti, ab, kw 29. #26-#28 OR 30. #25 AND #29 31. "policy".ti, ab, kw 32. "politic*".ti, ab, kw 33. "system".ti, ab, kw 34. #31-#33 OR 35. #30 AND #34
	Emcare	1. exp practice guideline/ 2. "guideline*".ab,kw,ti. 3. #1 OR #2 4. "implement*".ab,kw,ti. 5. "adher*".ab,kw,ti. 6. "uptake*".ab,kw,ti. 7. #4-6 OR 8. "knowledge translation*".ab,kw,ti. 9. "knowledge to action".ab,kw,ti. 10. "knowledge mobiliz*".ab,kw,ti. 11. "knowledge transfer".ab,kw,ti. 12. #8-11 OR 13. implementation science/ 14. #7 OR #13 15. #12 OR #14 16. #3 AND #15 17. "evidence-based practice*".ab,kw,ti. 18. "evidence-informed practice*".ab,kw,ti. 19. "evidence-informed policy*".ab,kw,ti. 20. "evidence-based policy*".ab,kw,ti. 21. #17-20 OR 22. #16 AND #21 23. "theor*".ab,kw,ti. 24. "model*".ab,kw,ti. 25. "framework*".ab,kw,ti. 26. #23-25 OR 27. #22 AND #26 28. "polic*".ab,kw,ti. 29. "politic*".ab,kw,ti. 30. "system*".ab,kw,ti. 31. #28-30 OR 32. #27 AND #31

	Health Systems Evidence (HSE)	1. Open search: ("clinical guideline" OR "practice guideline" OR "guideline*") AND ("implement*" OR “adher*” OR uptake) 2. ("clinical guideline" OR "practice guideline" OR "guideline*") AND Filter: Implementation strategies 3. #1 OR #2
	Canadian Public Policy Collection (for grey literature)	("clinical guideline" OR "practice guideline" OR "guideline*") AND ("implement*" OR “adher*” OR “uptake*”)
	PsychINFO,	1. ("practice guideline*” OR "clinical practice guideline*” OR "clinical guideline*” OR "Guideline*”) 2. ("implement*” OR "adher*” OR "uptake*”) 3. ("knowledge translation*” OR " knowledge to action*” OR " knowledge mobili*” OR "knowledge transfer”) 4. #2 OR #3 5. (“evidence based practice” OR "evidence-based practice*” OR “evidence-informed practice*” OR "evidence- informed policy” OR "evidence-based policy”) 6. ("theor*” OR “model*” OR "framework*”) 7. ("polic*” OR “politic*” OR "system*”) 8. #1 AND #4 AND #5 AND #6 AND #7
	Social Science abstract	1. ("practice guideline*” OR "clinical practice guideline*” OR "clinical guideline*” OR "Guideline*”) 2. ("implement*” OR "adher*” OR "uptake*”) 3. ("knowledge translation*” OR " knowledge to action*” OR " knowledge mobili*” OR "knowledge transfer”) 4. #2 OR #3 5. (“evidence based practice” OR "evidence-based practice*” OR “evidence-informed practice*” OR "evidence- informed policy” OR "evidence-based policy”) 6. ("theor*” OR “model*” OR "framework*”) 7. ("polic*” OR “politic*” OR "system*”) 8. #1 AND #4 AND #5 AND #6 AND #7
	Web of Science (Core Collection)	#1 TOPIC: ("clinical guideline*") #2 TOPIC: ("practice guideline*") #3 TOPIC: ("guideline*") #4 #1-#3 OR #5 TOPIC: ("implement*")

		#6 TOPIC: (“adher*”) #7 TOPIC: (“uptake*”) #8 #5-#7 OR #9 TOPIC: (“knowledge translation*”) #10 TOPIC: (“knowledge to action*”) #11 TOPIC: (“knowledge mobili*”) #12 #9-#11 OR #13 #8 OR #12 #14 #4 AND #13 #15 TOPIC: (“evidence-based practice*”) #16 TOPIC: (“evidence-informed practice*”) #17 TOPIC: ("evidence- informed polic*”) #18 TOPIC: ("evidence-based polic*”) #19 #15 - #18 OR #20 #14 AND 19 #21 TOPIC: ("theor*”) #22 TOPIC: (“model*”) #23 TOPIC: ("framework*”) #24 #22-#23 OR #25 #20 AND #24 #26 TOPIC: ("polic*”) #27 TOPIC: (“politic*”) #28 TOPIC: ("system*”) #29 #26-#28 OR #30 #25 AND #29

Appendix 3: Data Extraction Form

<table>
<tr><td>Data extractor:</td><td colspan="3"></td></tr>
<tr><td>Title:</td><td colspan="3"></td></tr>
<tr><td>Author(s):</td><td colspan="3"></td></tr>
<tr><td>Year of publication:</td><td colspan="3"></td></tr>
<tr><td>Publication status:</td><td colspan="3">☐ Peer-reviewed journal
• List specific journals:
☐ Grey literature</td></tr>
<tr><td>Country or region focus:</td><td colspan="3">☐ High-income country(ies)
• Number of countries:
• List specific countries:
☐ Low- and middle-income country(ies)
• Number of countries:
• List specific countries:</td></tr>
<tr><td>Methods used (Design) (type of paper)</td><td colspan="3">Primary research
☐ Systematic review (explicit search and selection criteria)
☐ RCT
☐ Interrupted time series
☐ Before-after study
☐ Cross-sectional
☐ Cohort study
☐ Qualitative study
☐ Case study
☐ Mixed methods (select other methods as applicable)
☐ Other (specify)

Non-research
☐ Conceptual review (no empirical basis)
☐ Discussion/policy or position paper
☐ Commentary/editorial/letter/correspondence
☐ Website content (e.g., Choosing Wisely website)
☐ Guideline</td></tr>
<tr><td>Summary of key findings or insights from the document</td><td colspan="3"></td></tr>
<tr><td colspan="4">Contribution to framework & concept mapping</td></tr>
<tr><td>Categories</td><td>Policy</td><td>Politics</td><td>Systems</td></tr>
<tr><td></td><td>Does this fit into problem, options, and implementation? If so, how?</td><td>Does this fit into institutions (i.e., federalism), interests (i.e., societal interest groups), and ideas (i.e., knowledge</td><td>Does this fit into governance, financial, and delivery arrangement? If so, how? (see HSE taxonomy http://ow.ly/lBGK30r4swJ)</td></tr>
</table>

		and values)? If so, how?	
Facilitators			
Barriers			
Strategies			

Appendix 4: Operationalizing the policy context considerations within the KTA framework for a cancer screening CPG

Action Cycle Stage	Examples of ways to operationalize policy context considerations
Adapt knowledge to local context	*Policy considerations:* • Actively inviting local cancer organizations to provide feedback on the implementation of the CPG to ensure the guidelines are being adapted to fit local conditions (e.g., cultural or religious values). *Political consideration:* • Hiring policy consultants who have a background in and experience with influential non-profit and/or patient advocacy groups related to the cancer care community, to aid the implementation team with making informed decisions. • Reviewing implementation priorities and objectives to ensure they are aligned with existing policies established to support cancer care with explicit effort being made to include relevant factors across the continuum of care (e.g., patient, provider, organization, and system supports). *Health system consideration:* • Creating education supports to aid local relevant policy stakeholders incorporated within the implementation process to ensure their foundational knowledge pertaining to implementation science concepts and cancer screening procedures is appropriate, so they can contribute in an informed way to discussions and change.
Assess barriers/facilitators to knowledge use	*Policy consideration:* • Conducting an organizational audit to identify any limitations (e.g., governance structure or human resource issues) acting as a barrier to the uptake of knowledge such as limiting who is involved or where the knowledge is used within the organization, which may hinder adherence to CPG recommendations. *Political consideration:* • Consulting with influential national and provincial/state physician associations to assess if CPG recommendations encroach upon any professional autonomy. *Health system considerations:* • Identifying what governmental supports (e.g., financial incentives) are available to aid clinicians and hospitals. • Assessing whether implementation efforts to connect and coordinate health system resources to support cancer patients, conflict with provincial/state or national regulations (e.g., professional scopes of practice or training and licensure requirements).

Select, tailor, implement interventions	*Policy consideration:* • Creating a list of resources (e.g., educational, logistical demands, clinical relevance) to help policymakers consulting with the implementation team in the planning process, better understand CPG objectives and priorities. *Political consideration:* • Consulting with influential hospital and physician associations to create integration strategies for organizational structures/processes that will aid in smoother adoption of the cancer screening. *Health systems considerations:* • Ensuring implementation efforts and recommendations are aligned with governance arrangements (e.g., requirements established for continuing competence and professional liability) within and across jurisdictions. • Creating a section within the CPG that outlines ways policymakers can take decisive actions for proactive policymaking that better supports cancer screening for diverse demographics and communities, such as how they can better support patient directed interventions targeting health literacy within Indigenous communities.

Appendix 5: Operationalizing the policy context considerations within the CFIR framework for a cancer screening CPG

Domain	Examples of ways to operationalize policy context considerations
Outer setting	*Policy considerations:* • Exploring how other jurisdictions have aligned external policies and incentives, such as public policies and governmental regulations, with cancer screening CPGs. ○ How were local policies identified, incorporated, and prioritized? *Political consideration:* • Inviting influential local health authorities and patient advocacy groups to provide feedback on implementation efforts and how cancer screening recommendations can be better framed/operationalized. *Health systems consideration:* • Adding policy analysts from the ministry of health/department of health with experience in creating policies for cancer care, onto the implementation team to help navigate the external policies and incentives relevant to cancer screening.
Inner setting	*Policy consideration:* • Having multiple versions of the CPG and a summary of recommendations to aid policy-relevant stakeholders involved in the implementation process, in better understanding both clinical concepts and where their tacit knowledge is most appropriate. *Political consideration:* • Inviting influential professional physician organizations (e.g., national and provincial/state) to be part of the interdisciplinary implementation team to ensure their concerns are addressed to aid in the adoption of the CPG by providers.
Characteristics of individuals	*Political considerations:* • Creating a section within CPG recommendations on how specific cancer screening recommendations align with provider practice dynamics (e.g., policies in place to support the use of electronic medical records). • Identifying and consulting with influential patient advocacy groups to ensure equity is a priority. ○ For instance, to ensure the language and approach the recommendations outline do not undermine patient autonomy of specific minority communities who may have cultural considerations that need to be addressed.

Process	*Political consideration:* • Having representatives from influential cancer advocacy groups be a part of preliminary steering groups to help inform implementation efforts. *Health systems consideration:* • Mapping any new recommendation onto existing policies for cancer patients to better aid both providers and patients.

Appendix 6: Mapping policy-relevant enrichments onto the KTA and CFIR framework

Policy-relevant enrichments	How does the enrichment map onto the policy context?	How do the enrichments map onto each relevant component of KTA?	How do the enrichments map onto each relevant component of CFIR?
Facilitators			
Policy legacy • Past policies, initiatives, and laws relevant to current implementation efforts.	Policy analysis • Helps to identify what past policies, available options, and implementation considerations were successful in the local context and may be relevant to current implementation efforts.	*Adapt knowledge to local context* • Examining the policy legacies of the local organization, community, or region can provide a more robust understanding of the contextual factors (i.e., social, political, and economic) acting in the backdrop that may facilitate implementation efforts. • Policy learning allows insights from similar jurisdictions to be leveraged to help make better informed decisions about how best to adapt knowledge to the local context. • The dissemination and uptake of knowledge in the local context can be facilitated by application of the most appropriate policy instruments. *Assess barriers/facilitators to knowledge use* • Critically exploring policy legacies in the local context can help to	*Outer setting* • Policy legacies allow external factors to be identified and leveraged to aid current implementation efforts as they relate to the diverse needs of patients, organizations, and/or jurisdictions. • Policy learning can aid in gaining insights from other jurisdictions which can facilitate collaboration efforts within inter-organizational networks as they engage with policy-relevant actors in the external environment. • Exploring available policy instruments within the outer setting can aid with implementation efforts by giving the implementation team a more robust catalogue of available instruments that may have otherwise been overlooked. *Inner setting* • Policy legacies can be used to explore the different ways that issues, priorities, and scope of implementation efforts have been framed in the past to better articulate communication strategies within current efforts. • Policy learning can provide insights about how culture (i.e., values, norms) can be better captured
Policy learning • Learning how similar implementation efforts within and across different jurisdictions were conducted and their level of success.	Policy analysis • Aids in identifying different policy options or implementation considerations that are possible in addressing an issue that are not obvious in the current local context. Political analysis		

<table>
<tr>
<td></td>
<td>• Helps to better understand the influence and impact governmental structures (i.e., branches or departments), different stakeholder groups, or regional social norms can have in facilitating or hindering implementation efforts.
Systems analysis
• Helps to capture jurisdictional variabilities in how decisions about governance, financial, and delivery arrangements within health systems, to gain insights relevant to implementation efforts.</td>
<td rowspan="2">identify barriers and facilitators that are not obvious or easily foreseeable.
• Policy learning can aid in not only identifying barriers/facilitators that emerged in other jurisdictions, but also how implementation teams in those jurisdictions best addressed them.
• Examining policy instruments relevant to implementation efforts can help to circumvent barriers or enhance existing facilitators identified.

Select, tailor, implement interventions
• A better understanding of policy legacies can help tailor implementation efforts in a manner that builds upon past successes while leveraging current strategies.
• Policy learning can aid in identifying, selecting, and adapting interventions from the insights of implementation teams in other jurisdictions, which can save time and cost.
• Leveraging various policy tools will ensure a more tailored approach to the local context.</td>
<td rowspan="2">in protocols and procedures to aid in implementation efforts to overcome culture barriers.
• Analysis of available policy instruments can aid in organizational commitment within implementation efforts by helping to match appropriate instruments with the processes being utilized.

Process domain
• Policy legacies can be explored to leverage previously successful approaches, processes, and evaluation tools within current implementation efforts in each jurisdiction.
• Policy learning can aid in providing insights from planning and executing approaches from other jurisdictions that implemented similar projects.
• Policy instruments can help in reflecting and evaluating implementation efforts to collect more thorough feedback.

Characteristics of individuals (i.e., individuals involved)
• Policy legacies can aid in better assessing current implementation readiness of individuals by highlighting approaches to enhance engagement and educational strategies that were successful in other policy-relevant efforts and similar implementation activities.
• Policy learning can provide insights into how organizations can facilitate a culture where buy-in is fostered by assessing how similar</td>
</tr>
<tr>
<td>Policy instruments
• Existing regulations,</td>
<td>Policy analysis
• Helps to identify and understand</td>
</tr>
</table>

mandates, or policy tools that can be leveraged to aid implementation efforts.	which policy instruments work best with different stakeholder groups. Systems analysis • Helps to capture the various policy instruments available within the health system, making it possible to identify which combinations may be effective.		organizations were successful in other jurisdictions. • Analyzing existing policy instruments within organizations and/or the health system can aid in identifying approaches (e.g., education materials) to support building competence among those involved in implementation efforts.
Barriers			
Policy supports • Organizational policies that have the capacity to aid implementation processes and activities such as policies to foster trust (i.e., options to contribute to decision-making process) within implementation hierarchy (e.g., opportunity to join a steering committee).	Policy analysis • Allows the implementation team to identify, categorize, and access existing available options and implementation considerations.	*Adapt knowledge to local context* • Policy supports can aid efforts to better match implementation priorities to local constraints (e.g., culture, regional restrictions, target population). • Understanding the role political resistance plays within implementation efforts can help to circumvent policy-relevant barriers inherently present in the local context (e.g., conflict between professional associations and patient advocacy groups over implementation priorities).	*Outer setting* • Identifying existing policy supports can help to better focus attention to areas where gaps in patient needs exist, which can be an underlying barrier to implementation efforts. • Efforts to foster relationships between inter-organizational networks can be hindered by political resistance from groups (e.g., professional associations) or networks whose interest conflict. • Exploring how policy networks play a role within implementation efforts can aid in better planning around external mandates and existing regulations. *Inner setting*
Political resistance	Political analysis		

<table>
<tr>
<td>• The level of threat any active resistance from interest groups (e.g., professional associations) poses to implementation efforts.</td>
<td>• Helps to identify the relevant interest groups and assess what institutions (i.e., government structures) and ideas (i.e., values, priorities, norms etc.) can be leveraged within the implementation unfolds (i.e., local context or outer setting).</td>
<td rowspan="2">• Policy networks can influence how implementation priorities are framed and at times, can voice conflicting demands.

Assess barriers/facilitators to knowledge use
• The lack of organizational policies can hinder implementation efforts within participating organizations and hinder the interplay between various policy-relevant stakeholders that have a vested interest in the outcome of implementation process.
• Political resistance can slow down or minimize the impact of implementation efforts by creating barriers grounded in policy concerns (e.g., concerns about expansion of scope of practice for some providers and not others) instead of implementation constraints (e.g., time, availability staff, level of expertise needed).
• Policy networks can have different barriers and facilitators that are not apparent in the context of implementation efforts (i.e., objectives, strategies, priorities), that can easily be overlooked.

Select, tailor, implement interventions</td>
<td rowspan="2">• Assessing existing policy supports can aid in identifying gaps and barriers to fostering an implementation climate more conducive to change.
• Exploring existing political resistance can help to identify areas within relevant organizations (e.g., leadership engagement, available resources, and access to information and knowledge) that are inadequate for addressing the consequences and implications of any coordinated resistance from policy-relevant actors and organizations.
• Examining relevant policy networks can help to better understand structural, communications, and cultural aspects of organizations that are acting as barriers (either directly or indirectly) to implementation efforts.

Process domain
• Auditing existing policy supports can aid in identifying essential activities within the implementation process (e.g., planning, executing) that are underdeveloped, inefficient, or inappropriate for the objectives of current implementation efforts.
• Approaches to recruit and involve appropriate individuals within implementation efforts can be hindered by the political resistance of organizations or individuals whose personal interest is at odds with implementation efforts (i.e., objectives, scope, target population, etc.,).
• Assessing existing policy networks can help to identify areas worth exploring when evaluating implementation efforts, such as refining feedback</td>
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<tr>
<td>Policy networks
• A set of relatively few policy-relevant actors with a stable, non-hierarchical and interdependent relationship that have a shared vision over the scope, aims, and general processes/outputs related to implementation efforts.</td>
<td>Political analysis
• Aids in capturing the concerns of various relevant stakeholder groups, allowing potential opportunities to address conflicting demands to be identified.</td>
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</table>

		• Policy supports have the potential to further refine implementation efforts (e.g., expand priorities to include reforms of organizational policies and infrastructure) to better capture and engage with policy actors, institutions, and systems. • Tailoring implementation efforts to anticipate political resistance will help to circumvent conflicts and save valuable resources (i.e., time and money). • Incorporating policy networks (i.e., understanding their role and priorities) into implementation processes allows for a more comprehensive approach, and ultimately, successful implementation.	mechanisms to better capture policy-relevant concerns related to the impact of policy networks. *Characteristics of individuals (i.e., individuals involved)* • Exploring existing policy supports can help to identify policies that undermine individual beliefs about their own capabilities to execute implementation objectives. • Understanding the political resistance implementation efforts attract, can help in combating organizational behaviour (e.g., misinformation and disinformation influencing attitudes about the intervention) that makes organizations vulnerable to such attacks. • Examining how relevant policy networks function (e.g., scope of relationships, formal and informal communication, consensus on policy issues) can aid in addressing barriers related to organizational culture (e.g., knowledge and beliefs, increasing competence, attitudes toward and value placed on the intervention).
Strategies			
Optimizing integration • Existing programs or services that can aid in devising clear integration strategies for organizational structures/processes.	Policy analysis • Helps to identify the institutions (i.e., governmental structures) that are involved in the delivery and oversight of relevant programs and services within	*Adapt knowledge to local context* • Strategies that leverage existing programs and services within the local context can better anticipate demands stemming from the policy context. • Incorporating the role local policy entrepreneurs play within implementation	*Outer setting* • Exploring strategies to optimize integration of existing programs and services that are policy-relevant can aid in addressing gaps in knowledge, service, and/or coordination as it relates to patient needs and resources. • Incorporating policy entrepreneurs in devising, promoting, and providing feedback on

	the context implementation unfolds (i.e., local context or outer setting). Systems analysis • Aids in identifying governance, financial, and delivery arrangements that are relevant to the programs and services within the implementation unfolds (i.e., local context or outer setting).	strategies will help to better identify conflicts of interest. • A better understanding of health system optimizers at the local level can help to devise more realistic priorities, expectations, and outputs from implementation efforts. *Assess barriers/facilitators to knowledge use* • Identifying salient policy instruments can aid in devising strategies that appropriately match expectations with implementation objectives (both short-term and long-term). • Different policy entrepreneurs have different priorities that at times can clash with the various objectives of the implementation team, requiring efforts to balance these competing voices to be explicitly considered throughout the implementation process in an iterative manner. • Health system optimizers can aid in identifying areas that may develop into barriers by highlighting how system constraints emerge throughout the implementation process	implementation efforts can aid networking strategies with external organizations. • To effectively use policy instruments within health systems, policy-relevant external factors (i.e., higher level factors at the meso- or macro-level such as national priorities) need to be meaningfully explored to ensure success of implementation efforts. *Inner setting* • Focusing on optimizing integration efforts within the inner setting can increase the implementation climate (i.e., absorptive capacity for change) while also helping to enhance existing policies relevant to the level of readiness for implementation of the organization (e.g., indicators of organizational commitment). • Adapting approaches used by policy entrepreneurs to frame issues, connect relevant stakeholders, and navigate conflicts (both real and perceived) to current implementation efforts, can aid in better devising organizational incentives to foster the implementation climate needed for success. • Exploring health system optimizers can aid in helping to foster a more appropriate, policy-sensitive organization that places extra emphasis on how norms and values in the organization incorporate the priorities of the policy context. *Process domain* • Strategies to optimize integration within implementation efforts can aid in the planning phase as policy-relevant factors and actors are being identified within the policy context.
Policy entrepreneurs • Individuals who can exploit opportunities to influence policy outcomes as means of promoting and facilitating implementation.	Political analysis • Helps identify key policy entrepreneurs within the local context and the driving factors (i.e., incentives, priorities, etc.) that are guiding their actions.		
Health system optimizers • Ways to better tailor policy instruments (i.e., legal, voluntary,	Systems analysis • Aids in understanding the governance,		

education, etc.) to support implementation efforts.	financial, and delivery arrangements relevant to the local context which provides an opportunity to identify areas where these arrangements can be leveraged to aid implementation efforts.	(e.g., some policy instruments demand attention at different times while others such as those related to financial budgets, are constant).
		
		Select, tailor, implement interventions
		• Incorporating integration strategies that explicitly consider the policy context (i.e., policy, political, and systems considerations) allows for appropriate (i.e., timely, cost-effective, etc.) implementation interventions to be prioritized.
		• Being cognizant of the role policy entrepreneurs play (e.g., helping frame issues, promoting implementation efforts, etc.) within the implementation process can help to avoid duplication of efforts and redundancies within implementation processes.
		• Health system optimizers can provide insights about the best strategies for incorporating and leveraging existing policy instruments to aid implementation efforts.
			• Policy entrepreneurs help to streamline and enhance all four essential activities involved in the implementation process:
			  o Planning (e.g., benchmarks, short-term and long-term goals, priorities)
			  o Engaging (e.g., attracting appropriate policy-relevant actors)
			  o Executing (e.g., working with implementation leaders)
			  o Reflecting and evaluating (e.g., providing policy-relevant feedback about the progress and quality of implementation)
			• Leveraging policies and strategies that prioritize the use of appropriate policy instruments can ensure more robust strategies are incorporated in the planning phase of implementation efforts.
			
			Characteristics of individuals (i.e., individuals involved)
			• Optimizing integration can support efforts to address concerns related to self-efficacy (e.g., confidence) and individual-level change (e.g., skillset) throughout implementation efforts to ensure objectives are achieved.
			• Policy entrepreneurs can aid in devising strategies to combat misinformation and gaps in knowledge /beliefs about the intervention, by leveraging their tacit knowledge in dealing with other policy-relevant issues.
			• Exploring how health system optimizers can aid organizations in better understanding how the policy context can be engaged within their organization, can highlight how staff perceive their role is situated when dealing with policy-relevant issues.

Chapter 3: Preface

Within the field of implementation science, there is an extensive pool of research that explores the factors that influence and the strategies that best support guideline implementation. Relatively little is known however, about how these factors and strategies are influenced by the policy context. This chapter builds upon the enriched implementation frameworks from chapter 2 by exploring how the enriched frameworks can better explain why some guideline implementation strategies work while others fail to yield expected impact. Using an explanatory multiple case study methodology, we explored how the enriched versions can hypothetically be applied using two cases from the U.S., with each case applying one of the frameworks of interest. Our findings help to foster a better understanding of the role that policy context plays in guideline implementation and highlights the potential added value of the enrichments. It also identifies areas within the enrichments that can be further refined to better capture and engage with the policy context, while making it easier for users to apply the enriched frameworks. I was responsible for developing the focus and design of the study with my supervisor (Dr. John N. Lavis), in addition to data collection, analysis, and interpretation. Dr. John N. Lavis also contributed to the analysis through an iterative process of interpretation and synthesis which produced further refinements to the two enriched implementation frameworks. I drafted the manuscript, and Dr. Lavis, Dr. Melissa Brouwers and Dr. Michael G. Wilson provided extensive feedback that were incorporated into the manuscript. All these individuals are co-authors on the manuscript.

Multiple explanatory case study of guideline implementation processes: Comparing existing explanatory frameworks with a policy-, political- and systems-enriched framework

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Keywords: clinical practice guidelines, implementation science, public policy, case study

Word count: 7443 (main text) 11, 789 (inclusive of abstract, exhibits, and references)

Abstract

Background: Clinical practice guidelines (CPGs) use the best available evidence to guide decision-makers in selecting the most clinically effective care options. Research within the field of implementation science has highlighted factors and strategies that best support guideline implementation. Recent research has highlighted how policy, political, and health systems considerations can inform guideline implementation efforts through the enriched versions of two existing guideline-implementation frameworks (the Knowledge-to-Action Framework (KTA) and the Consolidated Framework for Implementation Research (CFIR)). These enriched frameworks, however, have not been applied to see if they add value in explaining guideline implementation. This study examines how the enriched frameworks can hypothetically be applied using multiple case studies.

Methods: To pursue the study's objectives, a multiple case study design was employed. Two cases were sampled from the U.S., with each case applying one of the frameworks of interest. The first case applied the KTA framework to implement a gait and balance assessment in inpatient stroke rehabilitation. The second case applied the CFIR framework in assessing the barriers and facilitators to a kidney transplant program's implementation preparation (i.e., pre-implementation). Multiple data sources were drawn upon, including interviews, media, published literature, and reports and other documents.

Results: Our analysis identified 12 themes that can be grouped into three areas: 1) effectiveness of guideline-implementation strategies; 2) strengths of the original frameworks; and 3) the anticipated influence of the enriched frameworks. Many of these themes reinforce the role policy, political, and health systems considerations can play in guideline implementation.

Discussion: The two case studies provided unique insights into how implementation efforts can more systematically take the policy context into consideration. Key strengths of this study were the use of the enriched frameworks to pursue lines of inquiry and the use of multiple sources of data. Limited interview participation was a study limitation that was largely addressed by interviewing two-well positioned individuals. Future research should explore ways to refine, expand, and test the enriched frameworks.

Conclusions: The cases highlighted the potential added value of the enrichments to both the KTA and CFIR framework and identified areas for further refinement.

Word count: 344 (max 350)

Background

Clinical practice guidelines (CPGs) can support the provision of more effective, technically efficient, and cost-effective care.[1, 2] They provide crucial guidance to decision-makers (i.e., practitioners, policymakers, and relevant stakeholders) by highlighting what are the most effective clinical or health care options for a patient or the population (and who are the most appropriate providers and teams to offer these options), and by providing a benchmark against which care can be compared.[1, 2] CPGs are useful in situations where many possible interventions are available, and even where it is unclear what treatment options exist, or where the available evidence on the issue is limited.[1, 2]

In response to identified evidence-practice gaps, research has identified four clusters of factors that facilitate and hinder guideline implementation: 1) personal factors (e.g., clinicians' knowledge and attitudes); 2) guideline-related factors (i.e., trialability, plausibility, level of evidence); 3) implementation-related factors (e.g., resource limitations); and 4) context-dependent factors (e.g., organizational features, social norms).[2] Those examining the last of these four clusters -- context-dependent factors -- have tended to focus on the infrastructure of organizations, such as standardized processes.[2] What has been lacking is attention to the role and influence of the policy context within implementation efforts.[1, 33, 34] A critical interpretive synthesis (CIS) by Ali et al. sought to enrich two existing implementation frameworks – the Knowledge-to-Action Framework (KTA, a process model) and the Consolidated Framework for Implementation Research (CFIR, a determinant framework) – by incorporating policy, political, and health systems analysis considerations.[2,4, 32]

The KTA framework adopts a systems perspective which sees the process of applying evidence to practice as an iterative process.[4] It was developed based on the commonalities of

over 60 implementation science theories, frameworks, and models, and it is comprised of two components: 1) knowledge creation; and 2) action cycle.[4] The knowledge creation phase is focused on the production and synthesis of knowledge, while the action cycle is focused on the deliberate application of knowledge to support change and adoption of knowledge.[4] The CFIR framework focuses on identifying the factors that facilitate or hinder the uptake of evidence-based practices.[5] It is based on 19 implementation theories and composed of 39 constructs organized in the following five domains: 1) intervention characteristics; 2) inner setting; 3) outer setting; 4) characteristics of individuals involved; and 5) the process by which implementation is conducted.[5] CFIR can help guide implementation efforts throughout the entire implementation process, from the design of an intervention to its evaluation.[5]

The process of enriching the KTA and CFIR framework began by first identifying which stages were most appropriate to better engage with the policy context, and then expanding the existing framework at those identified stages.[32] This expansion was accomplished through a new 'layer' that attempts to explicitly explore the role of policy context considerations (see Figure 1 and Figure 2). This layer contains three subconstructs: 1) policy-relevant facilitators; 2) policy-relevant barriers; and 3) policy-relevant strategies.[32] This new layer and these subconstructs also take advantage of the existing domains/stages they interact with, so the policy context is also thoroughly explored when applying the original components of the frameworks.[32]

These enriched frameworks, however, have face validity but have not yet been applied to see if they add value in explaining (and in future, supporting) guideline implementation. A key gap now exists in understanding how the enriched frameworks can potentially provide a more fulsome explanation about why guideline-implementation strategies did or did not yield their

expected impacts. The objective of this study is to qualitatively explore how these enriched versions can hypothetically be applied using multiple case studies.

Research question

How can policy-, political- and system-enriched implementation frameworks better explain the outcome of guideline implementation efforts than traditional frameworks?

Design and methods

Design

We adopted an explanatory multiple case study as outlined by Yin[22-23] for this study. A case study approach is well suited and most relevant when one seeks to answer "why" or "how" questions. Case study research allows a particular phenomenon to be described with context (i.e., descriptive).[21-23] In addition, it has the potential to highlight causal links (i.e., explanatory) or compare both between and within cases when multiple cases are included.[21-23]

The case study addresses three lines of inquiry, which are worded here from the perspective of those involved in supporting guideline implementation:

1. Did the existing frameworks assist you in understanding how and why the implementation strategies led to the outcomes of your project?
2. Did your guideline implementation strategy change the clinical care offered? Did it lead to changes in patient outcomes?
3. Would the enriched framework provide you with a better understanding of how and why the implementation strategies led to the outcomes of your project?

These three lines of inquiry were explored through probing and open-ended interview questions that explore the planning, organizing, and execution of the implementation process within the multiple case studies, as well as through other data sources.

The multiple case study design is a suitable methodology for the lines of inquiry this study explores, since it allows the contextual factors to be explored. Two cases can begin to support the 'replication' (i.e., generalization) of findings across cases since, as Yin points out, each 'case' can be treated as a separate study which either predicts similar results (literal replication) or predicts contrasting results for anticipatable reasons (theoretical replication).[22-23] According to Yin, a few cases (i.e., 2 cases, like the current situation, or 3 cases) would be considered a literal replication.[22-23]

Case selection and description

Each case served as a unit of analysis in this study. The cases were selected from previously published implementation studies identified in a critical interpretative synthesis conducted by Ali et al.[32] Purposive sampling was used to select cases using the following criteria: 1) the aim of the implementation project was to change a clinical practice; 2) a clinical practice guideline was used to determine the desired clinical practice; 3) the Knowledge-to-Action (KTA) Framework or the Consolidated Framework for Implementation Research (CFIR) framework was explicitly used in the design of the implementation strategy; and 4) the implementation project was conducted between 2015 and 2020. All four criteria had to be met to be selected for inclusion.

Seven cases were identified as potential candidates for inclusion (see Appendix 2). Only two cases however, met all four inclusion criteria and were selected. Each of the two cases

employ one of the frameworks to guide the study's implementation design and evaluation. Of the five excluded cases, none explicitly used the KTA or CFIR framework in the design of the implementation strategy, three were not conducted within the period specified, and one case did not focus on clinical practice or use a clinical practice guideline.

The first case by Moore et al., applied the KTA framework to implement a gait and balance assessment in inpatient stroke rehabilitation. [24] The researchers sought to assess the effect of a gait assessment battery (GAB) on clinical adherence to recommendations and how that affects clinician perceptions (e.g., perceived value of measurement being used) and organizational outcomes (e.g., hospital leadership's view of the effect of the project on the hospital as an organization).[24] To identify appropriate measures for the GAB, the research team evaluated recommendations by the American Physical Therapy Association StrokeEDGE group and the published 2016 Stroke Rehabilitation Clinical Practice Guideline.[24] Three GAB recommendations were included: 1) the 10-meter walk test, including assistance levels; 2) 6-minute walk test, including assistance levels; and 3) the Berg Balance Scale.[24] The study, which was comprised of a pre- and post-training intervention, was conducted at Mary Free Bed Rehabilitation Hospital (MFB) in Grand Rapids, Michigan.[24] The KTA framework was used to guide the development and execution of a knowledge translation plan. The main outcomes of interest were clinician adherence to guideline recommendations and the effect this had on clinician perceptions and organizational outcomes.[24]

The second case, by Gordan et al., applied the CFIR framework in assessing the barriers and facilitators to a kidney transplant program's implementation preparation (i.e., pre-implementation). [25] The study was based on Northwestern Medicine's Hispanic Kidney Transplant Program (HKTP) which was established in 2006.[25] The HKTP is made up of 16 key

components that can influence (i.e., facilitate or hinder) patient-level effects (e.g., culturally targeted education, dialysis outreach, or follow-up appointments with nephrologists) and broader objectives (e.g., marketing to raise awareness about the program), and its components align with the National Quality Forum's Framework for Measuring and Reporting Cultural Competency.[25] It provides a way to measure and report culturally competency and outlines across all health care.[38] Using interviews and group discussions with transplant stakeholders, the CFIR was used to help identify implementation barriers and facilitators that could guide the interview design and aid in qualitative analysis.[25] The study was conducted at two American kidney transplant programs that perform many living donor transplants each year and serve a large Hispanic patient population.[25, 96]

Data sources

A key element of the case study method is the use of multiple sources of data. [21-23] A feature that is well documented for enhancing the validity of findings is by building in the method of triangulation. [21-23] Data were collected from documentary analysis and interviews.

Document analysis

Types of sources

Peer reviewed articles (any design) and grey literature reports including those that described policy, political or system context relevant to the implementation of the guideline were eligible to be included in the documentary analysis. Relevant terms and concepts underlying each case were used to guide initial sampling of key documents. Documents were included based on their relevance to implementation strategy and the framework used in each case.

Search strategy

Databases searched included: Canadian Public Policy Collection (for grey literature), EMBASE, Emcare, Health Systems Evidence (HSE), Medline, PsychINFO, Social Science Abstracts, and Web of Science. In addition, both Google and relevant websites from governmental and stakeholder organizations were searched (see Appendix 1 for details related to data collection and sampling). In particular, we searched the Alberta government's knowledge translation and implementation resources website, the National Implementation Research Network's Active Implementation Hub, and the American Institutes for Research's website for the Center on Knowledge Translation for Disability and Rehabilitation Research.[35-37]

Media analysis explored both newspaper articles and transcripts of broadcasts that speak to the cases, again including their policy, political and system context. LexisNexis was used to obtain data for media analysis. An electronic search strategy was developed using the themes and terms established from the analysis of documents and archival records (i.e., both peer-reviewed and grey literature).

Data extraction and analysis

Data were extracted by the principal investigator (AA). Documents were reviewed and data extracted based on the following domains: policy, political, and systems considerations; implementation strategies being utilized; and the role of stakeholder engagement within the implementation process. In particular, documents were reviewed to see how and to what extent these domains were considered and explored. The data were then integrated with findings from interviews through a critical examination of identified themes. This was accomplished by

reviewing where findings from the documents overlapped with identified themes and where the identified themes provided insights about how the different domains expanded how relevant factors were discussed within the documents.

Interviews

Sampling and recruitment

For sampling and recruiting participants, the principal investigator (AA) generated a list of potential interviewees for each case and a purposive sampling approach was used to select candidates from that list. For each case, three participants representing different perspectives within the guideline-implementation process were sought: 1) implementation project staff; 2) key external stakeholders involved in or supporting the implementation process; and 3) researchers involved in studying the implementation process.

Interview process

The principal investigator emailed potential participants and invited them to take part in this study. A description of the study and a consent form was provided to each candidate participant. Interviews were scheduled with individuals who consented to participate. In instances of no response, the principal investigator followed-up with potential participants at four weeks and again at six weeks. All interviews were conducted virtually and were recorded. Additional interviews were conducted if theoretical saturation was not reached with the initial three discussions.

Given the interviews were conducted virtually, written consent posed an additional burden on participants (i.e., signing, scanning, etc.) and as such, consent was obtained verbally at the

beginning of the interviews and audio recorded. The interviewer (AA) created field notes immediately after conducting each interview. Each interview lasted between 45 and 60 minutes. A formal method of tracking was in place to track the consent process using a Microsoft Excel spreadsheet. In particular, to obtain verbal consent, the principal investigator documented that: 1) the participant had a copy of the consent form; 2) the participant appeared to understand what the study entailed; 3) the participant was given the opportunity to ask questions; 4) the questions were answered to their satisfaction; and 5) the participant provided verbal consent. Records of verbal consent were signed and dated by the person obtaining the consent (i.e., the principal investigator).

Interviews were semi-structured, online (via Webex using a personal platform license), and based on the interview guide included in Appendix 3. Interviewees were asked how the enriched frameworks could potentially inform how they planned, how they managed priorities, and what notable differences they noticed between the enriched frameworks and the original frameworks. This interview guide was refined iteratively to better capture the themes and relationships identified from the initial stages of data collection and analysis. The principal investigator was responsible for conducting the interviews, transcribing the audio files, and archiving them into the case study database.

Data analysis

Interviews were transcribed verbatim and transcribed data were organized using NVivo software. A qualitative content analytical approach was utilized to code and further aggregate the data. Data collection and the first phase of coding were conducted concurrently. The transcripts were coded using a framework of areas of interest (e.g., based on the interview guide questions,

the three questions outlined above, and the components of the enriched frameworks). Themes were identified and refined through the use of qualitative reflective memos and a final codebook was developed based on the themes documented during data collection and the first phase of analysis. These memos were then used to re-code and analyze all of the transcripts. Data analysis ended once saturation was reached.

To manage conflicting perspectives, a plan was developed for any identified themes with conflicting responses in each case and were to be discussed by AA and JL, with particular attention paid to themes about areas that can better situate the policy context within implementation processes and warrant further research. To supplement the qualitative analysis, relational analysis would be used to integrate data. Relational analysis is useful when seeking to combine different categories, themes, or codes.[95]

To appropriately explore the first line of inquiry above, the proposed taxonomy by Per Nilsen (2015) was used.[1] This taxonomy distinguishes between different categories of theories, models, and frameworks in implementation science as means of aiding in the appropriate selection and application of implementation frameworks, both in research and practice.[3]

Data synthesis

Data from documentary analysis were used to explore findings from interviews and as a source of triangulation to verify priorities that were mentioned by stakeholders during interviews. Identified themes from interviews were examined through the three domains of focus during documentary analysis, exploring any insights an integrative approach may yield.

Results

We reviewed and analyzed a total of 62 documentary sources related to the cases, which included 45 scholarly publications, 13 reports and other documents (policy documents and media articles) and 3 websites (see Appendix 1 for further details about these documentary sources). In addition, 19 candidate participants were identified for possible interview (9 related to the stroke rehabilitation implementation project that used the KTA framework and 10 related to the kidney transplant implementation project that used the CFIR). Ultimately, two interviews (one from each case) were conducted and analyzed, both of whom were well-positioned researchers involved in studying the implementation process. The integrated results from the document analysis and the interviews, including the effectiveness of guideline-implementation strategies, success of the original frameworks, and the anticipated influence of the enriched frameworks are presented below for each case. Relational analysis was not used to manage conflicting perspectives since only two interviews (one from each case) were conducted and analyzed.

Case #1: Application of KTA

Effectiveness of guideline-implementation strategies

For implementation strategies to be successful in addressing the various factors that can hinder implementation efforts, these strategies must be guided by the best-available evidence (i.e., thorough, explicit, and prudent use of current best evidence in making decisions).[2-5, 26, 27]

Application of the KTA framework by Moore et al.,[24] reflected a thorough understanding of how best to utilize the framework in recognizing the problem and critically appraising available knowledge to address it. Using an iterative approach, they developed a knowledge translation (KT) plan, considering issues such as sustainability throughout the project and leveraging existing organizational processes (e.g., performance goals) relevant at each stage of

the action cycle. This was to ensure implementation of the assessment battery was accomplished in a manner that fostered high levels of adherence to recommendations.[24] Their findings showed the implementation of the assessment battery was successful, with a high level of adherence (85% adherence after 6 months).[24]

Data from the initial inquiry into the effectiveness of whether the guideline implementation strategy changed the clinical care offered revealed three themes regarding what was important: organizational buy-in, restructuring of organizational infrastructure, and usability (see Table 1).[1, 28-30] This was similar to the findings observed within documentary analysis, particularly within the peer-reviewed literature. Research findings highlighted the value of fostering an organizational culture that is open to changes in organizational structure, policies, and procedures.[39-42, 71-74, 87-94] This may be achieved through leveraging existing organizational infrastructure to identify areas that can help facilitate implementation efforts such as changing existing communication strategies to make implementation support documents easier to understand or using experienced staff to champion implementation priorities.[39-42, 71-74, 87-94]

Table 1: Themes identified regarding "Effectiveness of guideline-implementation strategies"

Theme	Excerpts (verbatim) to interview questions
Organizational buy-in (changing culture)	*" In it, and I think that there are a number of factors that led to that. In one of them is just it was really adopted as part of the organization's vision." - P1*
Restructuring of organizational infrastructure	*"And this is an organization that, you know, during the timeframe that we started implementing decided that they wanted to become a learning health system. And this was really a first step that would help them achieve that." - P1*
Usability	*"But as we were going through the process, and they were observing the benefits of measurement, and then hearing about the learning health system concept on the side,*

	they were able to kind of merge it and say this will be our first project, and this will lay the groundwork for future measurement implementation projects in our organization. So it was very effective." - P1

The interview findings also highlighted the value in better understanding the role policy, political, and health systems considerations play and how this can influence the level to which guideline-implementation strategies are successful. For instance, in identifying and better understanding health system concepts, there were noticeable changes in positive perceptions about the implementation by organizational leadership and staff, leading them to understand how the implementation of the gait and balance assessment aligned with organizational priorities (i.e., vision).[24] The original KTA framework captured many of the facilitators and barriers to implementation of the gait and balance assessment, such as helping to identify potential barriers within the local context where knowledge is to be used (i.e., the rehabilitation facility), but it did not easily capture other relevant factors at the health-system level that may act as barriers.

Success of original KTA framework

In exploring the second line of inquiry on how the existing frameworks helped in understanding how and why the implementation strategies led to the observed outcomes, the findings highlighted room for improvement. Interview findings and documentary analysis reaffirmed that the KTA framework is versatile enough to engage with multiple levels of analysis.[4, 31] There is an opportunity however, for it to be adapted to engage with and address the diverse needs stemming from the policy context. Themes identified from the interview process regarding the success of the existing KTA framework highlight some concerns that can guide

further adaptations to the KTA framework (see Table 2). These themes are consistent with documentary analysis. In particular, as it relates to how the original KTA framework can better capture and engage with the policy context by identifying how different stakeholders play a role within the implementation process.[35, 52-59, 64-70, 86-94] This may be accomplished by considering how different stakeholders are restricted by current regulations (e.g., scope of practice of nurses) or how differing priorities within and between organizations can hinder implementation timelines reflecting differing budget restrictions.[52-59, 64-70, 87-94]

Table 2: Themes identified regarding "Success of original KTA framework"

Theme	Excerpts (verbatim) to interview questions
Lack of robustness	*"Yeah, I mean, I think that the existing framework is a guide for the implementation process, and then encouragement to engage other frameworks and methods of measurement to assess the outcomes." - P1*
Need for a multifaceted approach	*"So I don't think it was because of the framework [alone], but because of our design of the project that we weren't able to isolate that it was probably this, it was probably this grouping of interventions [multifaceted approach]." - P1* *"But in the end, what we did find was that there were, you know, it was a multi-component implementation strategy that was guided by the knowledge action framework that that resulted in successful implementation outcomes." - P1*

Added value of the enriched KTA framework

The participants' concerns about challenges in collaboration efforts with other healthcare professionals and the existence of local policy networks and advocacy groups, highlight two examples of how a more explicit articulation of the policy context could strengthen the value of

the KTA framework.[26] Findings from interviews, and documentary analysis in this study further support the notion that the original KTA framework is amendable to and in need of, a better way to engage with implementation efforts that require the policy context. In particular, documentary analysis and interview findings point to the value in incorporating factors stemming from the policy context such as political resistance from stakeholder groups and access to available funding, in the planning process for guideline implementation.[36, 37, 43-51, 60-63, 85-94] In addition, identifying existing policies and health system arrangements can aid in devising more comprehensive implementation plans that better incorporate available staff within the decision-making process to achieve implementation priorities (e.g., budget, timeline).[36, 37, 43-51, 60-63, 85-94] Responses from the interview process corroborate these findings and highlight these are areas that the original KTA framework could better engage with (see Table 3).

Table 3: Themes identified from "Added value of the enriched KTA framework"

Theme	Excerpts (verbatim) to interview questions
Proactive engagement with policy	*"One of the things that I have run into, though, is planning for an implementation project. And then having a health a new health system level policy that's been implemented, that requires us to divert from our project and focus on that new policy that's in place. And so that slows down the implementation efforts and creates some frustration." - P1*
Need for specificity regarding the policy context	*"I, what I found, from my perspective, is that, for the most part, I hear a lot of barriers by just probing about, you know, those are there any specific policies or health centre health system barriers or incentives that would help facilitate this change. But it would be helpful to have kind of a specific set of questions that might be helpful to go through the process." - P1*
Need for a systematic approach	*"So um, I always think as I go through the KTA, especially on the assess barriers to and*

	facilitators to knowledge use, and even in the sustainability phase, and evaluate outcomes, actually, I think about policy, just broadly, I think about the patient, I think about the clinician, I think about the department or the unit that it's the implementation project is being done in, I think about the organization that we're implementing. And then I think about the external environment, like the health system, policies that are in place that in and, you know, reimbursement, that could take particularly be a barrier. And I do probe as we go through those phases, I do probe our participants on each of those levels. And, and I agree that, like, the literature in the book on the knowledge action framework, does kind of outline that, but they don't provide a systematic approach to assessing it but they do say, well, you can engage other frameworks in these different areas to do that." - P1
Difficulty identifying and engaging with policy relevant stakeholders	*"And I think having also just being able to talk with someone like is something coming down the pipe in the next, you know, six months to a year that could potentially divert our plans or put them on hold, because when things like that happen, we often when those kinds of policy changes happening in United States, usually it's tied to payment." - P1* *"I try to engage stakeholders from all levels of the organization and our barrier and facilitator assessment, as well as the sustainability assessment — thinking about what do we need to do to make this a sustainable change in practice. I don't typically engage people from outside of the facility. And it might be interesting to try to see if the if it might be something that our results could potentially inform policy in the future." - P1*
Need to be cognizant of the policy agenda	*"You can't implement too many things at one time. It's just very difficult to do. And so we've had to kind of put things on hold and it feels like projects get stalled a little bit it when those things happen." - P1*

	"And I have found that from a policy perspective when there is a policy or even a perceived policy, even if it's not really policy, but clinicians perceive it will be a policy at some point in the future. It is a huge facilitator." - P1
	"But having more specific considerations, or a list of things that we might want to, you know, go through as we try to implement and then consider how they might impact our implementation project, or how they might facilitate our implementation project as well, that could be helpful." - P1 *"Policy is, is one that's typically the barriers in my work that tend to come up first are the ones related to the patient and the clinician, and then the department itself. But it's after implementation is going that these other issues often come up of like, oh, wait, we've got to put this on pause and start this other project that's mandated by manage Medicare right now. Or there is, you know, another priority in the hospital that we have to manage to let's put this on on hold as well. So I think having, you know, just having a framework or something, even, you know, like a list of questions, things to consider related to health policy could be helpful." - P1*
Need to match implementation efforts to system constraints	*"So I could imagine from a process perspective, then there's another layer that we engage in, we look at, you know, whether, the the specific questions or specific stakeholders that we might want to consider, and maybe some guidance about what would be relevant and how it would be, you know, like, why when would we engage a specific stakeholder, you know, and again, that might be difficult for all of the different health systems out there, because they're all so different in the way that they operate and knowing like, what are the layers of stakeholders in the health system? How do we navigate that? And how do we, you know, when is it important to reach out to somebody externally to be on*

	that stakeholder team to assess barriers facilitators, and then also think about outcomes and even sustainability aspects of a project." - P1
Managing expectations	*"I think in general, organizations don't realize how much resource implementations project implementation projects take. And that is something that I think needs to be better understood, because I can't tell you the number of times I've gone into a project and then I hear complaints about, "wow, this takes a lot of resource like". Yes, it does, it takes a lot of resource to do this, it takes a you know, a lot of people a lot of focus." - P1*

The enriched KTA framework provides specific direction on how policy, political, and health system factors are systematically considered during the implementation process. It allows policy relevant facilitators, barriers, and strategies to be better captured and situated within the guideline implementation process. It does this by highlighting how implementation strategies can benefit from expanding the priorities set, incorporating policy relevant stakeholders, and situating implementation decisions within existing policy constraints (e.g., budgets, timelines). This is best captured in Table 4, highlighting the added value the enriched framework could potentially add to Moore et al.'s[24] approach.

Table 4: Implementation plan and results with activities described according to each phase of the KTA cycle (*Second columns reproduced verbatim)*

KTA phase	Methods for each phase (from original analysis)	Potential added value of the enriched framework
Adapt knowledge to local context	1. Review of current evidence for GAB in subacute patient populations. 2. Adaptation of the standardized administration procedures to fit into local context; recommendations for adaptations made by	• Reviewing implementation priorities and objectives to ensure they are aligned with existing policies at higher levels (i.e., meso- and macro-levels) within the jurisdiction. • Actively inviting local patient advocacy organizations to provide feedback on the

	clinicians, administrators, and researchers.	implementation strategy to provide input on decision-making regarding adaptations.
Assess barriers and facilitators to knowledge use	1. Survey to MFB clinicians that included adapted survey on perceptions, barriers, and facilitators and the Organizational Readiness to Implement Change survey. 2. Informal discussions about barriers and facilitators. 3. An iterative process of barrier and facilitator assessment, implementation of KT interventions, and monitoring occurred for 6 months until adherence consistently achieved >85%.	• Consulting with both national and provincial/state physician associations to identify contextual factors that may have been overlooked. • Structuring discussions about barriers and facilitators on categories relevant to the policy context (i.e., policy, political, and health systems considerations). • Conducting an organizational audit for Mary Free Bed Rehabilitation Hospital to identify any limitations (e.g., governance structure or human resource issues) that may hinder adherence implementation strategy.
Select, tailor, implement interventions	1. Barriers were categorized according to the Theoretical Domains Framework and KT interventions were selected. 2. Design of KT interventions codeveloped with the MFB clinicians and research team.	• Creating integration strategies for organizational structures/processes that explicitly consider policy, political, and systems considerations.

Source: Moore, J. L., Virva, R., Henderson, C., Lenca, L., Butzer, J. F., Lovell, L., ... & Hornby, T. G. (2020). Applying the Knowledge-to-Action Framework to Implement Gait and Balance Assessments in Inpatient Stroke Rehabilitation. *Archives of Physical Medicine and Rehabilitation*.

Case #2: Application of CFIR

Effectiveness of guideline-implementation strategies

To meaningfully address policy barriers (i.e., higher level factors at the meso- or macro-level), guideline-implementation strategies need to not only identify the most salient factors but also situate them in the appropriate context. Gordan et al.'s[25] application of the CFIR framework

in assessing the barriers and facilitators to a kidney transplant program's implementation preparation, highlights a great example of how these factors can be engaged with using effective guideline implementation strategies in the context of culturally competent care. Themes identified from the interview process regarding the effectiveness of guideline-implementation strategies are found in Table 5. These themes are consistent with findings from documentary analysis, which highlight how more comprehensive implementation strategies, such as those that consider how organizations can expand internal processes (e.g., creating multidisciplinary steering committees or expanding decision-making teams), can improve the chances of successful guideline implementation.[39-41, 71-73, 83-94]

Table 5: Themes identified from "Effectiveness of guideline-implementation strategies"

Theme	Excerpts (verbatim) to interview questions
Usability enhanced by supplementary strategies	*"But we also ended up finding other things, that we ended up developing our own essentially codes for understanding what else was happening, that the framework was not able to describe for us." – P2*
Restructuring of organizational infrastructure	*"And that was crucial for us to really understand what are these organizations being challenged by when trying to change an entire system to be able to implement the intervention? And how are and then that aligned also very much with like, how are they adapting the intervention? How are they changing it in any kind of way? It helped us understand how, yeah, they're moving around people, and they're reorganizing their structure also helped us understand like a broad organizational structure, like the culture, the hierarchy of it. " – P2*

<u>Success of original CFIR framework</u>

Findings from Ali et al, highlighted the CFIR's domains do not fully capture the policy context because the interplay between policy, political, and systems considerations is not as fragmented as the domains make them appear (i.e., they at times overlap, interact, and/or amplify the impact of implementation efforts).[32] Findings from the current study's interview process corroborate these findings (see Table 6). These themes are consistent with the findings from documentary analysis which highlights successful implementation strategies are multifaceted and able to capture the various demands from different stakeholders that can impact guideline implementation.[35, 52-59, 64-70, 86-94] For instance, having a multi-disciplinary team, using clear language in documents, and leveraging the tacit knowledge of organizational leaders has been shown to be effective strategies in guideline implementation.[35, 52-59, 64-70, 86-94]

Table 6: Themes identified from "Success of the existing CFIR framework"

Theme	Excerpts (verbatim) to interview questions
Lack of robustness	*"So barriers and facilitators was something that we added that we felt that the framework did not properly capture with, I guess, like the different activities that we had, but of course, like those would be double coded with some other aspect." – P2* *"So like I mentioned, we ended up having to add a lot of elements to the CFIR framework. So, I guess it was limited in that respect. And I suppose that if I'm just specifically talking about did the framework, as it was originally packaged, helps describe everything that we were interested in? No, it did not, it did not capture everything." – P2*
Need for a multifaceted approach	*"Yeah, I think, you know, we we reached a point where we had to add on, but it did help a lot like we we were able to identify some crucial issues that programmes were having when implementing this." – P2*

<u>*Added value of the enriched CFIR framework*</u>

Enrichments to the CFIR framework focused on building upon existing domains that explored policy relevant areas by adding new constructs that attempt to explicitly identify and engage with the policy context (see Figure 2).[32] Content analysis and interview findings in this study further support the notion that policy, political, and systems considerations require the different implementation components and stages not to be viewed in isolation. In particular, interview analysis reaffirm that relevant policy actors, institutions, and ideas can emerge simultaneously, each with their own respective priorities to be cognizant of for implementation efforts to be successful.[32] Themes identified from the interview process regarding the added value of the enriched CFIR framework are found in Table 7. These themes are consistent with findings from documentary analysis which point to the need for guideline implementation strategies to be considerate of the policy context. In particular, the need to consider the priorities of the local context such as those related to cultural differences, the limitations that can arise from organizational leadership (e.g., lack of effective communication style), and interconnectedness of various stakeholders (e.g., providers and their professional organizations) involved within the implementation process when assessing priorities.[36,37, 43-51, 60-63, 74, 82, 85-94] This case study did not provide sufficient detail about the methods used at each stage of the implementation plan to permit a detailed comparison with the potential added value of the enrichments similar to Table 4.

Table 7: Themes identified from "Added value of the enriched CFIR framework"

Theme	Excerpts (verbatim) to interview questions
Distinguishing between contextual factors (i.e., policy, political, and systems)	*"So, I guess this expanded framework would just help us better understand nuances or different aspects of how these organizations were preparing for implementing our intervention." – P2*

Aligning organizational priorities with policy, political, and system considerations	*"So, the change in the framework could potentially on our end, change how we design the intervention. So potentially, I mean, the facilitators and barriers are huge to understanding how the challenges that we're going to face when trying to package an intervention for other organizations to implement because it's not user centred, right, essentially. So like you what we found is like, we need to create interventions that are much more flexible, that are adaptable, that there are elements that are interchangeable, and then we are able also able to identify the pieces of the intervention that are absolutely critical, and there's no negotiation that organizations should kind of give up certain elements in favour for their comfort or like the facilitation of it like they were crucial elements …" – P2*
Providing a common language to engage with the policy context	*"Um, well, I think that in general, you know, it's seems like the CFIR framework changes a lot. So I think that that can be confusing for people. I think this is, this looks like a really simple framework. I don't think it's that challenging. I think it's pretty self explanatory. And just easily kind of breaks things down. I think some of the other frameworks just look a little bit more complex. I think that like for people on the ground, implementing things, of really simple framework is what they need, because they don't have time to learn new conceptual frameworks and models and learn how to use them. So this is just simple and easy to integrate into your thinking process." – P2*
Interconnectedness of the policy context	*"Yeah, I mean, I think it just kind of helps. Look at specific organizations as individual entities having their own individual issues, rather than like, assuming that all organizations are going to experience similar issues. So yeah, it just helps reframe how we're thinking about how end users are going to be implementing something, and how to communicate to them, I guess." – P2*

Cross-case comparison

Both cases highlighted three consistent perspectives. First, the existing implementation frameworks were viewed as appropriate, but that there was an opportunity for further refinement by engaging with the policy context. Second, the use of supplementary approaches simultaneously with the KTA and CFIR framework, such as using other existing implementation frameworks to overcome limitations was a common feature viewed as necessary. Third, the need for a guided, practical supplementary tool from the enriched frameworks was a need emphasized in both cases. These perspectives support the findings from the content analysis and interviews, but also helps to build upon the enriched frameworks by providing a direction and focus for future refinements.

Discussion

Principal findings

The two cases studied provide unique insights into the application of the KTA and CFIR frameworks that highlights the value of policy, political, and health systems considerations within implementation efforts. The application of the KTA framework to implement a gait and balance assessment highlights how strategies need to be multifaceted through their use of several knowledge translation interventions in conjunction with the KTA framework, to comprehensively deal with the policy context. The application of the CFIR framework in assessing the barriers and facilitators to a kidney transplant program provides a unique opportunity to explore a case that captures the various clinical, organizational, and social challenges that are relevant to the policy context. Both cases demonstrated that the original frameworks were capable of identifying policy relevant factors and strategies but struggled with

the overlap and interconnectedness of the policy context. Both cases also demonstrated the need for a systematic approach that provided the structure to understand the policy context, but the flexibility to adapt to the unique needs of their implementation priorities. Overall, the added value of the enrichments to both the KTA and CFIR framework is apparent from the need to supplement various strategies and other implementation frameworks to better engage with the policy context, which the enriched versions of both frameworks help to circumvent without sacrificing the dynamic nuances within the policy context.

Strengths and limitations

This study has three key strengths. First, studying multiple cases allows for case studies to reflect a more compelling account (i.e., generalizable) which allows for more confidence in the results while increasing the generalizability of the findings.[21-23] Second, the use of multiple sources of data for each case provided insights that no singular source could provide and allowed for triangulation of results.[21-23] Finally, analysis of multiple cases provides an opportunity to identify areas to further refine the two adapted frameworks that have been augmented to more explicitly integrate the policy lens. In particular, it provides a robust application of both the KTA and CFIR that helps to better identify areas the initial development of the enrichments lacked in clarity and suggests new avenues for expansion, as the current study required further integration of empirical and conceptual research from both implementation science and policy discourse.

This study also had two limitations. First, given both case studies explored different lines of inquiry, the search strategy may have results that minimized policy relevant documents as consequence of the clinical nature of implementation science and the issues each respective case explored. Second, the lack of participation within this study by all members of the research team

in both studies, potentially limited the insights and tacit knowledge available amongst the researchers involved in each respective study. This challenge was overcome however, through the insights of two well-positioned individuals and the use of extensive documentary analysis from multiple sources, spanning multiple policy relevant fields.

Implications for policy and practice

These research findings have policy and practice implications for relevant actors in the policy context, in the field of implementation science, and clinical practitioners seeking to use conceptual models able to engage with policy in a meaningful manner. For relevant actors in the policy context, our study highlights the influence the policy context can have on implementation processes (e.g., planning and logistics) and timelines (e.g., impact of new policies on implementation deadlines), as they collaborate with implementation teams. In particular, it highlights the capacity that actors in the policy context (e.g., policymakers, policy entrepreneurs, and interest groups) need to support implementation efforts, such as championing needed system-level changes or aligning networks to implementation timelines. For those within the field of implementation science, the findings showcase how policy, political, and health systems considerations can potentially influence (i.e., facilitate or hinder) how to foster the optimal environment for successful implementation, such as the need to align with existing policy options and health system arrangements. This in turn can aid in designing implementation approaches (e.g., identifying strategies to leverage existing policies, identifying potential collaborators, and modifying existing system arrangements). For clinical practitioners, the findings reaffirm the need for multifaceted approaches to leverage existing health system arrangements and to be mindful of policy constraints, including how decisions about care are

made, funded, and delivered. For instance, with the introduction of a new colorectal cancer screening guideline, clinical practitioners seeking to improve screening in community clinics can leverage existing health system arrangements and implementation strategies. This could capitalize on existing funding for nurse managers and training them to use new tracking systems and protocols to manage patients, which are two strategies that have been found effective for similar guidelines. Further refinement and expansion of the frameworks will allow policy, political, and systems considerations to be better captured and assessed within implementation efforts across various contexts.

Implications for future research

Future research should explore refining the enrichments reflecting the areas of added value the findings from the case studies allude to as means of further bridging the gap between policy agendas and implementation priorities. In particular, efforts to further refine the enriched frameworks should explore how implementation efforts that involve follow-up interventions can be better supported with policy, political, and health systems considerations, both to ensure adherence but also better anticipate potential policy relevant constraints (e.g., expansion of existing policies).

References

1. Gagliardi, A. R., & Alhabib, S. (2015). Trends in guideline implementation: a scoping systematic review. *Implementation Science*, *10*(1), 54.

2. Fischer, F., Lange, K., Klose, K., Greiner, W., & Kraemer, A. (2016, September). Barriers and strategies in guideline implementation—a scoping review. In *Healthcare* (Vol. 4, No. 3, p. 36). Multidisciplinary Digital Publishing Institute.

3. Nilsen, P. (2015). Making sense of implementation theories, models and frameworks. *Implementation science*, *10*(1), 53.

4. Graham, I. D., Logan, J., Harrison, M. B., Straus, S. E., Tetroe, J., Caswell, W., & Robinson, N. (2006). Lost in knowledge translation: time for a map?. *Journal of continuing education in the health professions*, *26*(1), 13-24.

5. Damschroder, L. J., Aron, D. C., Keith, R. E., Kirsh, S. R., Alexander, J. A., & Lowery, J. C. (2009). Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. *Implementation science*, *4*(1), 50.

6. Wilson, K. M., Brady, T. J., Lesesne, C., & NCCDPHP Work Group on Translation. (2011). An organizing framework for translation in public health: the Knowledge to Action Framework. Preventing Chronic Diseases, 8 (2), A46.

7. Kirk, M. A., Kelley, C., Yankey, N., Birken, S. A., Abadie, B., & Damschroder, L. (2015). A systematic review of the use of the consolidated framework for implementation research. *Implementation Science*, *11*(1), 72.

8. Dixon-Woods, M., Cavers, D., Agarwal, S., Annandale, E., Arthur, A., Harvey, J., ... & Riley, R. (2006). Conducting a critical interpretive synthesis of the literature on access to healthcare by vulnerable groups. *BMC medical research methodology*, *6*(1), 35.

9. Canadian Institutes of Health Research (CIHR). About knowledge translation. [http://www.cihr-irsc.gc.ca/e/29418.html]. Retrieved 5 April 2019.

10. Graham, I. D., Logan, J., Harrison, M. B., Straus, S. E., Tetroe, J., Caswell, W., & Robinson, N. (2006). Lost in knowledge translation: time for a map?. *Journal of continuing education in the health professions*, *26*(1), 13-24.

11. Jacobson, N., Butterill, D., & Goering, P. (2003). Development of a framework for knowledge translation: understanding user context. *Journal of health services research & policy*, *8*(2), 94-99.

12. Damschroder, L. J., Aron, D. C., Keith, R. E., Kirsh, S. R., Alexander, J. A., & Lowery, J. C. (2009). Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. *Implementation science*, *4*(1), 50.

13. Michie, S., Atkins, L., & West, R. (2014). The behaviour change wheel. *A guide to designing interventions. 1st ed. Great Britain: Silverback Publishing*, 1003-1010.

14. Klein, K. J., & Sorra, J. S. (1996). The challenge of innovation implementation. *Academy of management review*, *21*(4), 1055-1080.

15. Zahra, S. A., & George, G. (2002). Absorptive capacity: A review, reconceptualization, and extension. *Academy of management review*, *27*(2), 185-203.

16. Weiner, B. J. (2009). A theory of organizational readiness for change. *Implementation science*, *4*(1), 67.

17. May, C., & Finch, T. (2009). Implementing, embedding, and integrating practices: an outline of normalization process theory. *Sociology*, *43*(3), 535-554.

18. Glasgow, R. E., Vogt, T. M., & Boles, S. M. (1999). Evaluating the public health impact of health promotion interventions: the RE-AIM framework. *American journal of public health*, *89*(9), 1322-1327.

19. Meyers, D. C., Durlak, J. A., & Wandersman, A. (2012). The quality implementation framework: a synthesis of critical steps in the implementation process. *American journal of community psychology*, *50*(3-4), 462-480.

20. Stevens, K. R. (2013). The impact of evidence-based practice in nursing and the next big ideas. *Online J Issues Nurs*, *18*(2), 4.

21. Creswell, J. W. (2013). Qualitative Inquiry and Research Design: Choosing Among Five Traditions (3rd. ed.) Thousand Oaks, CA: Sage Publications.

22. Yin, R. K. (2013). Validity and generalization in future case study evaluations. *Evaluation*, *19*(3), 321-332.

23. Yin, R. K. (2014). *Case study research: Design and methods* (5th ed.). Thousand Oaks, CA: Sage.

24. Moore, J. L., Virva, R., Henderson, C., Lenca, L., Butzer, J. F., Lovell, L., ... & Hornby, T. G. (2020). Applying the Knowledge-to-Action Framework to Implement Gait and Balance Assessments in Inpatient Stroke Rehabilitation. *Archives of Physical Medicine and Rehabilitation*.

25. Gordon, E. J., Romo, E., Amórtegui, D., Rodas, A., Anderson, N., Uriarte, J., ... & Shumate, M. (2020). Implementing culturally competent transplant care and implications for reducing health disparities: A prospective qualitative study. *Health Expectations*, *23*(6), 1450-1465.

26. Bauer, M. S., & Kirchner, J. (2019). Implementation science: What is it and why should i care?. *Psychiatry research*.

27. Sackett, D. L., Rosenberg, W. M., Gray, J. M., Haynes, R. B., & Richardson, W. S. (1996). Evidence based medicine: what it is and what it isn't.

28. Brouwers, M. C., De Vito, C., Bahirathan, L., Carol, A., Carroll, J. C., Cotterchio, M., ... & Wathen, N. (2011). Effective interventions to facilitate the uptake of breast, cervical and colorectal cancer screening: an implementation guideline. *Implementation Science*, *6*(1), 1-8.

29. Kastner, M., Bhattacharyya, O., Hayden, L., Makarski, J., Estey, E., Durocher, L., ... & Brouwers, M. (2015). Guideline uptake is influenced by six implementability domains for creating and communicating guidelines: a realist review. *Journal of clinical epidemiology*, *68*(5), 498-509.

30. Gagliardi, A. R., & Brouwers, M. C. (2012). Integrating guideline development and implementation: analysis of guideline development manual instructions for generating implementation advice. *Implementation science*, *7*(1), 1-9.

31. Field, B., Booth, A., Ilott, I., & Gerrish, K. (2014). Using the Knowledge to Action Framework in practice: a citation analysis and systematic review. *Implementation Science*, *9*(1), 172.

32. Ali, A., Lavis, J.N., Brouwers, M.C., Wilson M.G., & Alvarez, E. (2022). *Using a policy lens to focus supports for clinical practice guideline implementation: A critical interpretive synthesis*. [Manuscript in preparation].

33. Becker, T., Kilian, R., & Koesters, M. (2017). Policies, guideline implementation and practice change–how can the process be understood?. *Epidemiology and Psychiatric Sciences*, *26*(2), 115-118

34. Ploeg, J., Davies, B., Edwards, N., Gifford, W., & Miller, P. E. (2007). Factors influencing best-practice guideline implementation: lessons learned from administrators, nursing staff, and project leaders. *Worldviews on Evidence-Based Nursing*, *4*(4), 210-219.

35. Alberta Health Services. (n.d.). *Knowledge translation & implementation science resources*. Alberta Health Services. Retrieved April 13, 2022, from https://www.albertahealthservices.ca/info/Page11163.aspx

36. *Module 1: An Overview of Active Implementation Frameworks*. National Implementation Research Network's Active Implementation Hub. (n.d.). Retrieved April 14, 2022, from https://nirn.fpg.unc.edu/module-1

37. *Center on Knowledge Translation for Disability and Rehabilitation Research (KTDRR) KT Library - Research Quality*. Knowledge Translation: Introduction to Models, Strategies, and Measures. (2018, March 26). Retrieved April 15, 2022, from https://ktdrr.org/ktlibrary/articles_pubs/ktmodels/

38. National Quality Forum (NQF). (2009). A comprehensive framework and preferred practices for measuring and reporting cultural competency: a consensus report.

39. Harrison, M. B., Légaré, F., Graham, I. D., & Fervers, B. (2010). Adapting clinical practice guidelines to local context and assessing barriers to their use. *Cmaj*, *182*(2), E78-E84.

40. Hall, S. F., Irish, J. C., Gregg, R. W., Groome, P. A., & Rohland, S. (2015). Adherence to and uptake of clinical practice guidelines: lessons learned from a clinical practice guideline on chemotherapy concomitant with radiotherapy in head-and-neck cancer. *Current oncology*, *22*(2), 61-68.

41. Cassetti, V., López-Ruiz, M. V., Pola-Garcia, M., García-García, A. M., Paredes-Carbonell, J. J., Pérula-De Torres, L. A., ... & EvaluAGPS Research Group. (2022). An integrative review of the implementation of public health guidelines. *Preventive Medicine Reports*, 101867.

42. Munce, S., Kastner, M., Cramm, H., Lal, S., Deschêne, S. M., Auais, M., ... & Brouwers, M. (2013). Applying the knowledge to action framework to plan a strategy for implementing breast cancer screening guidelines: an interprofessional perspective. *Journal of Cancer Education*, *28*(3), 481-487.

43. Stokes, T., Shaw, E. J., Camosso-Stefinovic, J., Imamura, M., Kanguru, L., & Hussein, J. (2016). Barriers and enablers to guideline implementation strategies to improve obstetric care practice in low-and middle-income countries: a systematic review of qualitative evidence. *Implementation Science*, *11*(1), 1-10.

44. McCluskey, A., Vratsistas-Curto, A., & Schurr, K. (2013). Barriers and enablers to implementing multiple stroke guideline recommendations: a qualitative study. *BMC health services research*, *13*(1), 1-13.

45. Wakida, E. K., Obua, C., Rukundo, G. Z., Maling, S., Talib, Z. M., & Okello, E. S. (2018). Barriers and facilitators to the integration of mental health services into primary healthcare: a qualitative study among Ugandan primary care providers using the COM-B framework. *BMC health services research*, *18*(1), 1-12.

46. Almazrou, S. H., Alfaifi, S. I., Alfaifi, S. H., Hakami, L. E., & Al-Aqeel, S. A. (2020, December). Barriers to and facilitators of adherence to clinical practice guidelines in the Middle East and North Africa region: A systematic review. In *Healthcare* (Vol. 8, No. 4, p. 564). MDPI.

47. Qumseya, B., Goddard, A., Qumseya, A., Estores, D., Draganov, P. V., & Forsmark, C. (2021). Barriers to clinical practice guideline implementation among physicians: a physician survey. *International Journal of General Medicine*, *14*, 7591.

48. Slade, S. C., Kent, P., Patel, S., Bucknall, T., & Buchbinder, R. (2016). Barriers to primary care clinician adherence to clinical guidelines for the management of low back pain. *The Clinical journal of pain*, *32*(9), 800-816.

49. Cahill, N. E., & Heyland, D. K. (2010). Bridging the guideline–Practice gap in critical care nutrition: A review of guideline implementation studies. *Journal of Parenteral and Enteral Nutrition*, *34*(6), 653-659.

50. Tomasone, J. R., Kauffeldt, K. D., Chaudhary, R., & Brouwers, M. C. (2020). Effectiveness of guideline dissemination and implementation strategies on health care professionals' behaviour and patient outcomes in the cancer care context: a systematic review. *Implementation Science*, *15*(1), 1-18.

51. Watkins, K., Wood, H., Schneider, C. R., & Clifford, R. (2015). Effectiveness of implementation strategies for clinical guidelines to community pharmacy: a systematic review. *Implementation Science*, *10*(1), 1-23.

52. Breimaier, H. E., Halfens, R. J., & Lohrmann, C. (2015). Effectiveness of multifaceted and tailored strategies to implement a fall-prevention guideline into acute care nursing practice: a before-and-after, mixed-method study using a participatory action research approach. *BMC nursing*, *14*(1), 1-12.

53. Stander, J., Grimmer, K., & Brink, Y. (2021). How to contextualize training on guideline-uptake for your setting. *Journal of Evaluation in Clinical Practice*, *27*(5), 1164-1167.

54. Stander, J., Grimmer, K., & Brink, Y. (2021). Time as a barrier to evidence uptake—A qualitative exploration of the concept of time for clinical practice guideline uptake by physiotherapists. *Journal of Evaluation in Clinical Practice*, *27*(2), 280-290.

55. Peters, S., Bussières, A., Depreitere, B., Vanholle, S., Cristens, J., Vermandere, M., & Thomas, A. (2020). Facilitating guideline implementation in primary health care practices. *Journal of Primary Care & Community Health*, *11*, 2150132720916263.

56. Ploeg, J., Davies, B., Edwards, N., Gifford, W., & Miller, P. E. (2007). Factors influencing best-practice guideline implementation: lessons learned from administrators, nursing staff, and project leaders. *Worldviews on Evidence-Based Nursing*, *4*(4), 210-219.

57. Jiang, V., Brooks, E. M., Tong, S. T., Heintzman, J., & Krist, A. H. (2020). Factors influencing uptake of changes to clinical preventive guidelines. *The Journal of the American Board of Family Medicine*, *33*(2), 271-278.

58. Harrison, M. B., Graham, I. D., Van Den Hoek, J., Dogherty, E. J., Carley, M. E., & Angus, V. (2013). Guideline adaptation and implementation planning: a prospective observational study. *Implementation science*, *8*(1), 1-14.

59. Hakkennes, S., & Dodd, K. (2008). Guideline implementation in allied health professions: a systematic review of the literature. *BMJ Quality & Safety*, *17*(4), 296-300.

60. Kastner, M., Bhattacharyya, O., Hayden, L., Makarski, J., Estey, E., Durocher, L., ... & Brouwers, M. (2015). Guideline uptake is influenced by six implementability domains for creating and communicating guidelines: a realist review. *Journal of clinical epidemiology*, *68*(5), 498-509.

61. Gagné, M. E., & Boulet, L. P. (2018). Implementation of asthma clinical practice guidelines in primary care: a cross-sectional study based on the Knowledge-to-Action Cycle. *Journal of Asthma*, *55*(3), 310-317.

62. Beauchemin, M., Cohn, E., & Shelton, R. C. (2019). Implementation of clinical practice guidelines in the healthcare setting: A Concept Analysis. *ANS. Advances in nursing science*, *42*(4), 307.

63. Spoon, D., Rietbergen, T., Huis, A., Heinen, M., van Dijk, M., van Bodegom-Vos, L., & Ista, E. (2020). Implementation strategies used to implement nursing guidelines in daily practice: a systematic review. *International journal of nursing studies*, *111*, 103748.

64. Forsner, T., Hansson, J., Brommels, M., Wistedt, A. Å., & Forsell, Y. (2010). Implementing clinical guidelines in psychiatry: a qualitative study of perceived facilitators and barriers. *BMC psychiatry*, *10*(1), 1-10.

65. Gagliardi, A. R., & Brouwers, M. C. (2012). Integrating guideline development and implementation: analysis of guideline development manual instructions for generating implementation advice. *Implementation science*, *7*(1), 1-9.

66. Li, J., Zhu, C., Liu, Y., Li, Z., Sun, X., Bai, Y., ... & Wu, X. (2022). Critical care nurses' knowledge, attitudes, and practices of pressure injury prevention in China: A multicentric cross-sectional survey. *International Wound Journal*.

67. Sprague, A. E., Oppenheimer, L., McCabe, L., Graham, I. D., & Davies, B. L. (2008). Knowledge to action: Implementing a guideline for second stage labor. *MCN: The American Journal of Maternal/Child Nursing*, *33*(3), 179-186.

68. Alanen, S., Välimäki, M., Kaila, M., & ECCE Study Group. (2009). Nurses' experiences of guideline implementation: a focus group study. *Journal of clinical nursing*, *18*(18), 2613-2621.

69. Ralefala, T., Mokokwe, L., Jammalamadugu, S., Legobere, D., Motlhwa, W. S., Oyekunle, A. A., ... & Martei, Y. M. (2021). Provider Barriers and Facilitators of Breast Cancer Guideline-Concordant Therapy Delivery in Botswana: A Consolidated Framework for Implementation Research Analysis. *The Oncologist*, *26*(12), e2200-e2208.

70. Ramerman, L., Hoekstra, P. J., & de Kuijper, G. (2018). Exploring barriers and facilitators in the implementation and use of guideline recommendations on antipsychotic drug prescriptions for people with intellectual disability. *Journal of Applied Research in Intellectual Disabilities*, *31*(6), 1062-1070.

71. Schipper, K., Bakker, M., De Wit, M., Ket, J. C. F., & Abma, T. A. (2015). Strategies for disseminating recommendations or guidelines to patients: a systematic review. *Implementation Science*, *11*(1), 1-17.

72. Unverzagt, S., Oemler, M., Braun, K., & Klement, A. (2014). Strategies for guideline implementation in primary care focusing on patients with cardiovascular disease: a systematic review. *Family Practice*, *31*(3), 247-266

73. Breneol, S., Curran, J. A., Marten, R., Minocha, K., Johnson, C., Wong, H., ... & Patiño-Lugo, D. F. (2022). Strategies to adapt and implement health system guidelines and recommendations: a scoping review. *Health research policy and systems*, *20*(1), 1-54

74. Fretheim, A., Munabi-Babigumira, S., Oxman, A. D., Lavis, J. N., & Lewin, S. (2009). SUPPORT tools for evidence-informed policymaking in health 6: Using research evidence to address how an option will be implemented. *Health research policy and systems*, *7*(1), 1-11.

75. Higuchi, K. S., Davies, B., & Ploeg, J. (2017). Sustaining guideline implementation: A multisite perspective on activities, challenges and supports. *Journal of clinical nursing*, *26*(23-24), 4413-4424.

76. Kovacs, E., Strobl, R., Phillips, A., Stephan, A. J., Mueller, M., Gensichen, J., & Grill, E. (2018). Systematic review and meta-analysis of the effectiveness of implementation strategies for non-communicable disease guidelines in primary health care. *Journal of general internal medicine*, *33*(7), 1142-1154.

77. Breimaier, H. E., Heckemann, B., Halfens, R. J., & Lohrmann, C. (2015). The Consolidated Framework for Implementation Research (CFIR): a useful theoretical framework for guiding and evaluating a guideline implementation process in a hospital-based nursing practice. *BMC nursing*, *14*(1), 1-9.

78. Prior, M., Guerin, M., & Grimmer-Somers, K. (2008). The effectiveness of clinical guideline implementation strategies–a synthesis of systematic review findings. *Journal of evaluation in clinical practice*, *14*(5), 888-897.

79. Al Zoubi, F. M., Menon, A., Mayo, N. E., & Bussières, A. E. (2018). The effectiveness of interventions designed to increase the uptake of clinical practice guidelines and best practices among musculoskeletal professionals: a systematic review. *BMC health services research*, *18*(1), 1-11.

80. Kitson, A., & Straus, S. E. (2010). The knowledge-to-action cycle: identifying the gaps. *Cmaj*, *182*(2), E73-E77.

81. Peters, S., Sukumar, K., Blanchard, S., Ramasamy, A., Malinowski, J., Ginex, P., ... & Gagliardi, A. (2022). Trends in guideline implementation: an updated scoping review. *Implementation Science*, *17*(1), 1-17.

82. Northwestern Medicine Launches Hispanic Brain and Spine Tumor ProgramHospital closes gap in neurological cancer care and provides better access for patients in the Hispanic community. https://advance-lexis-com.libaccess.lib.mcmaster.ca/api/document?collection=news&id=urn:contentItem:5WGF-1871-DXP3-R15S-00000-00&context=1516831.

83. Findings from Northwestern University Feinberg School of Medicine in Science Reported (Implementation and modification of an organizational-level intervention: a prospective analysis). https://advance-lexis-com.libaccess.lib.mcmaster.ca/api/document?collection=news&id=urn:contentItem:65XS-46B1-DY7R-R45C-00000-00&context=1516831.

84. Reports on Kidney Transplants from Northwestern University Provide New Insights (Impact of Having Potential Living Donors On Ethnic/racial Disparities In Access To Kidney Transplantation). https://advance-lexis-com.libaccess.lib.mcmaster.ca/api/document?collection=news&id=urn:contentItem:6607-71H1-JBSP-12K5-00000-00&context=1516831.

85. Assessing Youth Level of Service/Case Management Inventory Implementation Outcomes: Lessons from Five Diverse Pennsylvania Counties. https://advance-lexis-com.libaccess.lib.mcmaster.ca/api/document?collection=news&id=urn:contentItem:625B-TV11-DY41-71WN-00000-00&context=1516831.

86. Video Identifying New Directions in Mental Health Disparities Research: Innovations with a Multidimensional Lens - Day One, Part One. https://advance-lexis-com.libaccess.lib.mcmaster.ca/api/document?collection=news&id=urn:contentItem:621H-RTC1-F03R-N0RR-00000-00&context=1516831.

87. Chambers, D. A. (2019). Implementation Science at a Glance: A Guide for Cancer Control Practitioners (Nr. 19-CA-8055). National Cancer Institute. *Bethesda, MD, USA*.

88. Heiden, T., & Saia, T. (2020). Engaging stakeholders for research impact.

89. D'Angelo, C., Knack, A., MacLure, C., & Freeman, J. (2018). *Evidence synthesis on the conditions needed to translate research and drive innovation*. RAND.

90. Souffez-Marie-Claire, N. L. K. (2013). Facilitating a knowledge translation process: Knowledge review and facilitation tool.

91. Barwick, M., Dubrowski, R., & Petricca, K. (2020). *Knowledge translation: the rise of implementation*. Washington (DC): American Institutes for Research.

92. Alberta Health Services. (2020). Scaling-up and Spreading Innovations in Healthcare: An Overview of Best Practices. Edmonton, AB: Author.

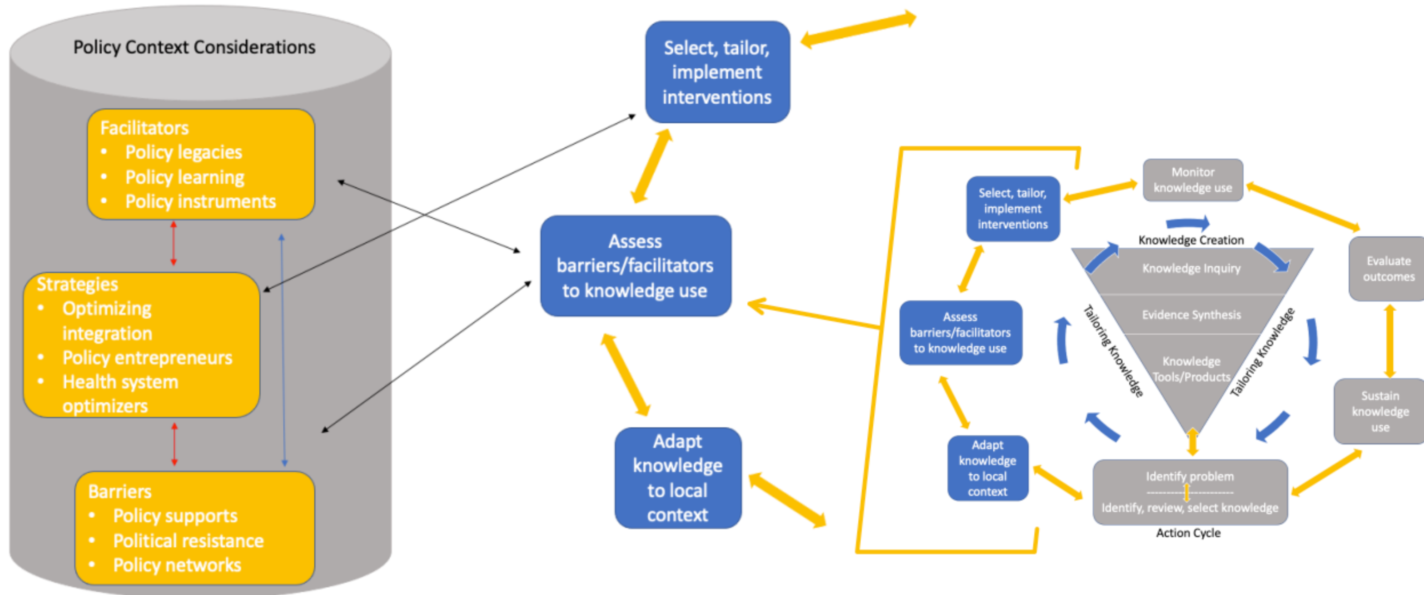
93. Pan American Health Organization. (2018). Strengthening national evidence-informed guideline programs. A tool for adapting and implementing guidelines in the Americas. Washington, D.C.: PAHO.

94. Derrick-Mills, T. (2020). Using Implementation Science to Systematically Identify Opportunities for Learning and Improvement.

95. Robinson, O. C. (2011). Relational analysis: An add-on technique for aiding data integration in qualitative research. *Qualitative Research in Psychology*, *8*(2), 197-209.

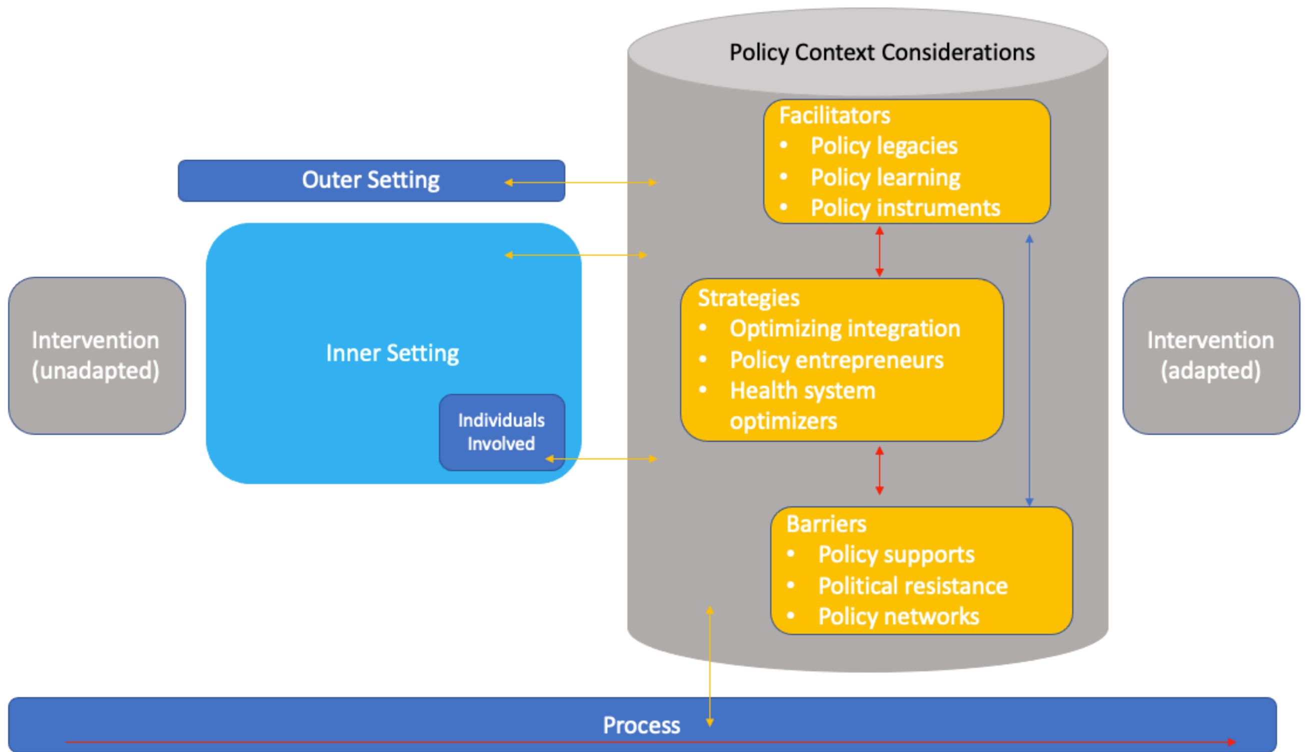
96. Gordon, E. J., Uriarte, J. J., Lee, J., Kang, R., Shumate, M., Ruiz, R., ... & Caicedo, J. C. (2022). Effectiveness of a culturally competent care intervention in reducing disparities in Hispanic live donor kidney transplantation: A hybrid trial. *American Journal of Transplantation*, *22*(2), 474-488.

Figure 1 - Enrichments to Knowledge-to-Action Framework



Note: Adapted from Graham et al.[4]

Figure 2 - Enrichments to the Consolidated Framework for Implementation Research



Note: Adapted from Damschroder et al.[5]

Appendix

Appendix 1: Details related to data collection and sampling

Data source	Search terms	Documents selected for inclusion	Additional details
Published literature • Canadian Public Policy Collection (for grey literature) • EMBASE • Emcare • Health Systems Evidence (HSE) • Medline • PsychINFO • Social Science Abstracts • Web of Science	("clinical guideline" OR "practice guideline" OR "guideline*") AND ("implement*" OR "adher*" OR uptake) AND ("Knowledge to action" OR "KTA" OR "Consolidated Framework for Implementation Research" OR "CFIR") ("clinical guideline" OR "practice guideline" OR "guideline*") AND ("implement*" OR "adher*" OR "uptake*") AND ("barrier*" AND "facilitat*")	45 (of 143 studies retrieved)	All retrieved documents were exported to EndNote. Titles and abstracts were read, and articles were included if they: 1. Described policy, political or system context relevant to the implementation of the guideline. 2. Described elements of the implementation process that provide insights into the case studies, including but not limited to, how human resources are organized and how priorities are assessed within implementation efforts. 3. Described facilitators, barriers, and/or strategies relevant to guideline implementation. 4. Described details about the cases selected for this study.
Policy documents and grey literature	Identified through: 1. Hand searches of reference lists 2. Google searches 3. Published literature	11	Of the documents sampled 1. 2 were related to engaging different stakeholders within the implementation process. 2. 5 were related to understanding and applying knowledge translation. 3. 4 were sampled for both cases because they contained information about adapting and implementing guidelines that were used to inform decisions.
Newspaper articles – LexisNexis database	("clinical guideline" OR "practice guideline" OR "guideline*") AND ("implement*" OR	5 (of 6 individual	Using NVIVO, all 6 retrieved articles were included in the first stages of analysis but only 5

	“adher*” OR uptake) AND ("Knowledge to action" OR "KTA" OR "Consolidated Framework for Implementation Research" OR "CFIR") ("clinical guideline" OR "practice guideline" OR "guideline*") AND ("implement*" OR “adher*” OR "uptake*") AND ("barrier*" AND "facilitat*") "Northwestern" AND "Hispanic Kidney Transplant Program"	articles retrieved)	were useful in developing an understanding of the selected case studies.

Appendix 2: Potential implementation examples using the KTA or CFIR framework identified and considered for inclusion

Framework	Focus	Country of study	Year of implementation	Citation
KTA	Researchers conducted a multi-faceted knowledge translation initiative that was targeted at the implementation of Cognitive Orientation to daily Occupational Performance (CO-OP) in inpatient stroke rehabilitation teams at five freestanding rehabilitation hospitals.	Canada	2017	McEwen, S. E., Donald, M., Jutzi, K., Allen, K. A., Avery, L., Dawson, D. R., ... & Linkewich, E. (2019). Implementing a function-based cognitive strategy intervention within inter-professional stroke rehabilitation teams: Changes in provider knowledge, self-efficacy and practice. *PloS one*, *14*(3), e0212988.
KTA	The study objective was to assess the effect of the study intervention on clinician adherence to the recommendations and its effect on clinician perceptions and the organization.	United States of America	2018	Moore, J. L., Virva, R., Henderson, C., Lenca, L., Butzer, J. F., Lovell, L., ... & Hornby, T. G. (2020). Applying the Knowledge-to-Action Framework to Implement Gait and Balance Assessments in Inpatient Stroke Rehabilitation. *Archives of Physical Medicine and Rehabilitation*.
CFIR	The study assessed barriers and facilitators to a kidney transplant program's implementation preparation.	United States of America	2016	Gordon, E. J., Romo, E., Amórtegui, D., Rodas, A., Anderson, N., Uriarte, J., ... & Shumate, M. (2020). Implementing culturally competent transplant care and implications for reducing health disparities: A prospective qualitative study. *Health Expectations*, *23*(6), 1450-1465.
CFIR	Examined the effectiveness of a Toronto Community Addictions Team on	Canada	2012	Draanen, J. V., Corneau, S., Henderson, T., Quastel, A., Griller, R., & Stergiopoulos, V. (2013). Reducing service

	service and substance use in Toronto.			and substance use among frequent service users: a brief report from the Toronto community addictions team. *Substance use & misuse*, *48*(7), 532-538.
CFIR	Focused on the implementation of full-service partnerships, supportive housing programs for persons with serious mental illness in California.	United States of America	2012	Gilmer, T. P., Katz, M. L., Stefancic, A., & Palinkas, L. A. (2013). Variation in the implementation of California's Full Service Partnerships for persons with serious mental illness. *Health services research*, *48*(6pt2), 2245-2267.
CFIR	Focused on the implementation of the awakening and breathing coordination, delirium monitoring/management, and early exercise/mobility bundle in a tertiary care setting.	United States of America	2012	Balas, M. C., Burke, W. J., Gannon, D., Cohen, M. Z., Colburn, L., Bevil, C., ... & Vasilevskis, E. E. (2013). Implementing the awakening and breathing coordination, delirium monitoring/management, and early exercise/mobility bundle into everyday care: opportunities, challenges, and lessons learned for implementing the ICU Pain, Agitation, and Delirium Guidelines. *Critical care medicine*, *41*(9), S116-S127.
CFIR	Focused on the implementation of Graded Repetitive Arm	Canada	Unclear	Connell, L. A., McMahon, N. E., Harris, J. E., Watkins, C. L., &

	Supplementary Program for upper limb stroke rehabilitation in Vancouver, British Columbia.			Eng, J. J. (2014). A formative evaluation of the implementation of an upper limb stroke rehabilitation intervention in clinical practice: a qualitative interview study. *Implementation Science*, *9*(1), 90.

Appendix 3: Interview guide for case study interviews

Interview Guide

Date:
Time:
Place:
Interviewer:
Interviewee:
Position of Interviewee:

Questions:

1. How would the enriched framework change how you organize and plan?
    a. Structure of guideline development group, budget, secure funding, etc.
2. How would the enriched framework change how you set, manage, and assess priorities?
    a. Topic selection, proposal priorities, stakeholder engagement, etc.
3. How would the enriched framework inform your implementation process?
    a. Did behaviours (greater provision of effective and efficient care) and (if possible) outcomes change – in other words, did or didn't the guideline-implementation strategies yield their expected impacts?
    b. Did the existing framework explain how and why the strategies (and an understanding of factors) did or did not yield their expected impacts?
    c. Did the enriched framework explain any better? How and why?
    d. How would the enriched framework inform how you communicate, collaborate, and interact with other guideline developers/implementers?
    e. How would the enriched framework inform how you approach different target audiences?
    f. How would the enriched framework inform how you incorporate relevant stakeholders?
    g. What potential limitations and strengths do you see with the enriched framework? How would you compare it to the framework(s) you use to support implementation efforts?

Chapter 4: Preface

While there is a significant level of attention given to understanding the factors and strategies that can impact guideline implementation, exploring the tacit knowledge of guideline developers and implementers can provide insights into the role of the policy context within implementation processes. This chapter contributes to the understanding about the role of the policy context within guideline implementation and the value of the enrichments by exploring guideline developers' and implementers' views on how the enriched frameworks can support guideline implementation. Using a formative evaluation study design and drawing on the findings from chapter 2 and the refinements to the enriched frameworks from chapter 3, this chapter seeks to: 1) understand what policy context considerations are most important within guideline implementation processes to guideline developers and implementers; and 2) identify how the enriched frameworks can be further refined to better captured and described these considerations. Our findings help to further highlight the importance of explicitly exploring the role of policy within guideline implementation efforts and helps to further encourage guideline experts and implementation science scholars to incorporate policy-relevant strategies within implementation processes. I was responsible for developing the focus and design of the study with my supervisor (Dr. John N. Lavis), in addition to data collection, analysis, and interpretation. Dr. John N. Lavis also contributed to the analysis through an iterative process of interpretation and synthesis which produced further refinements to the two enriched implementation frameworks. Kerry Waddell aided me in developing and refining the codebook through an initial analysis framework using a sub-sample of transcripts. I drafted the manuscript, and Dr. Lavis, Dr. Melissa Brouwers and Dr. Michael G. Wilson provided extensive feedback that were incorporated into the manuscript. All these individuals are co-authors on the manuscript.

A formative evaluation examining guideline developers' and implementers' views about how a policy-, political- and systems-enriched framework can support guideline implementation

Authors: Ali A, Lavis JN, Brouwers MC, Wilson MG, Waddell K

Keywords: clinical practice guidelines, implementation science, public policy, formative evaluation

Word count: 4627 (main text) 12, 426 (inclusive of abstract, exhibits, and references)

Abstract

Background: Clinical practice guidelines (CPGs) provide evidence-based guidance to clinicians and other decision makers and are particularly useful in situations with a high degree of uncertainty. Theoretical frameworks, many of which consider factors known to influence the adoption of evidence-based practices, have been developed to foster uptake of CPG recommendations. In a previous study, enriched versions of both the Knowledge-to-Action Framework (KTA) and the Consolidated Framework for Implementation Research (CFIR) were developed to incorporate neglected policy, political, and health system considerations that may influence the implementation of CPGs. This study attempts to expand on this work by determining what factors are important to guideline developers and implementers and how these factors can be better presented and described in the enriched frameworks to support guideline implementation.

Methods: Semi-structured interviews were conducted with expert guideline developers from each of the six World Health Organization regions, and guideline implementers who were selected from a single WHO member state (Canada). Interviewees were provided with relevant enrichment sections from the two frameworks to aid in their feedback to the questions. Interviews were conducted on-line, audio recorded, transcribed, and coded using a codebook that was developed by two coders. The interview data were analyzed using qualitative content analysis.

Results: Twenty-four interviews were conducted across the six WHO regions, 13 with guideline developers and 11 with guideline implementers. Overall, guideline developers and implementers found that the enrichments to the KTA and CFIR framework would be helpful in capturing and considering the implications of the policy context. They also found the enrichments would be

useful in planning and logistics activities, especially in managing the competing priorities of different actors.

Discussion: Our analysis highlighted areas where guideline developers and implementers found the enrichments could be further refined, including the need for more specific definitions of policy relevant constructs and practical complementary supports to accompany the enriched frameworks.

Conclusions: Principal findings of this study highlight the value of the systematic consideration of policy, political, and health systems considerations with the implementation of evidence-informed recommendations.

Word count: 334 (max 350)

Background

Clinical practice guidelines (CPGs) are defined as "statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options".[1] Some of the advantages of CPGs can best be seen when there are multiple interventions to choose from and the issue or context is complex.[3] CPGs can play a crucial role in supporting consistent delivery of clinically effective, technically efficient, and cost-appropriate care.[2-5] The implementation science discipline can be drawn up on to translate this aspiration into reality.

There are numerous factors that can influence (i.e., facilitate or hinder) CPG implementation efforts. One way these factors can be grouped is to consider four categories: 1) personal factors; 2) guideline-related factors; 3) implementation-related factors; and 4) context-dependent factors.[27-31] While clinical and organizational contexts are often considered within the fourth category of factors, the policy context is least understood.[2, 34, 35]

Two recent studies by Ali et al., sought to explore and better understand the role the policy context plays within CPG implementation efforts. These studies unpacked the policy, political and systems dimensions of the policy context.[32-33] The first study is a critical interpretive synthesis (CIS) that enriches two existing implementation frameworks that are often used to direct CPG implementation efforts: the Knowledge-to-Action (KTA) Framework and the Consolidated Framework for Implementation Research (CFIR).[32] The second study is a multiple case study of guideline-implementation processes that draws on and further operationalizes the enriched frameworks.[33] Both the CIS and case studies provide a more explicit understanding of policy, political, and system factors that influence the implementation of clinical recommendations.

The KTA framework is comprised of two distinct phases. The knowledge creation phase considers evidence creation from primary studies to synthesis to guidelines.[20, 21] The action cycle phase considers the steps to successfully promote uptake of evidence and the evaluation and sustainability of those efforts.[20, 21] Both of these phases can be iterative and inform one another.[20, 21] The results of the CIS can enrich several of the steps within the action cycle. Formal consideration of policy, political, and health system-level factors can support adaptation to the local context (step 2). For example, the recommended dosing schedule for a new vaccine may need to be modified to address limitations in the vaccine supply, a health system level problem. Similarly, assessing barriers/facilitators to knowledge use (step 3) and selecting, tailoring, and implementing interventions (step 4) can be better informed by asking about policy-relevant facilitators such as past policies that have created policy legacies like enhanced administrative capacities, policy-relevant barriers such as resistance from intertest groups, and policy-relevant strategies such as the use of policy entrepreneurs.[20, 21]

The CFIR is an implementation framework that helps to guide the effective implementation of evidence-based practices, from design to evaluation, by systematically considering factors that can support or hinder uptake.[5] It is comprised of 39 constructs which are divided into five domains.[5, 22] The results of the CIS can inform four of those domains: 1) the inner setting; 2) outer setting; 3) characteristics of individuals (i.e., individuals involved); and 4) the implementation process domain. Formal consideration of policy, political, and health system-level factors about the environment can help to better explain observed outcomes and relationships.[32] In the inner setting it may help to explain how existing framings of problems or how politically important organizations interact, may influence (i.e., facilitate or hinder) CPG implementation.[32] In the outer setting, it may help to identify existing health system delivery

arrangements (i.e., how care is delivered, by whom care is provided, and where care is provided) that may hinder guideline implementation.[32] Similarly, formal assessments of these factors can provide insights about how policy considerations impact individuals and implementation processes.[32] For instance, in the characteristics of individuals domain, it may help to highlight how the relationships amongst different stakeholders and the incentives they respond to, can influence their decisions which can impact implementation timelines.[32] In the implementation process domain, it may help to highlight what delivery arrangements (e.g., the need for culturally appropriate care) need to be prioritized within the implementation process. [32]

Findings from the CIS led to the KTA and CFIR framework being enriched. See Figure 1 and Figure 2 for enriched frameworks. In both frameworks, this was accomplished through a new layer called the policy context considerations that explicitly engages with and is sensitive to the policy, political, and systems considerations. This new layer is comprised of three subconstructs: 1) policy-relevant facilitators; 2) policy-relevant barriers; and 3) policy-relevant strategies.[32] Findings from the case studies helped to further build upon the enrichments from the CIS in two ways.[33] First, the findings from the case studies highlighted the need for the definitions and examples to more explicitly showcase how interconnected the policy context is, such as how connections and relationships among different policy-relevant stakeholders can impact implementation priorities (e.g., conflicting priorities among different groups).[33] Second, the findings from the case studies highlighted the need for the enrichments to more explicitly describe which type of consideration (i.e., policy, political, or system consideration) is being referred to, to better clarify for users.[33]

A key gap now exists in understanding guideline developers' and implementers' views about how these two policy-, political- and systems-enriched frameworks can support guideline implementation and be adapted to better support guideline implementation.

Research objective

The objective of this study is to establish content validation of the enriched KTA and CFIR frameworks. This study seeks to answer the questions: 1) w*hat policy, political, and systems considerations – as captured in two enriched frameworks -- are important within the implementation process for guideline developers and implementers; and 2) how can these considerations be better described and presented in two enriched guideline-implementation frameworks?*

The study explores how the planning and logistical processes before CPG implementation, such as organizing, managing priorities, and incorporating relevant stakeholders can change with the use of the enriched guideline-implementation frameworks. It also examines how the products, implementation processes and other activities involved during CPG implementation can change with the use of these frameworks. The key outputs arising from addressing this research question will be two refined enriched frameworks that reflect input from expert developers and implementers obtained through this current study (as well as from the previous case studies conducted).

Design and methods

This study employs formative evaluation as a study design. Formative evaluation – when applied in an implementation context as it is here – is an approach that allows researchers "to

explicitly study the complexity of implementation projects and suggests ways to answer questions about context, adaptations, and response to change".[8] Formative evaluation can use data from a variety of sources including both qualitative and quantitative data, with the former potentially including interviews with various stakeholders (e.g., patients, providers and health system leaders), and the latter potentially including publicly available databases including those based on community, regulatory, and policy data.[8,9] Formative evaluations are iterative in nature and allow to better identify and distinguish observed failures as either stemming from an intervention or arising from implementation efforts.[8] Here, data were collected using interviews that focus on anticipated uses of and improvements to two enriched guideline-implementation frameworks. For this study, the implementation projects were hypothetical to enable the exploration, identification, and assessment of salient processes that are relied upon by expert CPG developers and implementers across various CPG focused implementation efforts.

Sampling and recruitment

Guideline developers and implementers represent unique and sometimes overlapping groups that play a role in promoting the use of CPGs at local, national, and international levels. For this study, guideline developers were defined as individuals who develop, adapt, and/or update CPGs using the best-available evidence.[17] Guideline implementers were defined as individuals who undertake efforts to implement a given CPG. The implementation efforts may include dissemination, education and training, educational outreach visits and marketing, provision of decision-support systems (both manual or automated), and the coordinating of efforts among implementers by organizations (both with funding and integration efforts among

various stakeholders).[3,19] Developers who have an obligation to also engage in implementation activities were designated developers and not both.

Guideline developers were selected for semi-structured interviews from each of the six World Health Organization (WHO) regions. For the current study, five highly visible guideline groups in each region were selected based on citations (i.e., published guidelines), infrastructure (i.e., organization, scope of projects, etc.), years of experience, size of group membership, and knowledge of the groups through informal discussions with committee members and other experts. These criteria were used to identify and select the most established candidate groups amongst all identified groups. Maximum variation was not explored. The initial list of potential organizations was formulated from a preliminary document analysis and recommendations from experts.

Guideline implementers were selected for semi-structured interviews from a single WHO member state (Canada). Canada was selected based on three factors stemming from and related to its policy, political, and health-system features. First, Canada has on its policy agenda both quality improvement (QI) and knowledge translation (KT). This also includes the role of research in driving QI, including inputs to QI like guidelines.[23-25] Such topics have been a focus on the policy agenda since at least 2000 (the year in which a new national health research funding organization – Canadian Institutes of Health Research (CIHR) – was created with an explicit KT mandate).[23-25] Second, Canada has a well-developed (i.e., extensive, growing, and interconnected) community of guideline developers and implementers nationally and in health systems across the country.[23-24] Third, Canada has many structural and process related commonalities across provincial and territorial governments and health systems but enough variation to examine nuances in policy, political, and health system considerations.[23-24] As well,

given the multiple case study by Ali et al. was conducted in the U.S., the current study allows for the enriched frameworks to be explored in an additional country.[33]

Within Canada we sought candidates from three groups – 1) provincial quality councils; 2) practice improvement groups in provincial health authorities; 3) independent knowledge translation organizations – in Canadian provinces and territories. Similar to the list of developers, the initial list of potential organizations was formulated from a preliminary document analysis and recommendations from experts. All identified candidate groups were sought out for inclusion in this study to ensure maximum variation across Canada. To be selected, the guideline implementer's organization was required to meet at least one of the following two criteria: 1) have guideline use or guideline implementation as part of their mandate (e.g., use evidence sources such as guidance documents to inform their activities); and 2) support guideline implementation initiatives (e.g., an academic detailing program such as an outreach education program for health care professionals) as a result of an overlap with the organization's area of focus or expertise.

The head of each selected guideline-developing and guideline-implementing organization was approached using a personally addressed, standardized recruitment email.

The principal investigator generated an initial list of potential interviewees with 50 individuals being approached for interviews of which 30 came from the WHO regions responsible for guideline development (i.e., five from each of six regions) and 20 came from implementing organizations across Canada. Content saturation (the point at which no new relevant information is derived through further interviews) was used to determine whether to continue or stop recruitment of additional participants.

An email was sent to potential participants that invited them to consider taking part in this study (outlining the time commitment and use of WebEx), provided a brief overview of the study, and a copy of the consent form (which was reviewed later with the principal investigator). Since interviews were to be conducted virtually, written consent posed an additional burden on potential participants (i.e., signing, scanning, etc.) and as such, consent was obtained verbally at the beginning of the interviews and audio recorded. A formal method of tracking was established to track the consent process using a Microsoft Excel spreadsheet. To obtain verbal consent, the principal investigator documented that: 1) the participant had a copy of the consent form; 2) the participant appeared to understand what the study entailed; 3) the participant was given the opportunity to ask questions; 4) the questions were answered to their satisfaction; and 5) the participant provided verbal consent. Records of verbal consent were signed and dated by the person obtaining the consent (i.e., the principal investigator). In instances of no response, the principal investigator followed-up with potential participants at four weeks and again at six weeks.

Data collection

Data collection was the same for the guideline developers and the guideline implementers. The interviews focused on two stages of the implementation process for CPGs: 1) the design of the implementation plan (strategy and logistics); and 2) the execution of the implementation strategy. The interviewees were provided with the relevant enrichment sections from each of the two frameworks to aid in their feedback to the questions. The goal was to have experts share their insights across these stages to better assess and explore how the enriched frameworks aid in capturing the complexities within the policy context.

A semi-structured interview guide was designed (see Appendix 2A), pilot tested, refined, and used to direct each interview. At the planning and logistics stage, questions asked how the enriched frameworks could change how they organize, plan, and anticipate issues (e.g., from target audiences, relevant stakeholders, etc.). At the implementing stage, the interview questions asked how the enriched framework could facilitate or hinder efforts to execute their implementation plans, including whether (and how) they would adjust their products, implementation process, and tools (i.e., how they adapt or support tools for guideline implementation). Interviewees were asked about the particular framework they have experience with (i.e., either KTA or CFIR). In instances where the interviewee had experience with both frameworks, the interviewer (i.e., principal investigator) alternated between frameworks from one interview to the next, to ensure that in the event that time runs out in an interview, there will still be a balanced pool of interviews reflecting both frameworks to analyse.

Interviews were conducted on-line using the Webex planform. All interviews were audio recorded (with permission from participants) and transcribed verbatim. The interviewer created field notes immediately after conducting each interview. The interviews lasted between 30 and 60 minutes.

Data analysis

A codebook for the analysis was developed and refined by two coders (AA and KW) piloting an initial analysis framework using a sub-sample of transcripts. The codebook was initially developed based on a thorough review of the literature, insights gained from the CIS, a priori knowledge, and summary notes compiled from the interviews. The codebook was then refined based on themes identified and through feedback documented by each coder in applying

it. Analysis of the interview transcripts was conducted in NVivo using the finalized codebook. Following that, the final codebook was used by the lead author to code all of the interviews.

Several steps were taken to ensure rigorous qualitative research practices were met including: detailed note-taking during interviews; systematic data coding and analysis; detailed documentations of the decision making process for coding as a means of circumventing speculative conclusions and over-generalizations; the use of direct quotes to highlight participants' perspectives from which study findings and conclusions are based on; a thorough revision of data coding processes; and use of two researchers to decide on resultant themes.[13-15] This approach helped to increase rigor by decreasing any chance of overlooking key thematic ideas, while also ensuring both data collection and interpretation are done in a transparent manner.[14-16] Lastly, member checking was conducted by using key findings from a sample of 3 interviewees who had particularly rich interviews in bullet list form, shared once the data was coded and analyzed. Data were analyzed concurrently with summaries captured in a detailed report.

Results

In total 71 individuals representing 64 organizations were invited to participate, which included 45 developers and 26 implementers. Of these, 37 replied to the email invite and of which 24 agreed to take part in an interview. Overall, 13 guideline developers (participation rate 18%) and 11 guideline implementers participated (participation rate 16%). Non-responders did not reply to the email and as such, their reasons for not participating are unknown. The pool of participants ranged in experience with guideline implementation or development (from a few years to decades), experience with policy (from none to decades), and experience with clinical

practice (from none to decades). Developers interviewed were well-established, had experience with numerous guidelines, and represented all six WHO regions. Implementers interviewed represented all three groups sought after (i.e., provincial quality councils, practice improvement groups in provincial health authorities, and independent knowledge translation organizations), were a mixture of well-established and novice implementers, and consisted of different jurisdictional levels (two national and six different provincial organizations).

The results, including the perspectives on the enrichments to the frameworks overall, how the enrichments could potentially influence planning and logistics activities, and how the enrichments could potentially influence implementation efforts are presented below. Developers and implementers were aligned in reporting the enrichments as useful and in viewing that the components of each framework targeted for enrichments as appropriate. This general sentiment applied to both frameworks, however, a few expressed that the enrichments were more useful with the CFIR framework due to the extensive subconstructs already present. In particular, the enrichments were viewed by some developers and implementers as also helping to better understand how the original subconstructs within each CFIR domain could be used to engage with the policy context more effectively through the connections the enrichments could potentially highlight. Lastly, some developers identified notable regional differences (i.e., political, economic, or social factors) that limited the extent to which they could take advantage of any potential opportunities for insight the enrichments offered. For instance, the original frameworks can capture how some governance arrangements (e.g., regulations on scope of practice) and financial arrangements (e.g., hospital budgets) may impact implementation timelines, while the enriched frameworks can better capture and situate these health systems arrangements within other factors stemming from the policy context. However, the extent to

which the insights from the enrichments are leveraged to aid implementation processes may be limited by the political climate of the region. This was most noticeable within discussions about planning and logistics, and implementation. Some developers shared the limitations government institutions place on selecting priorities or topics to focus on, sharing that there was no opportunity to participate in the decision-making process (e.g., through consultation with policymakers) or room to explore the implementation team's priorities and interests. Table 1 provides an overall summary of interview findings.

Focus on enrichments

Guideline developers and implementers overall found the enrichments to the KTA and CFIR framework helpful and appropriate in situating the policy context within implementation efforts. Their perspectives varied with their level of experience, with more experienced developers and implementers sharing how ad hoc approaches have allowed them to identify policy, political, and health systems considerations prior to these enrichments. Themes identified from the interview process related to the impact and influence of the enrichments are found in Table 2 and Table 3 from guideline developers and implementers, respectively (see appendices 1). Significant variation was not observed across regions.

Planning and logistics

Whether developing or implementing CPGs, careful planning and logistics are needed to ensure that time and resources are used efficiently. Determining how policy, political, and systems factors are integrated into the implementation processes needs to be considered in the planning and logistic stages. For example, should policy leaders be at the table when decisions

are made? How will they be engaged in the implementation process? Significant variations were not observed between developers and implementers, but notable differences to the extent with which the enrichments helped were observed amongst participants with more experience. Some well-established developers and implementers voiced appreciation for the enrichments, particularly, how the policy, political, and systems considerations captured concerns that they were able to identify from years of experience. Their tacit knowledge helped them develop approaches and insights that aided in navigating the policy context which made the enrichments valuable but not profoundly insightful. Implementers on the other hand, represented a mixture of novice and well-established implementers. Novice implementers found the enrichments easy to follow, systematic and comprehensive. Themes identified from the interviews corroborate these findings (see Table 4 and Table 5 in appendices 1).

Implementation

For guideline implementation to have a better chance of success, the dynamic nature of the policy context must be explicitly considered throughout the implementation process. Understanding how policy, political, and health considerations can influence (i.e., hinder or facilitate) guideline development and implementation efforts requires identifying key junctures within implementation processes, situating objectives within appropriate constrains (e.g., provider, systems, etc.), and leveraging appropriate stakeholders to help circumvent potential challenges. Responses from the interview process corroborate these findings (see Table 6 and Table 7 in appendices 1). There were some notable differences in the perceived usefulness of the enrichments, with less experienced developers and implementers appreciating the structure and the unique aspects of the policy context, such as relationships among various stakeholders that

have competing interests with each other and with the implementation aspirations. In addition, the less experienced developers and implementers were more apt to comment on the flexibility of the enrichments such as the adaptability to various levels of analysis.

Refinement of enrichments

Enrichments to the KTA and CFIR framework sought to expand the original frameworks to better engage with the policy context. Direction on how to integrate policy, political, and systems considerations have the potential to allow guideline developers and implementers to better identify individuals, processes, and structures that are often neglected. Findings from the interviews highlight the need for better understanding and engagement with the policy context. In particular, the need for more specific definitions of policy relevant constructs and practical complementary supports. Table 8 summarizes enrichment to the original enrichments and outlines further refinements to the subconstructs. A complementary guiding of questions to aid developers and implementers utilizing the enriched frameworks can be found in Appendix 2B and Appendix 2C.

Further refinements to the enrichments were two-fold. First, broad definitions that captured the focus of each component of the policy context consideration stage were introduced. These definitions reflect the aspects about the components identified within interviews that were unclear to participants about what was deemed a policy-relevant facilitator, barrier, and strategy. Second, 20 additional considerations were identified (see Table 8) from the interviews to help situate and engage with the subconstructs within each component (i.e., policy-relevant facilitator, barrier, and strategy).

Six additional considerations for policy-relevant facilitators were introduced that attempt to better situate how policy legacies can inform current implementation priorities, how policy learning could be leveraged to better tailor implementation plans, and how policy instruments can be better incorporated within implementation plans. Seven additional considerations for policy-relevant barriers were introduced that attempt to further guide users of the enriched frameworks to identify the ways in which policy supports can limit implementation processes, how the risk posed by political resistance from different stakeholders can be better assessed, and how the exclusion of crucial policy networks can be avoided by the implementation team. Lastly, seven additional considerations for policy-relevant strategies were introduced that attempt to highlight how to efficiently identify existing programs and services relevant to the implementation team, how to better identify ways to leverage policy entrepreneurs throughout the implementation process, and how health system arrangements can more effectively be leveraged to support implementation priorities and timelines.

Discussion

Principal findings

The principal findings of this study demonstrate the value of the systematic consideration of policy, political, and health systems considerations with the implementation of evidence-informed recommendations. This value proposition was generally consistent for both developers and implementers regardless of size, experience, or region in which they were based. In addition, the need to further operationalize the concepts, especially with supplementary guiding questions, was a consistent finding regardless of regional variability.

By exploring the views of guideline developers and implementers, the findings of this study contribute to further increasing our understanding of the role the policy context plays within guideline implementation. In particular, it contributes to better understanding the potential benefits and challenges of explicitly considering policy, political, and health system considerations. Our findings document the level of engagement needed with the policy context throughout a given implementation project, from planning and logistics to guideline implementation, to best leverage the resources and expertise available within the policy context and to thereby increase the chances of successful implementation. The analysis of the views of guideline developers and implementers helped in teasing out issues and concerns not easily identifiable, reflecting both regional variability (e.g., political, economic, and social factors) and tacit knowledge (e.g., built up over years of experience). Finally, the refinements to the enriched frameworks highlight the need for further exploration of the identified policy-relevant facilitators, barriers, and strategies to better support guideline implementation.

Strengths and limitations

This study has one key strength related to the methodological approach employed. The use of a formative evaluation design allows for critical exploration of complex implementation projects to identify potential and actual influences.[7] Although this study explored anticipated issues, the use of a formative evaluation design provided the flexibility to find insights other designs may not have been able to capture. In particular, the formative evaluation design was flexible enough to provide insights about how guideline experts viewed the policy context, the different ways the enrichments could be adapted to reflect insights from their tacit knowledge,

and how different guideline experts in different jurisdictions would hypothetically respond to the changes the enriched frameworks propose to guideline implementation.

This study had two challenges. First, the benefits from regional variabilities inherent in the responses must be understood as being limited to the countries and individuals interviewed. Although the perspectives shared may reflect the overarching factors within a given region, this is not a definitive reflection of the regional differences. Second, the level of experience was not evenly distributed, and as such, the findings reflect the knowledge of the pool of participants who agreed to participate.

Implications for policy and practice

The research findings of this study have policy and practical implications for all those seeking to better understand and engage with the policy context. The refinements to the enriched frameworks explicitly capture the tacit knowledge of expert guideline developers and implementers, thereby allowing for better application to various implementation efforts. The supplementary guided questions provide a practical tool to aid users of the KTA and CFIR frameworks that considers the potential for limited expertise with the policy context. Policy, political, and health systems considerations will in turn be better identified, engaged with, and evaluated with a systematic approach that is flexible enough to reflect the user's tacit knowledge but structured enough to ensure high priority contextual factors are not overlooked or minimized. Thus, allowing policy related challenges to guideline recommendations and implementation priorities to be overcome if not avoided altogether. The enriched frameworks will be place online for public access.

Implications for future research

Future research should focus on prospectively evaluating how useful these refinements to the enriched frameworks are across the six WHO regions, for both guideline developers and implementers. The political, economic, and social differences inherently present within these six regions adds a different layer of complexity that could potentially offer more insight into the role of the policy context. In particular, it could help to explore whether and how the enrichments accelerate implementation efforts (e.g., planning, logistics) and/or have any impact on the implementation of evidence-informed recommendations (e.g., facilitate organizational buy-in). Regional differences can also potentially showcase the dynamic nature of the policy context and offer an opportunity for comparative analysis that can help to customize the application of the enriched frameworks to best address specific regional priorities, strengths, and challenges. Insights gained could facilitate policy learning and potentially help to create synergies across levels of government in a given jurisdiction.

References

1. Hayawi, L. M., Graham, I. D., Tugwell, P., & Yousef Abdelrazeq, S. (2018). Screening for osteoporosis: A systematic assessment of the quality and content of clinical practice guidelines, using the AGREE II instrument and the IOM Standards for Trustworthy Guidelines. *PloS one*, *13*(12), e0208251.

2. Gagliardi, A. R., & Alhabib, S. (2015). Trends in guideline implementation: a scoping systematic review. *Implementation Science*, *10*(1), 54.

3. Fischer, F., Lange, K., Klose, K., Greiner, W., & Kraemer, A. (2016, September). Barriers and strategies in guideline implementation—a scoping review. In *Healthcare* (Vol. 4, No. 3, p. 36). Multidisciplinary Digital Publishing Institute.

4. Jacobson, N., Butterill, D., & Goering, P. (2003). Development of a framework for knowledge translation: understanding user context. *Journal of health services research & policy*, *8*(2), 94-99.

5. Damschroder, L. J., Aron, D. C., Keith, R. E., Kirsh, S. R., Alexander, J. A., & Lowery, J. C. (2009). Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. *Implementation science*, *4*(1), 50.

6. Klein, K. J., & Sorra, J. S. (1996). The challenge of innovation implementation. *Academy of management review*, *21*(4), 1055-1080.

7. Meyers, D. C., Durlak, J. A., & Wandersman, A. (2012). The quality implementation framework: a synthesis of critical steps in the implementation process. *American journal of community psychology*, *50*(3-4), 462-480.

8. Stetler, C. B., Legro, M. W., Wallace, C. M., Bowman, C., Guihan, M., Hagedorn, H., ... & Smith, J. L. (2006). The role of formative evaluation in implementation research and the QUERI experience. *Journal of general internal medicine*, *21*(2), S1.

9. Elwy, A. R., Wasan, A. D., Gillman, A. G., Johnston, K. L., Dodds, N., McFarland, C., & Greco, C. M. (2020). Using formative evaluation methods to improve clinical implementation efforts: description and an example. *Psychiatry research*, *283*, 112532.

10. Streiner, D. L., Norman, G. R., & Cairney, J. (2015). *Health measurement scales: a practical guide to their development and use*. Oxford University Press, USA.

11. Jamieson, S. (2004). Likert scales: How to (ab) use them?. *Medical education*, *38*(12), 1217-1218.

12. Knapp, T. R. (1990). Treating ordinal scales as interval scales: an attempt to resolve the controversy. *Nursing research*, *39*(2), 121-123.

13. Kaur, M. (2016). Application of mixed method approach in public health research. *Indian Journal of Community Medicine: Official Publication of Indian Association of Preventive & Social Medicine*, *41*(2), 93.

14. Creswell, J. W., & Zhang, W. (2009). The application of mixed methods designs to trauma research. *Journal of Traumatic Stress: Official Publication of The International Society for Traumatic Stress Studies*, *22*(6), 612-621.

15. Leung, L. (2015). Validity, reliability, and generalizability in qualitative research. *Journal of family medicine and primary care*, *4*(3), 324.

16. Strauss, A., & Corbin, J. (1998). *Basics of qualitative research techniques*. Thousand Oaks, CA: Sage publications.

17. Gopalakrishna, G., Langendam, M. W., Scholten, R. J., Bossuyt, P. M., & Leeflang, M. M. (2013). Guidelines for guideline developers: a systematic review of grading systems for medical tests. *Implementation science*, *8*(1), 78.

18. Sackett, D. L., Rosenberg, W. M., Gray, J. M., Haynes, R. B., & Richardson, W. S. (1996). Evidence based medicine: what it is and what it isn't.

19. Vandvik, P. O., & Brandt, L. (2020). Future of Evidence Ecosystem Series: Evidence ecosystems and learning health systems: why bother?. *Journal of clinical epidemiology*, *123*, 166-170.

20. Graham, I. D., Logan, J., Harrison, M. B., Straus, S. E., Tetroe, J., Caswell, W., & Robinson, N. (2006). Lost in knowledge translation: time for a map?. *Journal of continuing education in the health professions*, *26*(1), 13-24.

21. Field, B., Booth, A., Ilott, I., & Gerrish, K. (2014). Using the Knowledge to Action Framework in practice: a citation analysis and systematic review. *Implementation Science*, *9*(1), 172.

22. Safaeinili, N., Brown-Johnson, C., Shaw, J. G., Mahoney, M., & Winget, M. (2020). CFIR simplified: Pragmatic application of and adaptations to the Consolidated Framework for Implementation Research (CFIR) for evaluation of a patient-centered care transformation within a learning health system. *Learning Health Systems*, *4*(1), e10201.

23. Graham, I. D. (2012). Knowledge synthesis and the canadian institutes of health research. *Systematic Reviews*, *1*(1), 1-2.

24. Tetroe, J. (2007). Knowledge translation at the Canadian Institutes of Health Research: a primer. *Focus Technical Brief*, *18*, 1-8.

25. Government of Canada, C. I. of H. R. (2021, September 22). *About Us*. CIHR. Retrieved November 13, 2022, from https://cihr-irsc.gc.ca/e/37792.html

26. Lavis J. N. Health systems evidence: Taxonomy of governance, financial and delivery arrangements and implementation strategies within health systems. Hamilton, Canada: McMaster Health Forum, 2017. https://www.mcmasterforum.org/docs/default-source/resources/16_hse_taxonomy.pdf?sfvrsn=6

27. Bauer, M. S., Damschroder, L., Hagedorn, H., Smith, J., & Kilbourne, A. M. (2015). An introduction to implementation science for the non-specialist. *BMC psychology*, *3*(1), 32.

28. Bauer, M. S., & Kirchner, J. (2019). Implementation science: What is it and why should I care?. *Psychiatry research*.

29. Conroy, M., & Shannon, W. (1995). Clinical guidelines: Their implementation in general practice. *The British Journal of General Practice*, *45*(396), 371-375.

30. Grimshaw, J., & Russell, I. T. (1993). Effect of clinical guidelines on medical practice: A systematic review of rigorous evaluations. *The Lancet*, *342*(8883), 1317-1322.

31. Pauly, M. V. (1995). Practice guidelines: Can they save money? Should they? *Journal of Law, Medicine & Ethics*, *23*(1), 65-74.

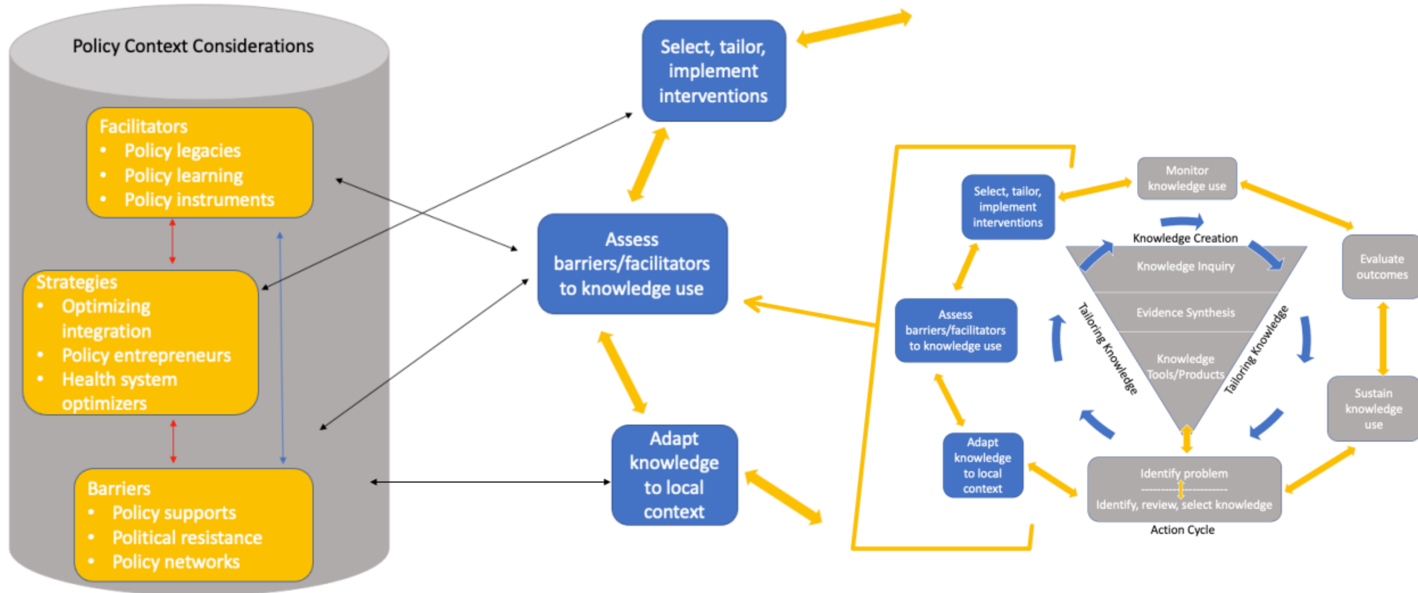
32. Ali, A., Lavis, J.N., Brouwers, M.C., Wilson M.G., & Alvarez, E. (2022). *Using a policy lens to focus supports for clinical practice guideline implementation: A critical interpretive synthesis*. [Manuscript in preparation].

33. Ali, A., Lavis, J.N., Brouwers, M.C., & Wilson, M.G. (2022). *Multiple explanatory case study of guideline implementation processes: Comparing existing explanatory frameworks with a policy-, political- and systems-enriched framework*. [Manuscript in preparation].

34. Becker, T., Kilian, R., & Koesters, M. (2017). Policies, guideline implementation and practice change–how can the process be understood?. *Epidemiology and Psychiatric Sciences*, *26*(2), 115-118.

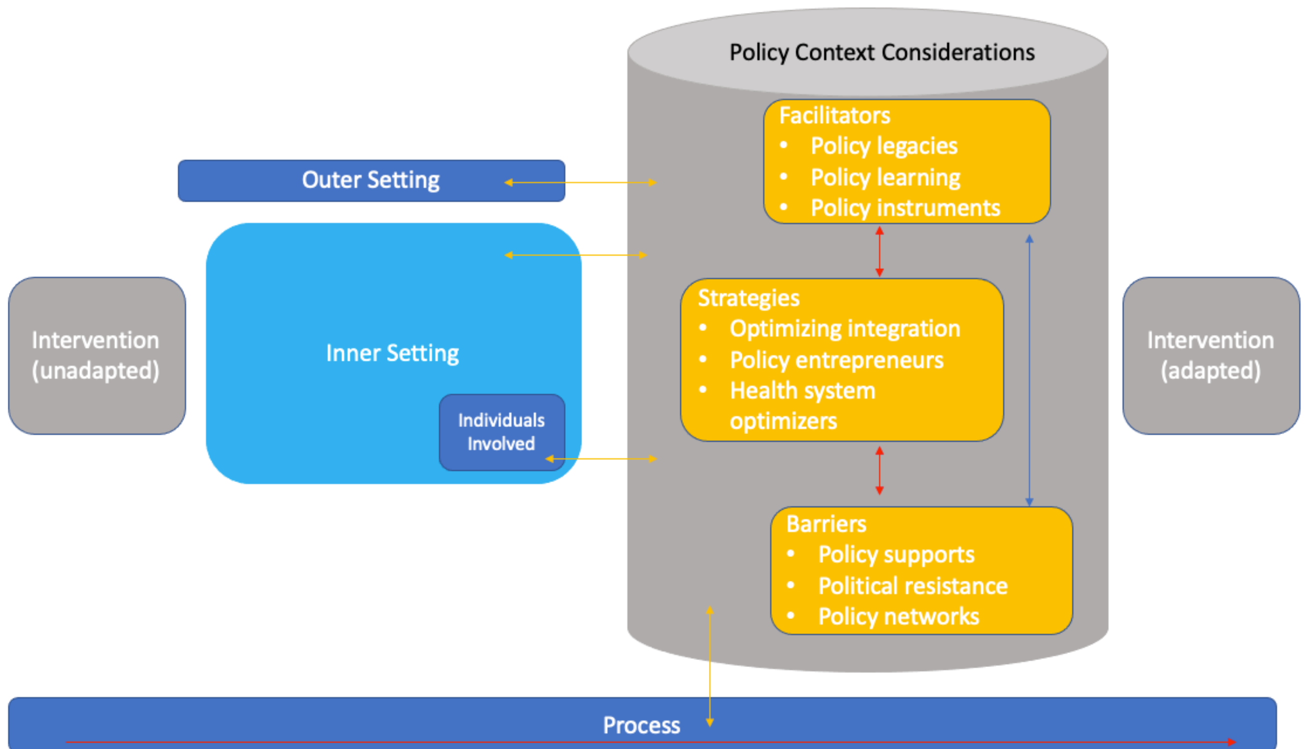
35. Ploeg, J., Davies, B., Edwards, N., Gifford, W., & Miller, P. E. (2007). Factors influencing best-practice guideline implementation: lessons learned from administrators, nursing staff, and project leaders. *Worldviews on Evidence-Based Nursing*, *4*(4), 210-219.

Figure 1 - Enrichments to Knowledge-to-Action Framework



Note: Adapted from Graham et al.[20]

Figure 2 - Enrichments to the Consolidated Framework for Implementation Research



Note: Adapted from Damschroder et al.[5]

Table 1: Summary of interview findings

Area of focus	Findings
Existing experience using KTA	• Many interviewees noted the ease with which the stages help them navigate the issues they needed to consider but allowed the flexibility to dictate the scope to their implementation demands. • Some interviewees voiced their appreciation with the ease with which the KTA allowed other frameworks to be used in conjunction with KTA.
Existing experience using CFIR	• Some interviewees found the extensive subconstructs helpful in giving more depth and room to further explore how their unique situations could be understood using CFIR. • Some interviews found the separation between the outer and inner setting helpful in understanding and engaging with the policy context.
Focus on enrichments	• All interviewees remarked that the enrichments were helpful and appropriate. • All interviewees described the need for a more practical supplementary tool, either in the form of guiding questions, checklists, or both. • The examples for how the enrichments could be operationalized were found very helpful in understanding the concepts and objectives of the enrichments.
Planning and logistics	• There is great interest in understanding policy, political, and systems considerations (both conceptually and practically). • Those without experience explicitly stated an eagerness to use the enriched frameworks. • Interviewees with extensive experience developing and implementing CPGs noted the relevance of the enrichments, but shared that their tacit knowledge has allowed ad hoc solutions/approaches that capture many of the same insights as the enrichments. • The 'policy considerations' enrichment was not understood by many interviewees. • The 'political considerations' enrichment was misunderstood by some interviewees; many did not consider political issues beyond government structures and actors.

	• There was high agreement among interviewees on the relevance and need for the health systems considerations.
Implementation	• Interviewees with the most extensive experience reported the enriched frameworks would not significantly change the products they produced or their choice of implementation methods but reported that the enrichments could be needed by others within their organization. • Several interviewees reported that these enrichments would help them be informed about the policy context in a more comprehensive fashion. • All interviewees reported that the enrichments would help build a common nomenclature, language, and definitions that could be used by developers, implementers and other stakeholders throughout a given implementation effort. • Some interviewees drew distinct lines between how the enrichments would aid their organizations and how the enrichments would aid in interacting with others (with the benefits of the latter being more evident).

Table 8: Refinement to policy context considerations

Original Framework	Policy context considerations	Draft of enriched framework	Final framework (with changes – definition and additional considerations – bolded)

Stages of the original KTA framework being addressed:
 	
Adapt knowledge to local context:
• This stage pertains to the process by which individuals or groups make decisions about the value, usefulness, and appropriateness of specific knowledge as it relates to their setting or circumstance.
• It includes any activities that these individuals or groups engage in to tailor the knowledge to the local context.
 	
Assess barriers/facilitators to knowledge use:
• This stage involves assessing the potential facilitators and barriers to the uptake of knowledge.
	Facilitators	*Original enrichment:*
		• Assessing the extent to which the activities underway relate to **usability**, **adaptability, and the role of organizations** in supporting implementation efforts (i.e., logistical, governance, etc.).
		
		Situate current implementation efforts using:
		• Past legacies:
		  ○ Considering what past policies, initiatives, and laws are relevant to current implementation efforts.
		• Policy learning:
		  ○ Evaluating how similar implementation efforts within and across
			Further refinement to enrichments:
			Goal:
			• To assess the extent to which the activities underway relate to usability, adaptability, and the role of organizations in supporting implementation efforts (i.e., logistical, governance, etc.).
			
			Definition:
			• Policy context-relevant facilitators are any policies, political processes or politics-involved stakeholders, and system arrangements that can explicitly or implicitly facilitate implementation efforts at any point within the implementation process.
			
			Specific considerations for implementation efforts:
			• Past legacies:
			  ○ Considering what past policies, initiatives, and laws are relevant to current implementation efforts.
			• Policy learning:
			  ○ Evaluating how similar implementation efforts within and across different jurisdictions were conducted and their level of success.
			• Policy instruments
			  ○ Assessing what regulations, mandates, or policy tools currently exist that can be leveraged to aid implementation efforts.
			
			Additional considerations:

<table>
<tr>
<td rowspan="2">It includes assessing the knowledge itself, those will be using the knowledge (i.e., adopters), and the context where this knowledge is to be used.
Select, tailor, implement interventions:
This stage pertains to the planning and executing interventions that have been identified to facilitate the intended changes.
This involves selecting and customizing interventions to better address the identified audiences and barriers.
<u>Stages of the original CFIR framework being addressed:</u>

Outer setting:
This domain pertains to the economic, political, and social context within which organizations are situated.</td>
<td></td>
<td><li style="list-style:none">
<li style="list-style:none">different jurisdictions were conducted and their level of success.
Policy instruments
Assessing what regulations, mandates, or policy tools currently exist that can be leveraged to aid implementation efforts.</td>
<td>Identify policies, options, and implementation considerations (both past and present) relevant to current implementation efforts.
Consider how and to what extent politics-involved stakeholders' views and experiences have been prioritized.
Identify what institutions may be able to help the implementation team and which stakeholders may have a vested interest in the policy instruments used.
Explore how other jurisdictions foster collaboration by identifying how these jurisdictions capture the nature of the problem (e.g., how the problem is framed to highlight how different groups can play a role).
Audit what governance (i.e., leadership supports), financial (i.e., aligned budgets), and delivery arrangements (i.e., commitments to integration of services) are in place to support or hinder implementation efforts.
Explore how different policy instruments map onto health system arrangements relevant to implementation efforts, such as how funding mechanisms to pay for services from health care organizations (e.g., hospitals) differs from the mechanisms used to pay for services from individual providers within a health system.</td>
</tr>
<tr>
<td>Barriers</td>
<td><u>Original enrichment:</u>
Assessing the extent to which the activities underway relate to the role support plays in implementation efforts, the role stakeholder engagement plays, and how resource scarcity</td>
<td><u>Further refinement to enrichments</u>:
Goal:
To assess the extent to which the activities underway relate to the role support plays in implementation efforts, the role stakeholder engagement plays, and how resource scarcity impacts implementation efforts at a given stage/domain.
Definition:</td>
</tr>
</table>

• It is operationalized within four subconstructs: 1. Patient needs and resources 2. Cosmopolitanism 3. Peer pressure 4. External policies and incentives Inner setting: • This domain pertains to the political, cultural, and structural features of the context within which implementation processes unfold. • It is operationalized within five subconstructs: 1. Structural characteristics 2. Networks and communications 3. Culture 4. Implementation climate 5. Readiness for implementation Process domain: • This domain pertains to essential activities of		impacts implementation efforts at a given stage/domain. Situate current implementation efforts using: • Policy supports: ○ Recognizing limited organizational policy support such as a lack of policies to foster trust (i.e., options to contribute to the decision-making process) within implementation hierarchy (e.g., opportunity to join a steering committee). • Political resistance: ○ Assessing the level of threat any active resistance from interest groups (e.g., professional associations) poses to	• Policy context-relevant barriers are any policies, political processes and politics-involved stakeholders, and system arrangements that can explicitly or implicitly hinder implementation efforts at any point within the implementation process. Specific considerations for implementation efforts: • Policy supports: ○ Recognizing limited organizational policy support such as a lack of policies to foster trust (i.e., options to contribute to the decision-making process) within implementation hierarchy (e.g., opportunity to join a steering committee). • Political resistance: ○ Assessing the level of threat any active resistance from interest groups (e.g., professional associations) poses to implementation efforts. • Policy networks: ○ Identifying the ways in which the exclusion of policy networks, such as having a lack of adequate patient/stakeholder involvement (i.e., provider-targeted strategies), can hinder implementation efforts. **Additional considerations:** • Identify barriers to using existing policy supports by highlighting the ways in which available options and implementation considerations are limited in their application for a given implementation effort.

the implementation process. • It is operationalized within four subconstructs: 1. Planning 2. Engaging 3. Executing 4. Evaluating Characteristics of individuals (i.e., individuals involved): • This domain pertains to the individuals involved within the intervention and/or the implementation process. • It is operationalized within five subconstructs: 1. Knowledge and beliefs about the intervention 2. Self-efficacy 3. Individual stage of change 4. Individual identification with organization 5. Other personal attributes		implementation efforts. • Policy networks: o Identifying the ways in which the exclusion of policy networks, such as having a lack of adequate patient/stakeholder involvement (i.e., provider-targeted strategies), can hinder implementation efforts.	• Assess if the lack of organizational policies can be circumvented with existing external policies, options, and/or implementation considerations. • Consider how the benefits of potential options may be unclear to those who will be affected (i.e., citizens/patients, providers, organizations, or system). • Assess how jurisdictional (i.e., institutional arrangements) and professional autonomy conflicts (i.e., set by past policies) may impact implementation efforts. • Audit administrative capacities that can potentially be used to support implementation efforts. • Identify available implementation strategies (e.g., provider targeted strategies such as educational outreach visits) that can be leveraged by the implementation team. • Identify system level components that influence organizational culture, such as the supports used to aid those providing and receiving care (e.g., electronic health records, safety monitoring systems, etc.).
	Strategies	<u>*Original enrichment:*</u> Assessing the extent to which the activities underway relate to the **streamlining of logistical considerations, restructuring of infrastructure, and adequate funding** throughout the implementation process can aid the stage/domain. Situate current implementation efforts using:	<u>*Further refinement to enrichments*</u>*:* Goal: • To assess the extent to which the activities underway relate to the streamlining of logistical considerations, restructuring of infrastructure, and adequate funding throughout the implementation process can aid the stage/domain. **Definitions:** • Policy context-relevant strategies are any set of actions, plans, tactics, thoughts, or behaviors which might be useful to organize and/or guide decisions to achieve desired implementation outcomes.

		• Optimizing integration through policy
		  ○ Identifying existing programs or services that can aid in devising clear integration strategies for organizational structures/processes.
		• Partnerships with policy entrepreneurs
		  ○ Leveraging individuals who can exploit opportunities to influence policy outcomes as means of promoting and facilitating implementation.
		• Health system optimizers
		  ○ Identifying ways to better tailor policy instruments (i.e., legal, voluntary, education, etc.)
			Specific considerations for implementation efforts:
			• Optimizing integration through policy
			  ○ Identifying existing programs or services that can aid in devising clear integration strategies for organizational structures/processes.
			• Partnerships with policy entrepreneurs
			  ○ Leveraging individuals who can exploit opportunities to influence policy outcomes as means of promoting and facilitating implementation.
			• Health system optimizers
			  ○ Identifying ways to better tailor policy instruments (i.e., legal, voluntary, education, etc.) to support implementation efforts.
			
			Additional considerations:
			• Explore the ways in which available policies, options and implementation considerations can be incorporated into implementation strategies.
			• Consider the different ways to potentially use elite opinions (i.e., opinion leaders) and policy entrepreneurs to:
			  ○ Advise on tailoring of implementation.
			  ○ Influence peers as champions.
			  ○ Assist with implementation.
			• Examine how ideas that contribute to being susceptible to misinformation, such as beliefs about the sources of evidence, allowing the implementation team to better formulate strategies that are more proactive and targeted at specific stages within the implementation process.
			• Explore how governance arrangements can be leveraged to support implementation strategies such as

		to support implementation efforts.	overcoming issues stemming from professional authority (e.g., liability protection). • Assess how investments in financial and delivery arrangements can be leveraged to support implementation efforts. • Identify ways standardizing implementation approaches and strategies across organizations (i.e., provider- and organization-targeted strategies) can influence (i.e., hinder or facilitate) implementation efforts. • Explore how the organization of health human resources can impact the implementation priorities being sought, such as how strategies focused on task shifting (i.e., the transferring of responsibility for delivering a particular service from one health care professional to another) can influence (i.e., facilitate or hinder) the implementation process.

Appendix

Appendices 1

Table 2: Themes identified regarding the enrichments from guideline developers

Theme	Elaboration	Excerpts (verbatim) to interview questions
Major themes		
• **Flexibility to capture dynamic nature of the policy context**	Many voiced how the enrichments could aid in capturing the various competing priorities, processes, and demands that arise within implementation efforts.	*" So I think that by considering the ability to balance the sort of the general recommendations we were making with the local context, identifying barriers and facilitators, and also the the, the strategic context, particularly resource utilisation, I think are important considerations" – P5*
• **Need to be cognizant of overarching contextual factors**	The enrichments were seen as providing more sensitivity and awareness to the higher-level factors at the meso- or macro-level that are not inherently obvious.	*"I would like to play a spatial emphasise, culture, economic and social influences, which are also, you know, somewhat related to the questions to you listed here. Because whatever facilitators, stretch ages and barriers, you know, they are also very close to culture, and economic and social influence. And different countries, you know, have different contexts." – P22*
Minor theme		
Organizational buy-in (changing culture)	The enrichments were seen as not only a way to navigate the policy context, but as a tool to foster buy-in within organizations through the consistent framing, flexibility, and common language the enrichments provide.	*"It's concise, and it's a good pathway for you know, anyone to have a look up the stages or what's next. And it facilitates buy-in from each different level."- P19*

Table 3: Themes identified regarding the enrichments from expert Canadian guideline implementers

Theme	Elaboration	Excerpts (verbatim) to interview questions
Major themes		
• **Need for specificity regarding the policy context**	In explicitly exploring policy, political, and systems considerations, the enrichments were seen as providing a path to engage with the policy context in a more comprehensive manner.	*"Like we don't have obviously we haven't like named these considerations as explicitly as you've done here, in terms of the framework, but I would say like just the structure and more of the practical ways that we operate are very much in line." – P12*
• **Broadening perspective beyond health systems**	The enrichments were seen as very useful in highlighting the interconnectedness of the policy context (i.e., the various institutions, actors, and processes).	*"So I'm not sure I can really comment on the, like thinking from a policy side or thinking from a political side, because I don't have that much experience. But I think from a health system side, I think this is very helpful. And I actually think that, as I'm sure you notice, like pretty big silos between policy, political and health system. And we all just kind of deal with, with what comes from those and complaining about it and make it work. But I think this is a great way of kind of bringing some of those pieces together and thinking through outside of the health system, again, I'm taking that lens of coming from the health system, outside of the health system, what are the other things that come into play? And how do those influence them? And what are, you know, I specifically like the facilitators and barriers piece on the policy side, because I think that's a huge piece of thing, piece of work within the health system that's often not really understood and therefore not factored in, but puts a huge pressure on work that's done with within the health system. So this is very helpful. I think it'll kind of help. Even you know, bring that forward in someone's mind when they're thinking through something."- P6*
Minor theme		
Need to understand the limitations of implementation efforts	The enrichments were viewed by some as a useful evaluation tool for evaluating and addressing gaps within their implementation efforts.	*"From an evaluation standpoint, I could offer because I think we often don't have like, for me, it's important for planning, but it's also important for understanding where an intervention or an attempt to implement guidelines might be falling down. And I want to know that in advance but as you do the initiative, and that's how our organisation operates as, we kind of use rapid cycles of tests of change*

		and how things getting implemented, you want formative evaluation going on. And this framework might offer some way to situate and identify areas where an initiative may or may not have been successful." – P2

Table 4: Themes identified regarding planning and logistics from guideline developers across the six WHO regions

Theme	Elaboration	Excerpts (verbatim) to interview questions
Major themes		
• **Balancing competing perspectives, priorities, and sources of knowledge (i.e., trade-offs)**	The enrichments were seen as identifying facilitators, barriers, and strategies in a way that makes salient connections (i.e., relationships, obligations, and/or priorities) not only more visible, but highlighting how implementation efforts need to translate these findings to actions that go beyond clinical effectiveness.	*"So, yeah, so going back to I think it's about what, so, who you engage with, at what stage and the sort of specific questions you're asking because we, I think, to really make this work, we need to get an understanding of the so what's the what's the trade off between having guidelines that reflect the best evidence that we would use traditionally in guideline development from a, you know, a sort of a purist? Do you do you your view questions, you'd look at the literature, at cetera, cetera. And that would give you a level and it's the degree to which a degree sorry, give you recommendations as a sort of a high level But it's then how do you translate it's that translation piece into making that come to life for a local context. So, to me, it's all about that, for that part of it. It's about the it's the adaptability. And the there's a trade, there's a trade off there, isn't there, because if you make if you make your recommendations too generic, it doesn't, it doesn't achieve anything, but you can't make them so specific for every every context. So I think part of this will be to allow or facilitate guideline recommendations to be adapted to some, you know, to an extent within a local context, and what we mean by local as well will vary." - P5*
• **Need to match implementation efforts to system constraints**	Many viewed the explicit attention to policy, political, and systems considerations within the enrichments, as a useful approach to track systems constraints and better anticipate barriers within implementation efforts.	*"Like, whenever we say that we have to implement this thing, so we need to mention that who will be providing the budget? Because ultimately, ultimately, everything will boil down to one point … that is budget." – P21*
Minor theme		
Managing expectations	The enrichments were seen as providing a more comprehensive approach to identifying	*"So, implementation of the guidelines is a bit political especially depends on the environment, sometimes people at high senior level consultant and needs they might oppose the guidelines. So you*

	incentives, conflicts of interest, and priorities amongst actors related to the policy context, allowing a means to better manage expectations of all stakeholders involved with implementation efforts.	*have to do to be able to communicate or to engage them in the process. So they can be an champion for drug development for the implementation rather than opponents." P3*

Table 5: Themes identified regarding planning and logistics from expert Canadian guideline implementers

Theme	Elaboration	Excerpts (verbatim) to interview questions
Major themes		
• **Need for a systematic approach**	The enrichments were seen as providing an approach that more comprehensively captured a diverse set of factors that do not easily allow implementation efforts to identify and engage with.	*"So like any topic that we're considering, undertaking, like we have a process where we reach out to the key decision makers related to whatever the technology or topic or issue is that we're addressing and a system for trying to feed back that information to give us a sense of like, what what if we were to do work on this? Like, what is the ... What does the landscape look like? What's important to decision makers? What's the political context? And what's the? Like, what's the timing? So if we were to find something, like if if we were to have like a recommendation that says we should be funding this, like, what are the chances that that would be well received, or like, like trying to make a judgement of like, the potential impact of our work in advance before we commit to doing it… So yeah, sorry, I really like I like the structure [of the enriched framework]." – P12*
• **Balancing competing perspectives, priorities, and sources of knowledge (i.e., trade-offs)**	The enrichments were viewed as offering a more meaningful way to identify, engage with, and incorporate various stakeholders whom implementers deem most important.	*"Yeah, I think it would, I mean, we use the KTA framework in, in kind of setting the prophecies for which we develop our, like clinical tools that our organisations developed, and also the way that we develop our services. And so I think this [enriched framework] would definitely influence both of those in that, like your first example of, of the development group, not that we develop guidelines, but in all the work that we do have, you know, for every topic that we address, whether we're addressing that through our services, or through our tools, we have clinical working groups and advisory committees that we convene, that include health care workers and health system representatives to inform that work. And I think if we were taking this lens, and adding this, looking at the policy context, considerations cylinder or whatever you call that, I think that a huge piece of that would would be having those people around the table. And I think, I think as we, as we do our work more and more, we're thinking about all the ways that those working groups and*

		advisory committees need to be expanded to include more voices. And I think, I think this [enriched framework] would really look, if we were taking this and implementing it would definitely inform who would be around those tables."- P6
Minor theme		
Need to be cognizant of the policy agenda	The enrichments were viewed as better situating the policy context (e.g., capturing the various policy agenda items) for implementers, bringing more stability in an otherwise dynamic context.	*"I think just from what you've shared with me, and I may be sure to earlier is just that appreciation of the role of policy. Because again, it's not explicit, it's not top of mind for me. I tend to go to who's going to use this evidence? Who's going to who's going to need to support this, this effort? Like I would have never guessed, beyond health professional organisations, the early example I gave you are large scale change initiative, I wouldn't really have guessed that the Ministry of Health would have had a role to play in ensuring that guidelines were implemented because my thought didn't go to barriers of fee schedules. Because I'm like, you know, doctors want to do the right things. They want the best outcomes for the patients, you know, yes, I understood conceptually that we needed to improve access to get people in there. But you know, and get them computers and be able to track and all that kind of stuff. But the idea that, wow, the biggest barrier here might be that we have a 10 minute appointment. And we're asking people to talk and implement guidelines, that's going to take them longer than a 10 minute appointment. So you know, that we arrived there, but having this in advance might have been helpful to kind of think that through." – P2*

Table 6: Themes identified regarding implementation activities from guideline developers across the six WHO regions

Theme	Elaboration	Excerpts (verbatim) to interview questions
Major themes		
• **Giving a common language and/or process**	The enrichments were seen as providing a common language for developers to plan, collaborate, and execute CPG development activities in an efficient manner.	*"Again, it [enriched framework] provides a model of of showing how we've arrived at what you've arrived at. So, again, it gives transparency of purpose, transparency of, of process." – P5*
• **Flexibility to aid varying levels of tacit knowledge**	Developers found the enrichments helpful regardless of the level of experience with CPG development. Seasoned developers appreciated the connections being captured, while those with less experience found the structure helpful in navigating the policy context.	*"Yes, and I think what this can do, again, as appropriate amplification is help help the young and naive person who wants to change the world help them understand different people come at this problem with different viewpoints, and different jobs that they absolutely have to do. And as much as I much as I screaming at the hospital executives, the truth is they do have a job to do and that job is to see to it that the money flows well enough. So I mean, because if you have to shut down the hospital, nobody's getting treated. So they've got they've got to take care of that business." – P16*
Minor theme		
Difficulty identifying and engaging with policy relevant stakeholders	Policy, political, and systems considerations were seen as providing a perspective that better captured various stakeholders within the policy context that CPG developers may have overlooked or minimized.	*"Yeah, we have different stakeholders and guideline development, either those who are users or this the insurance companies or we have the students, medical students, we have the patient themselves anyone who benefit or can be affected by the guidelines. So yeah, that this will help me to, to choose all to focus on whom to to add more focus and what was what will be the best approach because it's also having the whole component together can help also to assist the whole situation and to sit the structure of the process for guideline implementation." – P3*

Table 7: Themes identified regarding implementation activities from Canadian guideline implementers

Theme	Elaboration	Excerpts (verbatim) to interview questions
Major theme		
• **Lack of robustness**	The enrichments were viewed as providing the structure, conceptual underpinning, and prevalent perspective of the policy context in a manner that implementers could understand and appropriately apply.	*"So sometimes, you know, we've done like a report on a new technology for a very specific population. And we have some recommendations, we think they're like, okay, like, let's do something with this, it's important work. But the reality is, like, that's just such a tiny piece of the puzzle for someone who works like in that area, like maybe they're trying, like, we are talking about Internet delivered cognitive behavioural therapy for anxiety. And they're talking about how do we improve access to mental health for Canadians? You know, and so like, it's great that your project address this tiny little piece. And it's great to know that that is a clinically cost-effective intervention. But like, what does that mean in the grand scheme? And so it also like, yeah, I feel like this kind of forces us to like, situate us situated in the bigger picture. And then also just recognise, like, our evidence is important, but it is. It's just one of the pieces. I think we struggle with that we love to say like, this is, like our report was so important. And it led to this policy change and this policy change. And it's really difficult to say like, that was a result of [our] evidence, like it's a result of the political context, the timing, the like, advocacy from a number of different groups that work in that space, and then decisions that have nothing to do with what the evidence is." – P12*
• **Difficulty identifying and engaging with policy relevant stakeholders**	Political considerations within the enrichments were seen as helpful in identifying the incentives and conflicts of interests that implementers struggled to manage throughout the implementation process (i.e., planning, executing, evaluating).	*"Yeah, I guess, the main thing would be expanding the audience for dissemination. Because again, right now, our dissemination of our products and services very much focused within health care and primary care. And so if we're building the perspective, the policy perspective into our products, and implementation services, would also want to include those folks on the credit dissemination side to make them aware. So I guess we're just really broadening our dissemination plan." – P6*
Minor theme		

Need to understand the influence (i.e., facilitate or hinder) of jurisdictional variability	The enrichments were seen as providing a comprehensive approach to not only be aware of the various policy, political, and systems considerations relevant to implementers, but understand how and to what extent they interact to amplify each other relative to the priorities of CPG implementers.	*"But having an absence of understanding of variabilities within the province, is a very challenging and potential barrier, I think, to effective policymaking because you could look at potential trends and see, okay, the provinces doing better or worse, and then you say, I need to act on this because it's getting worse or I don't compare very well. But within the province, and at a more local level, find very different realities that you might make decisions that have influenced in various ways in the absence of that understanding. So, where variabilities are very important to understand and that's something that we find sometimes gets missing in the political context, when we try to understand." – P15*

Appendices 2

Appendix 2A: Interview questions

Demographics

Age:

Guideline experience:
___ Developer ___ Implementer

How many years have you practiced clinically (if applicable)? ____________

How many years of experience do you have as a policymaker (if applicable)? ____________

Knowledge-to-Action (KTA) Framework

Focus on enrichments

Placeholder for the description of enrichments

1. Tell me what are your overall thoughts are on the enrichments made to the KTA framework?
2. What are your impressions of the enrichments for policy considerations?
3. What are your impressions of the enrichments for political considerations?
4. What are your impressions of the enrichments for health systems considerations?
5. What (if any) are areas or factors that you feel were overlooked in enriching this framework?

Planning and logistics for implementation

Placeholder for description of enrichments pertaining to planning and logistics

1. How do you see the enriched frameworks changing how you organize and plan?
    - Structure of guideline development group, budget, secure funding, etc.
2. How do you see the enriched frameworks changing how you set, manage, and assess priorities?
    - Topic selection, proposal priorities, stakeholder engagement, etc.
3. How do you see the enriched frameworks changing how you communicate, collaborate, and interact with other guideline developers/implementers?
4. How do you see the enriched frameworks changing how you select topics and target audiences? [Developers]

5. How do you see the enriched frameworks changing how you approach different target audiences and issues? [Implementers]
6. How do you see the enriched frameworks changing how you incorporate relevant stakeholders? [Implementers]

Implementing

***Placeholder for description of enrichments pertaining to implementation**

1. How do you see the enriched frameworks changing how you adjust your product?
2. How do you see the enriched frameworks changing how you adjust your implementation process?
3. How do you see the enriched frameworks changing how you create and execute a dissemination plan for guideline adoption?
4. How do you see the enriched frameworks changing how you develop, adapt, or support tools for guideline implementation?

Consolidated Framework for Implementation Research (CFIR):

Focus on enrichments

***Placeholder for the description of enrichments**

1. Tell me what are your overall thoughts are on the enrichments made to the CFIR framework?
2. What are your impressions of the enrichments for policy considerations?
3. What are your impressions of the enrichments for political considerations?
4. What are your impressions of the enrichments for health systems considerations?
5. What (if any) are areas or factors that you feel were overlooked in enriching this framework?

Planning and logistics for implementation

***Placeholder for description of enrichments pertaining to planning and logistics**

7. How do you see the enriched frameworks changing how you organize and plan?
    - Structure of guideline development group, budget, secure funding, etc.
8. How do you see the enriched frameworks changing how you set, manage, and assess priorities?
    - Topic selection, proposal priorities, stakeholder engagement, etc.
9. How do you see the enriched frameworks changing how you communicate, collaborate, and interact with other guideline developers/implementers?
10. How do you see the enriched frameworks changing how you select topics and target audiences? [Developers]
11. How do you see the enriched frameworks changing how you approach different target audiences and issues? [Implementers]

12. How do you see the enriched frameworks changing how you incorporate relevant stakeholders? [Implementers]

Implementing

Placeholder for description of enrichments pertaining to implementation

1. How do you see the enriched frameworks changing how you adjust your product?
2. How do you see the enriched frameworks changing how you adjust your implementation process?
3. How do you see the enriched frameworks changing how you create and execute a dissemination plan for guideline adoption?
4. How do you see the enriched frameworks changing how you develop, adapt, or support tools for guideline implementation?

Closing question for implementers:

Who else do you think of as Canadian implementers who I may want to speak to?

Appendix 2B: Guiding questions to help operationalize the refinements to the policy context considerations within KTA stages

Stage	Guiding questions
Adapt knowledge to local context	• Have you considered creating a review process that leverages local policy actors and networks to provide feedback related implementation recommendations and related activities? o What local policy actors or networks exist? • Have you considered expanding the implementation team by adding local/national policymakers, policy analysts, or other policy relevant actors? • Have you considered hiring policy consultants to assess policies, initiatives, and regulations at the local context, that may influence (i.e., hinder or facilitate) implementation efforts? • Have you conducted a scan of local policies (i.e., a jurisdictional scan) to ensure implementation efforts are aligned with relevant past efforts (i.e., past policies, initiatives)? • Have you considered using policy learning to support/leverage the success of implementation efforts? • What training can your implementation team provide to policy relevant stakeholders to address gaps in knowledge pertaining to implementation concepts and activities?

Assess barriers/facilitators to knowledge use	• What governance (i.e., leadership supports), financial (i.e., align budgets to objectives), and delivery arrangements are in place to support and guide diffusion of implementation efforts?
	• What governance supports (e.g., clear mandates) exist that can influence (i.e., facilitate or hinder) inter-organizational collaboration and policy networks engagement with implementation efforts?
	• Have you consulted with professional organizations involved in CPG implementation efforts to appropriately assess professional autonomy and jurisdictional conflicts that may impact implementation efforts?
	• What potential shortcomings in organizational infrastructure can you identify within participating organizations as they pertain to:
	    ○ Administrative capacities to support implementation efforts?
	    ○ Infrastructure to support, compensate, and train all policy relevant stakeholders?
	    ○ Information/communication technology training and support?

Select, tailor, implement interventions	• What continuing education support programs exist to support policymakers involved in CPG implementation? • Have you considered consulting with policy relevant stakeholders to devise clear integration strategies for organizational structures/processes? • In what ways can you better tailor implementation efforts to existing policy instruments (i.e., legal, voluntary, education, etc.)? • Have you considered expanding recommendations to include a section for policymakers? • Have you considered outlining identified opportunities to invest significantly in financial and delivery arrangements that support implementation efforts?

Appendix 2C: Guiding questions to help operationalize the refinements to the policy context considerations within CFIR domains

Stage	Guiding questions
Outer setting	• Have you reviewed how similar guideline recommendations were implemented in different jurisdictions? • Have you considered creating a macro-level report (i.e., provincial or state-level) on the level of implementation success achieved on this issue? • Have you sought out local authorities to provide feedback on implementation plans and policy relevant recommendations? • Have you conducted an audit of the organizational infrastructure of relevant organizations to ensure sustainability, ease of access, and that organizational and user strengths are being matched to policy priorities?

Inner setting	• Have you considered having policy relevant stakeholders provide feedback on the implementability of proposed recommendations?
	• Have you considered using recommendations and guideline formats that appeal to policy relevant stakeholders?
	• Are you using contextualized materials (i.e., procedures and protocols) and tailored implementation training to explicitly target relevant policy networks and users?
	• Have you considered adding policy relevant stakeholders (i.e., policymakers and policy analysts) to the implementation team?
	    • Have you considered how this might aid in defining target end user populations and mitigating conflict of interest to help facilitate CPG implementation?
	    • Have you considered how this might help in raising awareness about the facets of the implementation effort, the CPG involved, or relevant supports (i.e., tools, protocols, etc.)?
	• Have you outlined anticipated time and resource constraints within your CPG recommendations?
	• Has your implementation team considered offering training to aid policy relevant stakeholders in understanding implementation processes, concepts, and priorities?

Characteristics of individuals	• Have you considered creating a section within CPG recommendations specifically for policymakers to frame implementation benefits in a manner that aligns with the outcomes important for local policy initiatives and policies?

	• Have you considered consulting with policy analysts to identify best practices for managing contradictory or complex evidence for policy relevant stakeholders? • Has the implementation team identified and consulted with relevant organizations that can hinder CPG implementation? ◦ Have you explored how these organizations can actively resist actions and processes that threaten professional autonomy (e.g., scope of practice) and create conflict of interest, or involve cross-jurisdictional supports?

Process	• Have you considered using structured guideline implementation programs with clear objectives, priorities, and methods throughout the implementation process specifically for policy audiences (i.e., policy relevant stakeholders)?
	• How can your implementation team build new recommendation actions onto existing policy efforts?
	• Do you have policy relevant stakeholders helping to steer implementation efforts to better tailor priorities within specific contexts (i.e., patients, diseases, or locations)?
	• Is the implementation team using prominent policy stakeholders (i.e., policymakers, policy analysts) as intermediates to help support implementation efforts by endorsing CPGs, supporting peers, and facilitating administration of the CPG implementation?
	• Have you considered selecting appropriate health systems relevant intermediates (i.e., based on experience, expertise, etc.) to aid in better identifying policy priorities, training barriers, and available policy supports important within the implementation process?
	• How are you adapting recommendations to local conditions and budgetary constraints?
	    ◦ Do you have a review process established to ensure policy changes at the local level are reflected in implementation efforts?
	• Have you considered creating strategic and operational plans that are informed by policy priorities as they relate to:
	    ◦ Human resources (both number and type)?
	    ◦ Multidisciplinary teams?
	    ◦ Communication infrastructure?

Chapter 5. Conclusion

The three studies presented in chapters 2-4 of this dissertation aid in better understanding the role policy context can play within clinical practice guideline (CPG) implementation efforts. In particular, the studies unpack how policy, political, and health systems considerations influence (i.e., facilitate or hinder) CPG implementation and provided insights into which strategies are best for engaging with the policy context. This concluding chapter outlines: 1) the principal findings from the studies presented in chapters 2-4; 2) the theoretical, methodological, and substantive contributions of this dissertation; 3) the strengths and limitations of the dissertation; and 4) the implications of the dissertation for policy and practice and for future research.

Principal findings

The studies within this thesis explore how and in what ways the policy context – in particular, policy, political and system considerations – influences and can be leveraged to support CPG implementation. The first study (chapter 2) used a critical interpretive synthesis (CIS) approach to systematically review and integrate literature from different fields, topics and sources to enrich two existing guideline-implementation frameworks (the Knowledge-to-Action Framework and the Consolidated Framework for Implementation Research). This study represents the first comprehensive attempt to identify facilitators, barriers, and strategies in CPG implementation related to the policy context (i.e., policy, political, and health systems considerations) and to place them alongside the more traditional guideline- and practitioner-level considerations. It first systematically identified policy context-related facilitators, barriers, and

strategies within the available literature and then juxtaposed these findings to existing concepts, relationships, and structures within the KTA and CFIR models. The analysis then led to the identifying of new concepts, contextualizing of existing concepts for the policy context, and identifying existing concepts within the models that already captured policy, political, and systems considerations. This allowed framework enrichments to be anchored to salient factors identified from the CIS and ensured policy considerations (i.e., policy, political, and health systems) could be made explicit both within implementation efforts and future research activities.

The second study (chapter 3) provides unique insights on the potential of the enriched KTA and CFIR frameworks to have impact on real-world applications. The cases sampled in this study differ not only in which framework was used but also in the implementation method, scope, and target population. This allowed the enriched frameworks to be explored in different settings, which provided an opportunity to analyze how policy context-relevant factors could influence implementation efforts. The study found the enriched frameworks could highlight how different stakeholders influenced the decision-making process, how organizational structure impacted priorities, and how the iterative nature of the planning process is informed by the policy context. Findings highlighted the effectiveness of guideline-implementation strategies, success of the original frameworks, and the anticipated influence of the enriched frameworks. The analysis also identified issues and concerns stemming from the policy context that highlight how the role of policy can be subtle and act in ways that connects multiple aspects of the implementation process. These findings suggest that explicitly considering policy, political, and health systems considerations is complementary to the current guiding priorities within implementation efforts. In particular, it provides a means of bringing to the forefront a common

thread that could link and amplify the factors that increase the chances of successful implementation efforts. Findings from this study led to the enriched frameworks being changed in two ways: 1) definitions and examples used were refined to better highlight the interconnectedness of the policy context; and 2) references to policy, political, and systems considerations were more explicitly described to better clarify which considerations were being referred to.

The final study (chapter 4) focused on guideline developers' and implementers' views about what is most salient within the enriched frameworks for supporting guideline implementation efforts and what needed further adapting to better support guideline implementation. This study offered an opportunity to establish content validation of the enriched KTA and CFIR frameworks. Its focus on the entire implementation continuum, from planning and logistics to products and implementation processes, allowed for a comprehensive analysis on how the enriched frameworks can potentially address the gap in our understanding of the role of the policy context within implementation efforts. The analysis identified that the enrichments were valued most by developers and implementers for four reasons: 1) for the flexibility when capturing the policy context; 2) for the level of sensitivity to and awareness of overarching factors (i.e., meso- and macro-level); 3) for the comprehensive approach for engaging with the policy context; and 4) for highlighting the interconnectedness of the policy context.[1, 3, 5-7] By examining the views of guideline developers across the globe, cultural and contextual factors that highlight salient similarities and variabilities within the policy context were identified. The findings detailed the perspectives on the enrichments to the frameworks overall, how the enrichments could potentially influence planning and logistics activities, and how the enrichments could potentially influence implementation efforts. The need for an explicit and

systematic consideration of policy, political, and health systems considerations with the implementation of evidence-informed recommendations was echoed by both guideline developers and implementers. Findings from this study led to the newly added construct in the enriched frameworks (i.e., the policy context considerations), to be further refined through the addition of explicit conditions to consider when applying the construct.

Novel contributions

This dissertation makes a number of contributions to the field of implementation science. These contributions are discussed below and categorized as theoretical, methodological, and substantive contributions.

Theoretical contributions

Although there are many theoretical approaches (i.e., models and frameworks) within the field of implementation science, the role of the policy context within implementation is not sufficiently captured in many of these approaches.[1, 2, 4, 8] The principal theoretical contribution of this thesis is that it enriches two existing theoretical frameworks that incorporate policy, political, and health systems analysis within the implementation process, the Knowledge-to-Action Framework (KTA, a process model) and the Consolidated Framework for Implementation Research (CFIR, a determinant framework). These enriched frameworks make explicit the value, importance, and necessity of engaging with the policy context within implementation efforts (see appendix to the overall thesis). The enriched frameworks provide a more nuanced understanding of the role of the policy context in implementation and identifies

factors most salient to guideline developers and implementers through its iterative refinement across the studies. The first study identified the most salient factors (i.e., facilitators, barriers, and strategies that are policy relevant) that impact CPG implementation efforts and introduced a new construct within each respective framework. The second study explored the real-world application of each respective framework and identified areas to further refine the enriched frameworks from documentary and interview analysis that explored the potential application of the enrichments. Lastly, the third study leveraged the tacit knowledge of guideline experts (both developers and implementers) to further refine the enriched frameworks by identifying conditions to consider when applying the constructs within the enriched frameworks.

Methodological contribution

This dissertation has two methodological contributions. The first is the unique interdisciplinary approach taken. Combining multiple theories, models, and frameworks from various fields such as health systems and policy frameworks, political science, and multiple frameworks from implementation science (KTA and CFIR), allowed the enriched frameworks to be developed in a robust manner. The insights garnered through such an interdisciplinary approach highlights the unique findings and insights that are possible which is not available from using one discipline alone and more importantly, encourages scholars within implementation science to expand their analysis when exploring the role of the policy context. The second contribution to methodology is the novel application of theory from political science to inform and guide an analysis that has historically been grounded more specifically in implementation science. Policy, political, and health systems frameworks do not easily fit into the concepts,

relationships, and priorities within implementation science. The process of explicitly exploring salient connections between the constructs within these frameworks, and subsequently juxtaposing that analysis onto the implementation frameworks, provided a rich opportunity for unique insights to emerge.

Substantive contributions

There were two substantive contributions made by this thesis. First, it provides enriched versions of the two existing implementation frameworks that can better identify, engage with, and evaluate concerns stemming from the policy context. In particular, the enriched frameworks better capture the policy relevant facilitators, barriers, and strategies that need to be considered throughout the implementation process. This also offers an opportunity to implementation science scholars to explore and build upon the existing scholarship with a new perspective. Second, it better articulates the role of policy within guideline implementation allowing the implications for not prioritizing policy within implementation processes to be more evident. In particular, it clarifies the role policy-relevant stakeholders (e.g., institutions, professional organizations) play within the implementation process, including how they can be incorporated within the implementation team, what strategies are useful when dealing with them, and what strategies they may use to influence implementation efforts.

Strengths and limitations

Collectively, the studies of this dissertation have three major strengths. First, a major strength is the combination of methods used across the three studies. The first study (chapter 2) provided a unique systematic and comprehensive analysis of the policy, political, and health

systems literature in the context of CPG implementation. This supported the development of the two enriched frameworks that integrated empirical and conceptual research from implementation science, knowledge translation, and political science. The second study's (chapter 3) use of multiple case studies provided a robust opportunity to retrospectively apply both the KTA and CFIR that helped to better identify areas within the enrichments that lacked clarity and other areas that offered room for expansion. The third study's (chapter 4) use of a formative evaluation allowed the insights from the tacit knowledge of guideline developers and implementers to enhance the applicability of the enriched frameworks.

The second major strength is the explicit focus on the policy context throughout the entire CPG implementation process. From planning and logistics to evaluating dissemination plans and adjusting outcome measures (e.g., products, services), the analysis centred the role of the policy context. This was aided by the integration of multiple sources of evidence. The policy context requires multiple concepts and approaches to better understand and engage policy, political, and health systems considerations. A multidisciplinary approach allowed insights to be garnered from a variety of domains, some interconnected while others were siloed from implementation pursuits. This provided a comprehensive approach that was sensitive to the demands of the policy context (e.g., policy agendas, interest groups, governance arrangements etc.) but flexible enough to support implementation efforts. A narrow exploration of guideline implementation could not have captured the nuances the enriched frameworks are capable of engaging with, nor allowed refinements that integrated the complex priorities found within the policy context.

The third major strength is the practical nature of the line of inquiry in each of the studies in this thesis. Given that there is relatively limited exploration of policy within implementation science, despite its known importance, this thesis sought to fill this gap by focusing on how the

findings could be applied in the real-world. This was accomplished through an explicit effort to further refined insights in a manner that can be applied to many different implementation efforts beyond CPG implementation. For instance, identifying who specifically should be sought to consult the implementation team, such as policy analysts and patient advocacy groups. In addition, the iterative nature of how the two frameworks were further refined across the three studies, position them well to meet the demands of implementation pursuits in different contexts. Each study identified ways to further operationalize the constructs within the enrich frameworks to help potential users see the practical ways it could be useful.

This dissertation also had three limitations worth discussing. First, the entire thesis focused solely on CPGs. The policy context and, exploring what policy, political, and health systems considerations are important, is relevant across multiple facets within implementation science. The role of the policy context is complex, involving many conceptual and methodological approaches to best understand and engage with policy which is relevant and needed within implementation scholarship more generally. If the objective is to ensure the best-available evidence is translated into practice, a better understanding of the role and influence of the policy context across the full range of implementation tools and approaches is necessary.

The second limitation has to do with the methods used throughout the dissertation. The clinical nature of CPG implementation has resulted in a significant pool of literature that is clinical or provider focused. The search strategy used in each study (e.g., to identify studies for inclusion in the synthesis or 'cases' to be examined in the case study) may have limited policy relevant documents identified which could have better situated the analysis and potential implications discussed. This limitation did not pose a significant concern given the use of a

comprehensive search strategy and constant comparative method being used until saturation was reached.

Implications

Implications for policy and practice

The research findings of this dissertation have several policy and practice implications for guideline implementers and developers, and for policymakers. There are two main implications that best situate the research findings for those seeking to better understand and leverage the role of the policy context within implementation efforts.

First, CPG developers and implementers should use the enriched framework. The integrative approach to enriching the two existing implementation frameworks highlights how implementation science has the capacity and foundational principles to better engage with the policy context. This dissertation highlights that policy, political, and health system considerations are not only appropriate for capturing nuanced factors within implementation efforts, but they offer a unique opportunity to more critically explore the objectives guideline developers and implementers rely on CPGs to address. It also demonstrates the need for scholars within the field of implementation science to expand the pool of literature they draw on to better understand and engage with the policy context.

Second, policymakers should engage with CPG developers and implementers to help with the application of the enriched frameworks. This dissertation demonstrates the role of the policy context is beyond the existence of policy documents. The dynamic nature of the policy context requires the implementation science community, from researchers to practitioners, to see the policy context as an ecosystem with numerous actors, processes, and approaches. This

requires not only understanding the influence and impact of underlying motivations (i.e., interests, ideas, etc.) can have on implementation efforts, but taking a proactive approach to identify and manage the various political nuances that can influence implementation efforts. Given this, engaging with policy requires a multidisciplinary approach that is iterative and can anticipate potential conflicts and challenges arising from the policy context (e.g., processes, actors, and priorities).

Implications for future research

The findings of this dissertation highlight four important areas for future research. First, future research should formally test the enriched frameworks to critically evaluate if their application meaningfully supports CPG implementation. In particular, using the enriched frameworks to aid in assessing the facilitators and barriers to implementation or using them to develop a multicomponent implementation plan. Special attention should be given to how the enriched frameworks engage with areas of overlap between policy priorities and implementation timelines. For instance, examining how the enriched frameworks help to inform the decision-making process (e.g., capturing relevant policies and initiatives) or guide implementation efforts through any policy challenges (e.g., regulations).

Second, future research should consider the role, influence, and extent to which cultural and regional variabilities impact the enriched frameworks. The policy context is influenced by the culture and social norms that make up the jurisdiction it is situated within. Although study three (chapter 4) explored the views of guideline developers across the globe, the focus was not on exploring specific regional variabilities. Future research into what external factors shape the policy, political, and health systems considerations viewed most influential to implementation

efforts, would serve to further expand our understanding of the role of policy. For instance, this could be explored through an examination of how a new international CPG is implemented across the six WHO regions.

Third, exploring the views of policy-engaged stakeholders that engage with CPG implementation efforts is an area for future research. The findings of this thesis highlight the numerous policy-engaged stakeholders that guideline implementers should consider, however, understanding their perspective on how the policy context can better support implementation efforts could be very insightful and could help with further framework enrichments.

Fourth, future research should explore how the findings of this thesis translate to other implementation tools and approaches. Policy, political, and health systems consideration offer insights to better support implementation efforts by identifying tools and approaches that can lead to better implementation outcomes. Given that the policy context acts in the backdrop for most implementation activities, understanding how different implementation tools and approaches can be enriched through policy is a reasonable line of inquiry.

Overall, this thesis demonstrates important insights from the policy context that can have a transformative impact on the implementation efforts of CPGs. The three studies integrate and expand the scholarship from which both the implementation and policy community can draw from by painting a more nuanced picture of the key junctures, relationships, and processes that bind the two fields. These insights can be utilized to support guideline implementation, but more importantly, offers a new perspective to explore the role of policy within implementation efforts.

References

1. Ogden, T., & Fixsen, D. L. (2014). Implementation science: A brief overview and a look ahead. *Zeitschrift für Psychologie*, *222*(1), 4.

2. Fischer, F., Lange, K., Klose, K., Greiner, W., & Kraemer, A. (2016, June). Barriers and strategies in guideline implementation—a scoping review. In *Healthcare* (Vol. 4, No. 3, p. 36). MDPI.

3. Francke, A. L., Smit, M. C., de Veer, A. J., & Mistiaen, P. (2008). Factors influencing the implementation of clinical guidelines for health care professionals: a systematic meta-review. *BMC medical informatics and decision making*, *8*(1), 1-11.

4. Gagliardi, A. R., Brouwers, M. C., Palda, V. A., Lemieux-Charles, L., & Grimshaw, J. M. (2011). How can we improve guideline use? A conceptual framework of implementability. *Implementation Science*, *6*(1), 1-11.

5. Nilsen, P., Ståhl, C., Roback, K., & Cairney, P. (2013). Never the twain shall meet?-a comparison of implementation science and policy implementation research. *Implementation Science*, *8*(1), 1-12.

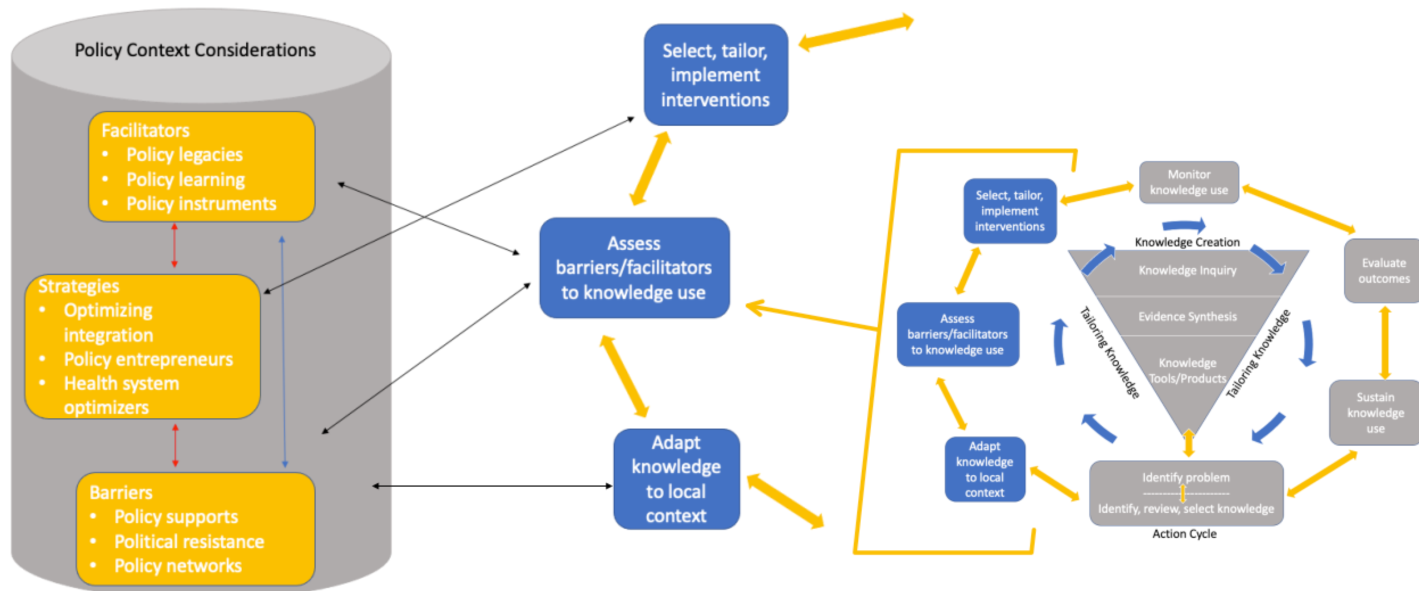
6. Olswang, L. B., & Prelock, P. A. (2015). Bridging the gap between research and practice: Implementation science. *Journal of Speech, Language, and Hearing Research*, *58*(6), S1818-S1826.

7. Wensing, M. (2015). Implementation science in healthcare: Introduction and perspective. *Zeitschrift für Evidenz, Fortbildung und Qualität im Gesundheitswesen*, *109*(2), 97-102.

8. Nilsen, P. (2020). Making sense of implementation theories, models, and frameworks. In *Implementation Science 3.0* (pp. 53-79). Springer, Cham.

Appendix

Figure 1 - Enriched Knowledge-to-Action Framework

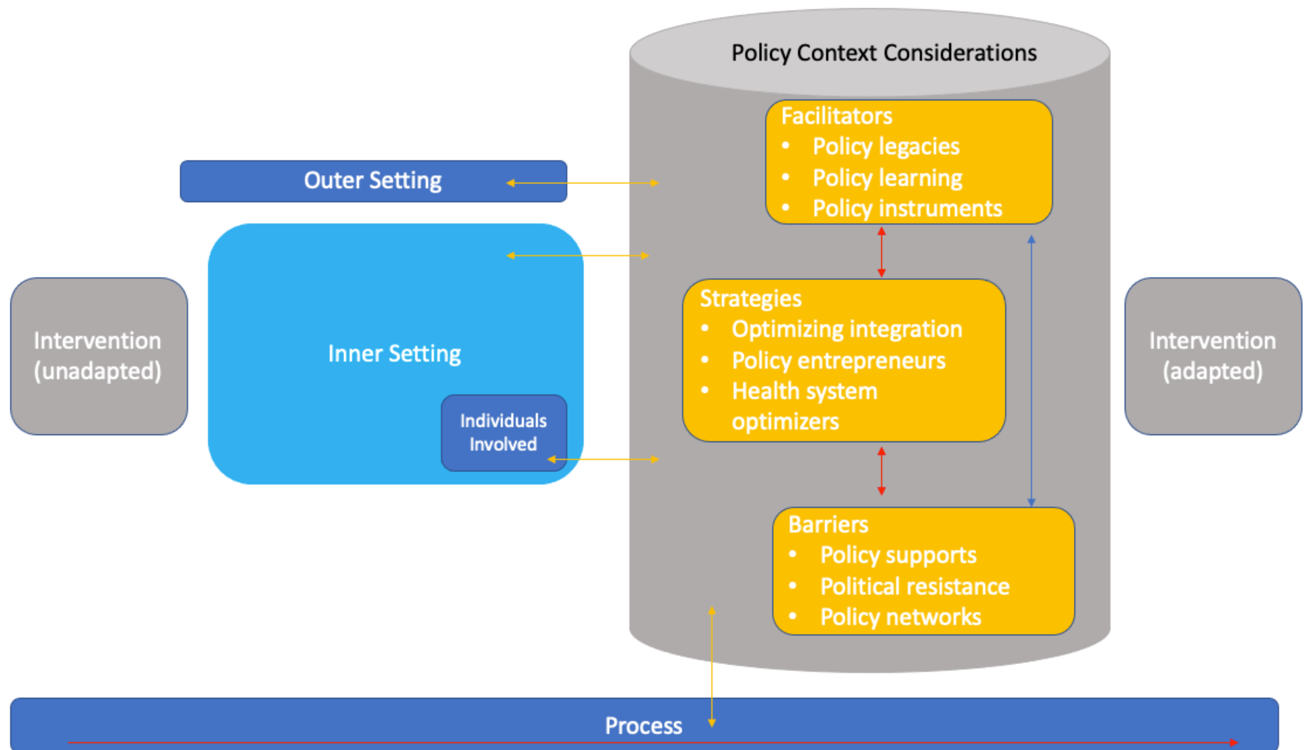


Note: Adapted from Graham et al.

Source:

Graham, I. D., Logan, J., Harrison, M. B., Straus, S. E., Tetroe, J., Caswell, W., & Robinson, N. (2006). Lost in knowledge translation: time for a map?. *Journal of continuing education in the health professions*, *26*(1), 13-24.

Figure 2 - Enriched Consolidated Framework for Implementation Research



Note: Adapted from Damschroder et al.

Source:

Damschroder, L. J., Aron, D. C., Keith, R. E., Kirsh, S. R., Alexander, J. A., & Lowery, J. C. (2009). Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. *Implementation science*, *4*(1), 50.