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Going beyond the traditional tools of implementation science

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Going beyond the traditional tools of implementation science

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Editorial: Going beyond the traditional tools of implementation science

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Editorial on the Research Topic
Going beyond the traditional tools of implementation science

Introduction

Implementation science is evolving and novel approaches are required to account for the complexity of implementation processes. The Research Topic *Going Beyond the Traditional Tools of Implementation Science* called for papers presenting innovative approaches to advance our knowledge on implementation.

Theories, models and frameworks

Research in implementation science employs three types of tools to understand and explain implementation and to close the research-practice gap. A crucial tool is the use of theories, models and frameworks (TMFs) to identify, describe and evaluate determinants (usually distinguished into barriers and facilitators), processes and outcomes of implementation. Five of the contributions concerned TMFs.

Birken et al. describe the development of the Organization Theory for Implementation Science (OTIS) framework which seeks to increase researchers' familiarity with organizational influences on implementation. Their paper describes the use of concept mapping and iterative consensus-building to identify six conceptually distinct domains, encompassing 70 constructs from nine organization theories. The domains reflect concepts that are central to organization theory, including, for example, autonomy and power, but which are less commonly addressed in implementation science.

Another perspective on organizational influences is provided by Scheuer. Translation theories take a process view that uses the sequence of events, activities and choices by "translators" (e.g., healthcare providers) to explain outcomes of implementation processes. According to the translational perspective, the spread of anything, e.g., a clinical guideline, is in the hands of people who may act in many different ways to modify or add to it. Contrasting with most implementation science TMFs, translation theories downplay the possibility to foresee what determinants may influence implementation.

Steerling et al. present a scoping review examining eight studies concerning trust when implementing AI systems in healthcare. Trust as a theoretical construct is rarely explicitly considered in the TMFs in implementation science but may be critical to understand AI systems implementation. The authors found that most studies had an individual perspective where trust was directed toward the AI technology. However, the review also included studies that focused on trust as relational between people within the context of the AI application.

Few determinant frameworks in implementation science account for the sustainment of evidence-based practices. Nadalin Penno et al. describe the Sustaining Innovations in Tertiary Settings (SITS) framework, which addresses determinants to sustainment specifically. They combined a systematic review and theory analysis of known sustainability TMFs with results from a case study using mixed methods to examine the ongoing use of an evidence-based practice in tertiary care. SITS consists of seven sustainability constructs, including innovation, adopters, leadership and management, inner context, inner processes, outer context, and outcomes.

Meza et al. present a different perspective on TMFs by showing how researchers can engage in a process of theorizing that draws on empirical data rather than treating existing theories as static products. Researchers who use TMFs deductively in studies usually fail to inductively modify theory based on their findings. The authors argue that theorizing can advance theory, thus contributing to improved explanation of implementation. They provide an example of how a theory theorizing can be constructed through developing causal explanations.

Strategies

Another type of tool is the development and application of strategies for facilitating the implementation of evidence-based practices. These should ideally be matched to existing determinants to reduce barriers and harness facilitators to implementation. Three of the contributions focused on strategies.

Jones et al. used intervention mapping to identify and match strategies to barriers and to develop programmes to improve familial hypercholesterolemia (FH) care. The paper includes a scoping review and a parallel mixed method study using interviews and surveys. Barriers were found to exist for all components (identification, cascade testing and management) and all levels (patient, clinician and health system) of FH care. The authors listed strategies specific to FH care that others can adopt to their local context.

Stakeholder involvement is increasingly emphasized in implementation science. Woodward et al. describe the development of a consumer engagement implementation strategy called Consumer Voice (set of trust-building tools). The tools were developed in a multi-step human-centered design process in the context of a suicide prevention intervention in Arkansas. They are available online, consisting of slides, audiovisual content with written text and templates.

Ingvarsson et al. used applied behaviour analysis to understand and develop de-implementation strategies. The analysis focused on the unnecessary use of x-rays for knee arthrosis in a primary care centre. The analysis provided the basis for the development of a lecture and feedback meetings as two strategies to reduce this practice. The results were inconclusive but indicated a behaviour change in the desired direction.

Research methodology

A third type of tool in implementation science is the research methodology used to investigate the process and outcomes of implementation efforts. Robust research methods must be used, and appropriate measures are needed to document the process and outcomes, including the effectiveness of various strategies. Four contributions addressed research methods and measures to study implementation.

Pinero de Plaza et al. present the development and testing of a novel evaluation method, the PROLIFERATE framework, which combines ecological (e.g., emergent system properties) and social logic models (study of individuals, groups and organizations) with the predominantly mechanistic logic of implementation science (i.e., bringing evidence-based interventions into practice). The paper describes examples of ongoing research to demonstrate how the framework can be used for co-designing innovations and evaluating implementation processes and outcomes.

Harvey et al. present a discussion paper advocating context-responsive study designs, i.e., designs that have high degree of adaptability and better align with the realities of implementation practice. The paper is based on workshop discussions among the authors and consultations with an international group of researchers and practitioners. The paper emphasizes the importance of engagement between implementation researchers and practitioners and acceptance of more flexible study designs.

Swindle et al. propose Evidence-Based Quality Improvement (EBQI) as an example of a method to achieve community engagement in implementation research and practice. EBQI expands on quality improvement and involves a deliberative and partnered process emphasizing a partnership between research and practice. The method involves activities such as selection and tailoring of implementation strategies and iterative adaptations of innovations.

Fixsen et al. emphasize the need for commonly used measures of implementation processes and outcomes. They argue that lack of valid measures has hindered the advancement of knowledge on implementation. The paper presents a literature review on measures on implementation variables resulting in 32 articles including measures of 23 implementation variables such as implementation fidelity.

Discussion

The papers on the three tools of TMFs, strategies and research methodology in implementation science present novel approaches that strive to capture the complex and dynamic nature of real-

world implementation. The field has medical origins in the evidence-based movement, yet real-world implementation has been found to be highly context-dependent. The themes of the papers exemplify the balancing act within the field whereby context-specific studies are needed as well as studies that produce findings that can be generalized across contexts for more broadly applicable conclusions. This Research Topic points to the importance of a social science perspective to understand how humans and organizations act and interact in their social environment.

Author contributions

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Strategies to reduce low-value care – An applied behavior analysis using a single-case design

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Introduction: Implementation science has traditionally focused on the implementation of evidence-based practices, but the field has increasingly recognized the importance of addressing de-implementation (i.e., the process of reducing low-value care). Most studies on de-implementation strategies have used a combination of strategies without addressing factors that sustain the use of LVC and there is a lack of information about which strategies are most effective and what mechanisms of change might underlie these strategies. Applied behavior analysis is an approach that could be a potential method to gain insights into the mechanisms of de-implementation strategies to reduce LVC. Three research questions are addressed in this study: What contingencies (three-term contingencies or rule-governing behavior) related to the use of LVC can be found in a local context and what strategies can be developed based on an analysis of these contingencies?; Do these strategies change targeted behaviors?; How do the participants describe the strategies' contingencies and the feasibility of the applied behavior analysis approach?
Materials and methods: In this study, we used applied behavior analysis to analyze contingencies that maintain behaviors related to a chosen LVC, the unnecessary use of x-rays for knee arthrosis within a primary care center. Based on this analysis, strategies were developed and evaluated using a single-case design and a qualitative analysis of interview data.
Results: Two strategies were developed: a lecture and feedback meetings. The results from the single-case data were inconclusive but some of the findings may indicate a behavior change in the expected direction. Such a conclusion is supported by interview data showing that participants perceived an effect in response to both strategies.
Conclusion: The findings illustrate how applied behavior analysis can be used to analyze contingencies related to the use of LVC and to design strategies for de-implementation. It also shows an effect of the targeted behaviors even though the quantitative results are inconclusive. The strategies used in this study could be further improved to target the contingencies better by structuring the feedback meetings better and including more precise feedback.

KEYWORDS

low-value care, de-implementation, single-case design, primary care (MeSH), physicians, applied behavior analysis (ABA)

1. Introduction

Implementation science has traditionally focused on the implementation of evidence-based practices (1), but has lately also included the de-implementation of LVC (2). De-implementation is the process of reducing LVC (i.e., practices that lack scientific support for their efficacy or effectiveness and overuse of effective practices, such as patients that do not benefit and costs that exceed benefits) (3–6). The most common types of LVC are non-indicated antibiotics, potentially inappropriate medication for the elderly, unnecessary imaging, and unnecessary lab tests (7). One noticeable difference with de-implementation compared to implementation is that it often requires some health care professionals' behaviors to be decreased (e.g., the use of a specific LVC practice) and some behaviors to be increased (e.g., the use of an alternative practice) (8). This implies that de-implementation needs to encompass strategies to decrease and increase behaviors.

Implementation science is accumulating knowledge about strategies. The current state-of-the-art is that strategies should match the local factors impacting behavior rather than expecting particular implementation strategies to always be superior to others (9). With regard to de-implementation, numerous local factors have been found to influence the use of LVC, including care processes, financial incentives, and perceived pressure from patients, other professionals, or the system (7, 10–12). However, there is insufficient knowledge about which factors might be relevant for choosing effective strategies. Knowledge is also required to determine which mechanisms are needed to target a factor (13, 14). Mechanisms are the processes or events responsible for the changes produced by a strategy (15). In other words, mechanisms explain how or why a strategy works by providing a specific description on how the factors influencing behaviors are altered in a given context (14). Thus far, only a few studies have explored the mechanisms behind strategies for implementation and de-implementation (14). Understanding the local factors influencing the use of LVC and mechanisms of possible strategies could help to design strategies that focus both on increasing and decreasing the behaviors influencing the use of LVC.

Behavior change theories, such as the theory of planned behavior and operant learning theory, have been proposed as suitable methods for understanding mechanisms of strategies (16). Specifically, operant learning theory has been suggested to be related to de-implementation because it distinguishes between processes to increase and decrease behaviors (17). It is commonly referred to as applied behavior analysis, which focuses on how behaviors are established, maintained, and extinguished in response to their environment (18, 19). In applied behavior analysis, mechanisms are represented as so-called contingencies, including which contingencies maintain current behaviors and how these contingencies can be changed through different behavior change strategies. Contingencies can either be related to antecedents and consequences in the environment (the three-term contingency) or to rule-governing behaviors. Applied behavior analysis could be a valuable addition to further researchers' understanding of factors in the environment that maintain behaviors related to the use of LVC and how de-implementation strategies can be designed to reduce the use of LVC.

This study demonstrates how applied behavior analysis can be used to understand contingencies related to the use of LVC and how de-implementation strategies can be developed by arranging alternative contingencies. We will also present how a commonly used evaluation method within applied behavior analysis called single-case design can be used.

Three research questions were addressed:

(1) What contingencies related to the use of LVC can be found in a local context and what strategies can be developed based on an analysis of these contingencies?
(2) Do these strategies change targeted behaviors?
(3) How do the participants describe how the strategies influenced contingencies and the feasibility of the applied behavior analysis approach?

2. Materials and methods

In this study, we used applied behavior analysis to develop de-implementation strategies for LVC. The strategies were evaluated using a single-case design for an analysis of quantitative data to address research question 2 and a qualitative design for an analysis of interview data to address research questions 2 and 3.

The methods section describes the setting and recruitment and presents the key principles and procedures of the applied behavior analysis. This is followed by a description of the single-case design methodology and the qualitative analysis methods.

2.1. Setting and recruitment

The study was set within a primary care center in Stockholm, Sweden. The Swedish health care system is tax funded and consists of 21 regions throughout Sweden, with Stockholm having the largest population (2.5 million). Each region is responsible for the provision of care, including primary care, of its citizens (20).

This center was recruited from managers in primary care centers that previously participated in an explanatory interview study that aimed to describe management strategies related to the use of LVC (21). All 12 managers that participated in the previous study were invited to this study. Three managers expressed initial interest and after an information meeting, one agreed to participate. The participating center is publicly owned, has approximately 12,500 listed patients, and 12–13 employed physicians, which is a slightly above average for a primary care center in Region Stockholm. During this study, a total of 23 different physicians worked at the center, with 12–13 working per month.

2.2. Key principles of applied behavior analysis

Applied behavior analysis is a practical approach that has been used to achieve behavior change in various settings, including health care organizations (22). It has previously been used to increase staff attendance (23), improve compliance with routines (24–26), and increase emergency department efficiency (27). It has also been used to understand the mechanisms underlying management strategies to de-implementation (21). However, its potential contribution to implementation science has not been fully realized yet.

One of the key principles within applied behavior analysis is the three-term contingency (28). This involves the assumption that behaviors are maintained, changed, or extinguished through a combination of behavior antecedents (an event that precedes the behavior) and behavior consequences (an event that follows the behavior) (29, 30) (see **Table 1** for key principles and concepts). Known factors that influence the use of LVC, such as expressed expectations from a patient, can be both an antecedent (the expressed expectation of receiving the LVC) and a consequence (the expressed thanks or relief from the patient after receiving the LVC). To design a strategy to influence the use of LVC, these contingencies need to be changed to support behavior change.

Another key principle is rule-governed behaviors (28), which are behaviors that are learned without having experienced the real-life consequences (31). Rules usually state the expected behavior and the consequences that will follow. Many of our behaviors are learned through rules (32). This is necessary when the process of trial and error is too time-consuming or could have a severe negative impact. For instance, in medical education, it is not acceptable to use trial and error to learn advanced medical procedures, but instructions (rules) can speed up learning. This makes rules a powerful tool for influencing behaviors.

Behaviors learned through rule-governing tend to be more inflexible and less influenced by antecedents and consequences. If a behavior needs to be robust in an environment where there are antecedents and consequences that encourage less suitable behaviors, using rule-governing can be beneficial. In contrast, when behaviors need to be flexible in a changing environment, rule-governing can instead cause problems. The factors influencing the use of LVC, such as uncertainty or disagreement about what is considered LVC, could be related to a lack of a clear rule that states what practices to avoid or the presence of a competing rule suggesting that the practice should be used.

TABLE 1 Key principles and concepts within applied behavior analysis.

Key principle	Concepts	Description
Three-term contingency	Antecedent	An event that precedes and signals an expected behavior and the consequences that will follow.
	Consequences	An event that comes after the behavior that maintain, change, or extinguish behaviors.
Rule-governing	Rule	An instruction that states the expected behavior and the expected consequences for performing the behavior.

2.3. The applied behavior analysis procedure

To develop strategies based on applied behavior analysis, we applied a six-step process (29) adapted for de-implementation (see **Table 2**). All of these steps are preferably performed together with the managers and employees to combine their knowledge about the local context with the researchers' expertise in behavioral analysis. All six steps were followed in this study. In addition to the six steps described in the literature, we also explored how the participating physicians described how the strategies influenced contingencies and the feasibility of the applied behavior analysis approach.

2.3.1. Step 1. Specify which LVC to de-implement

X-rays for knee arthrosis was chosen as the target LVC based on a participatory process involving physicians and the manager at the center. The project was presented at a physician meeting (May 2021) and different examples of LVC that might be relevant based on the literature and local relevance were discussed. The manager made the final decision on which LVC practice to de-implement. The choice was justified based on a new guideline advising against overuse of this particular examination (33) and existing data indicating that the center had a higher use of the practice compared to other centers in the region.

Arthrosis causes degeneration of cartilage in the knee capsule that over time can become gradually more painful, making it difficult for patients to move naturally. Updated guidelines from the National Board of Health and Welfare in Sweden (33) were published in January 2021, which recommended that patients with suspected knee arthrosis be provided a diagnosis based on medical history, clinical symptoms, and a physical examination. The guidelines do not recommend ordering an x-ray unless the patient is referred to an orthopedic specialist for surgical treatment. The recommended treatment for knee arthrosis is physical therapy, weight loss (if relevant), pain medication, and physical aids. Surgery is the last step, and only then may an x-ray be necessary. There are several reasons why an x-ray is considered LVC for knee arthrosis: It exposes the patients to unnecessary radiation, it is costly, and it delays the diagnosis and, by extension, the treatment for the patients. Lastly, in the

TABLE 2 Process for developing and evaluating strategies based on applied behavior analysis (adapted for de-implementation).

1. Specify which LVC to de-implement.
2. Identify specific behavior changes related to the use of that LVC.
3. Develop an accurate and reliable means of measuring key results and/or behaviors.
4. Conduct an analysis of the contingencies influencing behaviors related to the chosen results.
5. Develop and implement strategies targeting those contingencies.
6. Track and evaluate the effects of the strategies.

early stages of arthrosis, it is not always possible to verify a patient's condition through an x-ray examination (33).

2.3.2. Step 2. Identify behaviors related to the unnecessary use of x-rays

Three behaviors related to the unnecessary use of x-rays for knee arthrosis were identified as targets for change: (1) a decrease of referring patients to x-ray examination when the examination was not warranted; (2) an increase of diagnosing patients with arthrosis without using an x-ray (by clinical assessment); and (3) a decrease of diagnosing patients with general knee pain while waiting for the results of the unnecessary x-ray. Identification of behavior changes were performed by the first author of this study, who is trained in applied behavior analysis and the manager at the center.

2.3.3. Step 3. Develop an accurate and reliable means of measuring key results and/or behaviors

X-ray use and diagnoses of arthrosis and general knee pain were measured with data from the centers administrative registers and the quality assurance system. The monthly number of x-rays ordered at the primary care center was collected from central administrative register by their administrative staff and the use of the two diagnoses per month was collected from the local quality assurance system by the medically responsible physician at the primary care center. All data was on center level; it was not possible to extract data on an individual level.

2.3.4. Step 4. Conduct an analysis of the contingencies influencing behaviors related to the chosen results (research question 1)

Contingencies relevant to the general use of LVC at the center were discussed at a meeting with all physicians at the center (May 2021). Two of the authors facilitated the discussion (SI and HH). Afterwards, SI and the manager further investigated the chosen LVC (i.e., unnecessary use of x-ray for knee arthrosis). The discussion with the physicians and the managers did not use technical jargon or terms from applied behavior analysis but rather featured questions such as what they believed might influence unnecessary use of x-rays. The answers were then categorized using the three-term contingency and rule-governed behavior.

2.3.5. Step 5. Develop and implement strategies targeting the identified contingencies (research question 1)

At the meeting with physicians, possible strategies to reduce LVC in general were discussed. Strategies were developed based on a combination of the physicians' general suggestions and a specific discussion with the manager related to the chosen LVC practice. The suggested strategies were evaluated by the researchers based on their expected impact on the identified contingencies influencing unnecessary use of x-rays. As a result, the strategies were classified as either influencing rule-governing behavior or three-term contingencies related to unnecessary use of x-rays. In addition, this study's choice of strategies was also guided by how feasible the strategies were to implement without using too many of the center's resources.

2.3.6. Step 6. Track and evaluate the effects of the chosen strategies (research question 2)

To evaluate whether the chosen strategies changed the target behaviors, we assessed three outcomes: (1) the number of x-rays ordered (expected to decrease); (2) the number of patients diagnosed with arthrosis (expected to increase); and (3) the number of patients with a less specific diagnosis of knee pain (expected to decrease). All outcomes were directly linked to the targeted behaviors as ordering an x-ray (behavior) is directly translatable to number of x-rays ordered. Only collective data on center level (i.e., not at the individual physician level) were available. However, this outcome was deemed relevant since the strategies were developed to target everyone working at the center.

2.3.6.1. Single-case design

The effects were tracked using a single-case design, which is common in applied behavior analysis because it aligns with a perspective of science that emphasizes understanding "the black box" of change by closely monitoring the behavior of interest and how it changes following the adjustment of factors believed to influence the behavior (i.e., by applying strategies that change the three-term contingency or rule-governed behavior). Rather than evaluating changes in outcomes for groups of units (i.e., individuals, workplaces) before and after an intervention, a single-case design involves studying behavior change for each unit separately by using several data points over time and by distinguishing between a baseline phase and one or several intervention phases (34). To distinguish between the effects of different strategies, each strategy can be tracked through several data points to offer them time to influence behavior before another strategy is presented. The single-case data will be presented according to the Single-Case Reporting Guideline in Behavioral Interventions (35).

Following a single-case design, the data were collected each month for a period of 15 months (from June 2021 to August 2022) during four phases for all three outcomes.

Phase A: Baseline (no strategy introduced); six months before the introduction of the first strategy (i.e., June to November 2021).

Phase B: Three months after the introduction of the first strategy (i.e., December 2021 to February 2022).

Phase C: Three months after the introduction of the second strategy (i.e., March to May 2022).

Phase D: Follow-up (i.e., June to August 2022).

2.3.6.2. Analysis of single-case data

To analyze the single-case design data, a graphic presentation of the data was visually analyzed following the standards for single-case design (28, 36) (see **Table 3**).

A predictable and stable baseline involves a consistent pattern in level or trend. A consistent pattern in level means that all or most data points are on a similar level and a trend could be stable, increasing, or decreasing. Examining data within each phase to determine the pattern also involves finding a consistent

TABLE 3 Standards for single-case design: four steps and six features for analyzing single-case design data. .

Steps:
Step 1. Documenting a predictable and stable baseline
Step 2. Examining data within each phase to determine the pattern with each phase
Step 3. Comparing visual data between each phase to interpret if the implemented strategies influenced the data
Step 4. Integrating the information from all phases to evaluate if there is any demonstration of an effect
Features:
(a) level
(b) trend
(c) variability
(d) immediacy of the effect
(e) overlap in data between phases
(f) consistency of data patterns across similar phases

pattern in level or trend. Comparisons between phases means looking at similarities or differences in level, trend, or variability. If differences are found, the immediacy of the effects involves if the change happens at the first data point for the new phase or gradually over time during the phase. Overlap in data between phases involves an analysis of how many of the data points in the phases overlap with data points of the comparing phase. Consistency of data patterns across similar phases involves analyzing if similar phases, such as baseline phases, show a similar pattern or if intervention phases are similar. This feature is difficult to apply to this study because there were two different strategies and follow-up is not likely to function as a return to baseline.

In addition to visual analysis of the data, the mean and standard deviation were calculated for each phase. Differences between the phases were evaluated using Cohen's *d* for effect size, and the overlap between phases was evaluated using the Nonoverlap of All Pairs (NAP) (37).

2.3.6.3. Interviews

In addition to exploring how the strategies changed target behaviors using a single-case design, we also conducted individual interviews with the participants to capture their perception of the effect of the chosen strategies. The interviews were held after the strategies were implemented (May and June 2022). All physicians in the center were invited to participate in the interviews ($n = 12$), and four agreed to participate. In addition, all physicians who participated provided written consent. A semi-structured interview guide was used. The questions focused on their views on the specific LVC, how they perceived the strategies, and the usefulness/feasibility of the design and evaluation process. Questions on the strategies included aspects they felt did not work well, how the strategies could be improved, and if the strategies were perceived as feasible to use for the de-implementation of the other LVC.

2.3.6.4. Analysis of the interviews

The interviews were recorded and transcribed verbatim. Data from the interviews were analyzed using conventional content analysis according to Graneheim and Lundman (38) using NVivo software. The transcribed interviews were first read through several times to obtain a general view of the material. The first author then inductively coded, using line-by-line coding. The codes were then grouped into preliminary categories. During this time, memos were written to capture general ideas related to the interpretation of the codes. These ideas were then tested in the data, and the first author revised the categories. Representative quotes were selected to illustrate the categories. All authors reviewed the final categories and quotes.

2.3.7. Analyzing how the participants describe the contingencies of the strategies and the feasibility of the approach – research question 3

Data from the interviews related to the contingencies and the feasibility were analyzed separately. All answers were first coded inductively using content analysis. Answers related to contingencies were then coded deductively using the concepts from applied behavioral analysis three-term contingency and rule-governed behavior. This was done both for the contingencies that participants had pointed out as influencing their use of the chosen LVC and the lack thereof. Finally, the answers related to the feasibility of the design process and evaluation method were coded inductively using content analysis.

3. Results

The results section is divided into three subsections, each responding to a different research question.

3.1. What contingencies related to the use of LVC can be found in a local context and what strategies can be developed based on an analysis of these contingencies (RQ1)?

Based on the information received through the meetings with the physicians and the manager of the center, an applied behavior analysis was conducted to identify antecedents and consequences and rules governing LVC behavior (**Figure 1**). The analysis indicated that the most important reasons for using x-rays (i.e., the contingencies) were for cases when patients expressed their expectation to receive an x-ray to diagnose their symptoms (an antecedent to order an x-ray) and when they reacted in the form of expressed relief or gratitude for receiving an x-ray when the physicians ordered one (a consequence reinforcing the behavior ordering an x-ray). A rule-governing behaviors related to ordering x-rays was that if you order an x-ray (behavior), the patient can be better diagnosed (expected consequence of the behavior).

Based on the contingencies, two strategies were developed: a lecture and feedback meetings. The first strategy, the lecture, aimed to introduce a competing rule-governing the chosen behaviors, specifying why they should not order x-rays for arthrosis unless for referral to an orthopedic surgeon, how to diagnose arthrosis without ordering an x-ray, and what warning signs to be aware of when diagnosing arthrosis to avoid missing

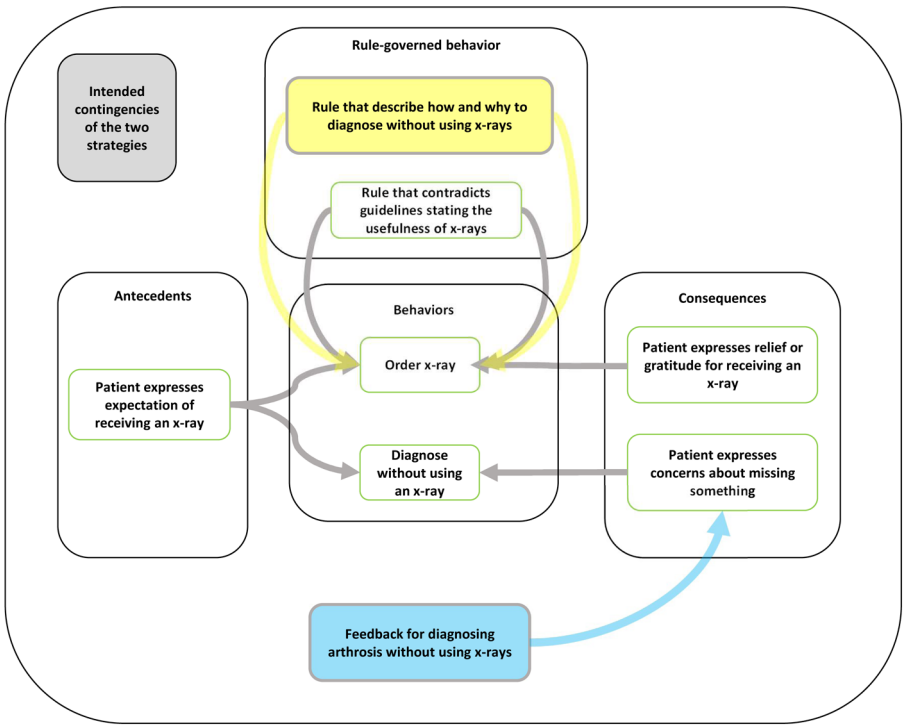

FIGURE 1
Connecting strategies to the analysis of contingencies specific to the unnecessary use of x-rays for arthrosis using applied behavior analysis. The yellow box shows how the lecture introduced a new rule to govern behaviors related to diagnosing arthrosis without using an x-ray. The blue box shows how the feedback meetings would add a new consequence to encourage the participants to diagnose arthrosis without using an x-ray.

an alternative diagnosis. The new rules would be: do not order an x-ray unless the patient is eligible for knee surgery, and: if you diagnose knee arthrosis without using an x-ray (behavior) the patient will faster receive the correct treatment (expected consequence of the behavior). The lecture was held by a physiotherapist at a rehab center with which the primary care was already collaborating. The lecture was planned in collaboration with the manager and the medically responsible physician, and during the meeting they expressed their support for following the new guideline. The physiotherapist presented verbally and through a PowerPoint presentation the national guidelines for diagnosing and treating arthrosis state that an x-ray is not recommended. The lecture included a hierarchy of treatment options depending on the severity of the symptoms, a description about why one should not order unnecessary x-rays for arthrosis, how to diagnose arthrosis without using an x-ray examination, and why one does not need to use the general knee-pain diagnosis. Compared to the previously published guideline with the span of 80 pages of single-spaced lines, the instructions were brief and formatted as bullet points to clarify which specific behaviors were according to the guideline in an accessible way. The instruction also included so-called red flags and a checklist for symptoms to be vigilant about in order to avoid missing a more serious diagnosis, still without having to order an x-ray. The lecture was delivered face to face in group format, attended by all physicians at the center. The entire lecture was 45 min, of which the presentation was around 20 min, and the remaining 25 min were used to give the participants the opportunity to ask questions and discuss the information.

The second strategy, feedback meetings, aimed at influencing the three-term contingencies related to the chosen behaviors by adding a consequence related to diagnosing arthrosis without using an x-ray. The new three-term contingency would then be: patient expresses expectations on receiving an x-ray (antecedent), diagnose arthrosis without using an x-ray (behavior) to receive feedback and support from colleagues and the medically responsible physician (consequence). A total of three meetings were held monthly and were hosted by the medically responsible physician whose responsibilities included quality of care. During the meetings, one of the researchers (SI) presented data on how the center was performing in three areas: how many knee x-rays had been ordered, how many patients had been diagnosed with arthrosis, and how many patients had been diagnosed with general knee pain. The meetings aimed at lessening the effects of the pre-existing contingencies related to using unnecessary x-rays for diagnosing arthrosis by increasing antecedents and consequences to diagnosing arthrosis without using unnecessary x-rays. Antecedents included discussions on what clinical signals should function as antecedents for ordering or not ordering an x-ray and consequences in terms of receiving support from colleagues and the medically responsible physician for not diagnosing patients with arthrosis without using an x-ray.

Examples of discussions held at both the lecture and the feedback meetings were (1) how to communicate with patients

who strongly request an x-ray; (2) how to feel secure that the patients' symptoms were not related to a more severe diagnosis (e.g., cancer); (3) lack of correlation between visible arthrosis on an x-ray and severity of the symptoms for the patient; and (4) problems with convincing patients that physiotherapy would be helpful for their symptoms.

All physicians at the center were invited to participate in the lecture and the feedback meetings. Ten participated in the lecture, six in the first feedback-meeting, five in the second, and four in the third. The number of participants per meeting depended on how many physicians were at the center on the day of the meeting.

3.2. Do these strategies change targeted behaviors (RQ2)?

The findings regarding the use of x-rays, arthrosis diagnosis, and general knee-pain diagnosis are presented using visual and statistical examination of the data.

3.2.1. Use of x-rays

During the baseline phase, the number of x-rays ordered per month varied but remained relatively stable around a mean value of 7.8 x-rays ordered per month showing a predictable and stable baseline (step 1) (Figure 2). Additional visual presentation of the single-case design data can be found in APPENDIX 1 (Supplementary Material). When examining the data within each of the four phases to determine the pattern of each phase (step 2), the baseline phase showed an increasing trend and a low variation. During the lecture phase, there was a decreasing trend and an increased variation with a mean of 7.0 x-rays per month, varying from 3 to 14 x-rays ordered per month. The feedback phase had a decreasing trend and smaller variation with a mean of 8.0 x-rays per month. The fourth phase, follow-up, had an increasing trendline and a low variation.

When comparing the visual data between each phase to interpret if the strategies influenced the data (step 3), there was a difference in level, trend, and variability between the baseline and the lecture phase but no clear immediate effect. The first data point in the lecture phase was higher than all points in the baseline phase, and the two following data points were lower than all data points in the baseline. During the feedback phase, there was a difference in trend, but not in level and variability, compared to the baseline phase, and there was a difference in level and variability compared to the lecture phase. The difference in level was immediate compared to the lecture phase. All data points in the feedback phase overlapped with the data points in the baseline phase. The follow-up phase had a lower level than all other phases and an increasing trend similar to the baseline but a larger variability. The first two data points in the follow-up phase overlapped with none of the other phases, whereas the third data point overlapped with one data point per phase. There was no consistency of data patterns across the different phases (step 4).

The statistic measure NAP between phases shows there were a large number of nonoverlapping pairs in the lecture phase compared to the baseline (Table 4). The NAP was lower when comparing the baseline to the feedback phase and higher when comparing the baseline to the follow-up. None of the NAP for

TABLE 4 Number of patients referred to an x-ray: the mean value and standard deviation for the four phases and effect size using Cohen's *d* and nonoverlap of All pairs (NAP).

	Baseline	Lecture	Feedback	Follow-up
Mean	7.8	7.0	8.0	5.0
Standard deviation	2.5	6.1	2.6	5.3
Effect size compared to baseline Cohen's *d*		0.18	0.7	0.7
Effect size compared to baseline NAP		67	53	69
p-value NAP		0.26	0.5	0.22

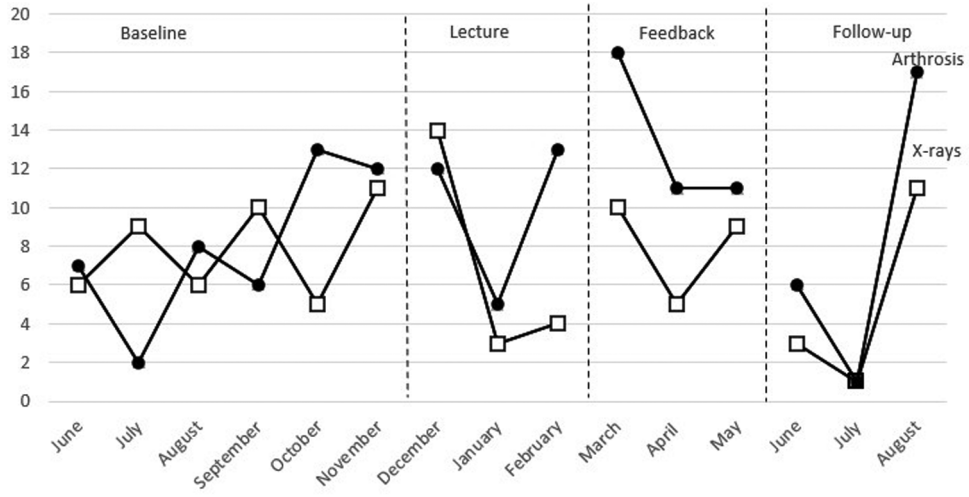

FIGURE 2
Combined data from number of x-rays ordered and number of patients receiving arthrosis diagnosis.

the baseline compared to the other phases was significant. The effect size calculations indicate no large effects.

3.2.2. Arthrosis

Data for the number of patients receiving arthrosis diagnosis can be seen in Figure 2 (compared with x-rays) and Figure 3 (compared with the number of patients receiving the diagnosis of general knee pain). Additional visual presentation of the single-case design data can be found in APPENDIX 1 (Supplementary Material). During the baseline phase, the number of patients receiving arthrosis diagnosis showed a large variation with a mean of 8.0 per month, demonstrating that the baseline phase was not predictable and stable (step 1). When examining the data within each phase to determine the pattern of every phase (step 2), the baseline phase showed an increasing trend and a large variation. The lecture phase shows an increasing trend and a large variation. The mean number of patients receiving the diagnosis was 10.0 per month. The feedback phase had a decreasing trend, and there was a small variation. The mean value was 13.3. During follow-up, the trend was increasing, and there was a large variation. The mean was 8.0.

Comparing visual data between each phase to interpret if the strategies influenced the data (step 3), there was a difference in level and variability between the baseline and the lecture phase. There was no immediate effect between the two phases. The feedback had a higher level than both the baseline and the lecture phase, a variability similar to the lecture phase, and a different trend (decreasing) compared to both the baseline and the lecture phase. There was an immediate effect between the lecture phase and the feedback phase. The follow-up phase had a level similar to the baseline, a larger variability than all other phases, and an increasing trend like the baseline and the lecture phase. There was an immediate effect between the feedback phase and the follow-up phase. There was no consistency of data patterns across the different phases (step 4).

NAP indicates there were a small number of nonoverlapping pairs in the lecture phase compared to the baseline (Table 5). The NAP was higher when comparing the baseline to the feedback phase and lower when comparing the baseline to the follow-up. None of the NAP had a significant *p*-value. Only the feedback phase compared to the baseline had a large effect size.

3.2.3. General knee pain

Data for the number of patients receiving arthrosis diagnosis can be seen in Figure 3 (compared to the number of patients receiving arthrosis diagnosis). Additional visual presentation of the single-case design data can be found in APPENDIX 1 (Supplementary Material). During the baseline, there was a large variation suggesting that the baseline phase was not predictable and stable (step 1). When examining the data within each phase to determine the pattern of each phase (step 2), the baseline phase had a large variation and a decreasing trend. The mean value of patients received the diagnosis of 6.7 per month. The lecture phase has a decreasing trend and a small variation. The mean number of patients receiving the diagnosis was 4.0 per month. The feedback phase had an increasing trend and a small variation. The mean value was 7.0. The follow-up phase had a decreasing trendline and a small variation and had the mean value of 5.7.

Comparing visual data between each phase to interpret if the strategies influenced the data (step 3), there was a difference in level and variability between the baseline phase and the lecture phase. There was no immediate effect. The feedback phase had a similar level as the baseline phase but a decreasing trend compared to all other phases. There was an immediate effect between the lecture phase and the feedback phase. The follow-up

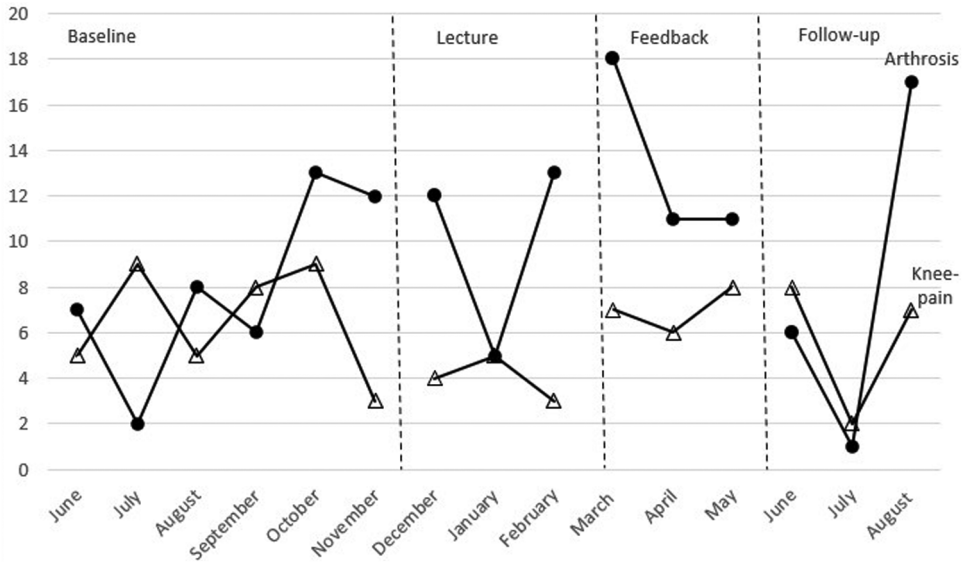

FIGURE 3
Combined data from the number of patients receiving arthrosis diagnosis and knee-pain diagnosis for the four phases.

phase had a trend similar to all phases except for the feedback phase, a lower level than the baseline and the feedback phase, and the same variability as the baseline. There was no immediate effect between the feedback phase and the follow-up phase. There was no consistency of data patterns across the different phases (step 4).

NAP indicates there were a high number of nonoverlapping pairs in the lecture phase compared to the baseline (Table 6). The NAP was lower when comparing baseline to the feedback phase and higher when comparing baseline to follow-up. None of the NAP has a significant *p*-value. Only the lecture phase compared to the baseline had a large effect size.

TABLE 5 Number of patients receiving arthrosis diagnosis: the mean value and standard deviation for the four phases and effect size using Cohen's *d* and nonoverlap of All pairs (NAP).

	Baseline	Lecture	Feedback	Follow-up
Mean	8.0	10.0	13.3	8.0
Standard deviation	4.0	6.0	4.0	8.2
Effect size compared to baseline Cohen's *d*		0.5	1.3	0.0
Effect size compared to baseline NAP		61	78	42
p-value NAP		0.35	0.12	0.7

TABLE 6 Number of patients receiving the general knee-pain diagnosis: the mean value and standard deviation for the four phases and effect size using Cohen's *d* and nonoverlap of all pairs (NAP).

	Baseline	Lecture	Feedback	Follow-up
Mean	6.5	4.0	7.0	5.7
Standard deviation	2.5	1.0	1.0	3.2
Effect size compared to baseline Cohen's *d*		1.3	0.26	0.29
Effect size compared to baseline using NAP		81	47	64
p-value NAP		0.09	0.6	0.3

3.2.4. Combining x-rays and arthrosis data

Inspecting the combined data from x-rays and arthrosis revealed that the number of x-rays ordered exceeded the number of patients receiving arthrosis diagnosis on two occasions during the baseline and at the first data point during the lecture phase, but not after that, suggesting that more patients received unnecessary x-rays before the lecture.

3.2.5. Combining arthrosis and knee pain data

The combined data from arthrosis and knee-pain diagnosis showed a similar pattern, with more data points in the baseline where the number of patients diagnosed with knee pain exceeded the number of patients receiving arthrosis diagnosis, suggesting that more patients received an unnecessary knee-pain diagnosis, whereas the opposite pattern appeared in the strategy and follow-up phases (Figure 3).

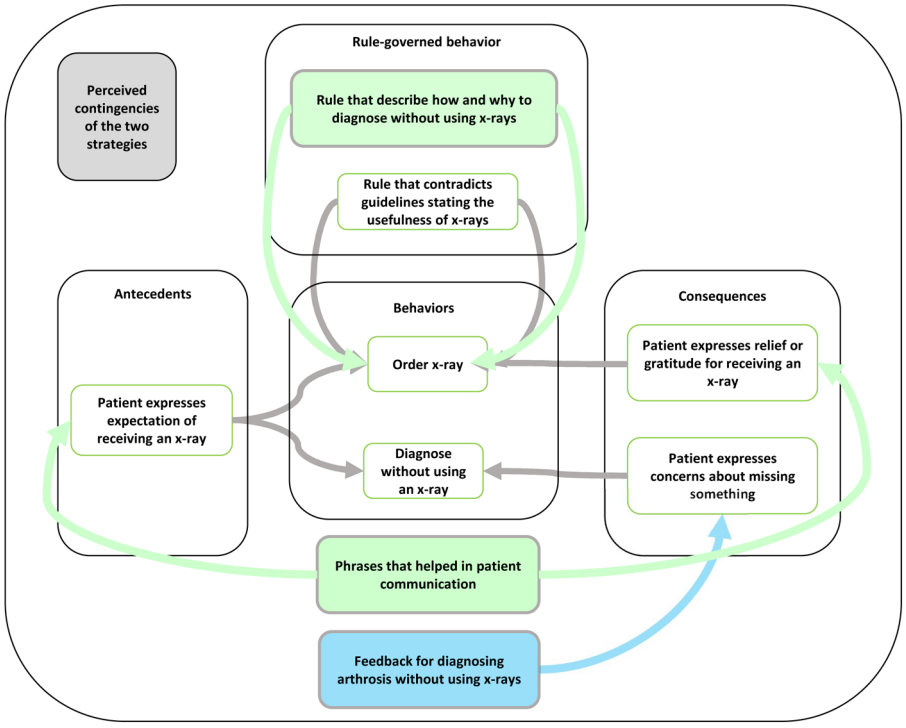

FIGURE 4
Key principles, concepts, participants' perceptions of the mechanisms specific to the use of x-rays, and how the strategies targeted those mechanisms. The green boxes show how both strategies influenced the targeted contingencies, and the blue box shows how the feedback meetings influenced the targeted contingencies.

3.3. Qualitative data: do the strategies change targeted behaviors?

All participants described that the strategies had influenced their use of LVC. These effects can be grouped into four categories: (1) noticing that their own use of x-rays had been reduced; (2) talking more to patients about the lack of benefit from using x-rays; (3) improving their way of diagnosing arthrosis without using x-rays; and (4) being unsure of how to interpret the effect.

The category Noticing that their own use of x-rays had been reduced were related to their subjective perception of how many x-rays they had ordered since the implementation of the first strategy. Some described that they had ceased using x-rays except for when referring to a specialist in orthopedic surgery, whereas others said they were more aware of when they ordered an x-ray that was unnecessary and that they were more selective when doing so.

> "I don't believe I have ordered any since the lecture—well, yes, some—but those were related to a referral to an orthopedic surgeon" (IP2).

The category "Talking more to patients about the lack of benefit from using x-rays" summarized physicians' descriptions of how they talked more to patients about the lack of benefit from using x-rays after the strategies had been implemented. They described using phrases that they picked up from the lecture and from discussions with their colleagues during the feedback meetings in their conversations with patients.

> "I believe that it has influenced my use of x-rays, by how I talk to the patients—that an x-ray is not needed until it is time for surgery" (IP3).

The category "Improving their way of diagnosing patients without using an x-ray" included both how to diagnose patients with arthrosis without using an x-ray and the importance of doing so. Physicians described new insights about x-rays potentially leading to missed or delayed diagnoses because the symptoms of arthrosis are not visual on an x-ray until late in the development of the disease.

> "What resonated with me especially was that there is a risk that we miss diagnosing patients with arthrosis if we wait for an x-ray, and if that doesn't show anything, we do not trust our own assessment of the patient's symptoms" (IP4).

The category "Being unsure of how to interpret the effect" included statements about difficulties in interpreting the feedback received during the feedback sessions and the confidence in their own perception of change. All participants perceived that there had been an effect, but some were not sure about how and to what extent the strategies had led to effects.

> "I like to think that it has influenced our way of thinking, but I am not sure" (IP1).

3.4. Qualitative data – how do the participants describe the contingencies of the strategies and the feasibility of the applied behavior analysis approach (RQ3)?

3.4.1. Contingencies

We analyzed contingencies using the concepts three-term contingency and rule-governed behavior, comparing the participants' descriptions to the analysis from before development of the strategies (see Figure 1). The comparisons confirmed the relevance of the contingencies underlying the strategies identified beforehand but also indicated that both strategies influenced other contingencies than expected. The lecture (expected) and the feedback meetings (not expected) changed the self-developed rule of needing to satisfy patients' expectations by enabling the physicians to satisfy the patients' expressed expectations without unnecessary x-rays when diagnosing arthrosis (Figure 4).

> "I believe that we discussed this during the meeting, and this is what it is mostly about. How you, in a pedagogical way, respond to the patient's thoughts, concerns, and wishes and then to deliver your assessment of it all (symptoms and the patient's perspective). I believe it is easier to avoid unnecessary use of x-rays if you work patient centered" (IP4).

Both the lecture (not expected) and the feedback meetings (not expected) influenced the three-term contingencies related to patients' reactions to not receiving an x-ray. The participants described how they had started to use new phrases while talking to the patients, which influenced the patients' reaction, leading them to express gratitude for their diagnosis without receiving an x-ray.

> "And that is something that I find valuable to convey to the patients also, that in an early stage, there is a risk of us underdiagnosing (arthrosis) if we rely on the results from an x-ray. That is a takeaway message from the lecture" (IP4).

The feedback meetings (expected) also influenced the behavior of diagnosing patients with arthrosis without using an x-ray by adding consequences encouraging this behavior. This was done by receiving feedback and providing a more general form of support from talking to their colleagues about issues related to not using x-rays to diagnose arthrosis.

> "Above all, I believe that since we were able to talk amongst ourselves and simply be able to reflect and talk about it. That is what I believe was especially valuable" (IP4).

3.4.2. Feasibility

We found four categories related to the participants' perceptions of the feasibility of the applied behavior analysis approach. The participants described it as feasible because the strategies had the potential to influence their behaviors and the approach could be beneficial for other examples of LVC. They

also provided suggestions for how the strategies could be further improved.

Overall, the participants found the design and evaluation process feasible. However, not all clearly remembered participating in the initial participatory process of identifying the LVC practice and factors, indicating that the latter was more important to them. Nevertheless, all participants perceived the choice of LVC as relevant. They stated that they had been aware of x-rays being LVC before the implementation of the strategies but that the strategies had been helpful in reducing their use.

> "I believe it is reasonable to try to reduce the use. Since it is possible to diagnose arthrosis clinically, is it reasonable both from a financial perspective and based on our goal to avoid unnecessary examinations in general" (IP3).

They also described the chosen strategies as relevant for targeting their use of unnecessary x-rays and stated that the format for delivering the strategies had been well incorporated into their normal collaborations and routines.

> "It's good that it came up at the physicians' meetings and didn't go on for too long. But we still have the physicians' meetings regularly, so it was a good forum to take it there" (IP4).

All participants described other examples of LVC, such as lab tests, cardiology examinations, antibiotics, gastroscopy, and colonoscopy, in which a similar approach could be beneficial, including selecting LVC based on their quality assurance system, inviting someone to provide a short lecture on why it is considered LVC, and measuring and providing feedback on their use.

Some suggestions for improvements were also provided, particularly for the strategies. Two suggestions on how to improve the lectures were proposed. The first was to prepare the participants before the lecture or start with an introduction clarifying the purpose of the lecture on reducing the use of x-rays for arthrosis based on the knowledge that they are not necessary. It was perceived as more implied than explicitly articulated. This was described as an effect of the hectic work situation for physicians and the fact that they often dropped in at meetings without being prepared for what was to be discussed.

Another suggestion was to include some sort of practice of diagnosing patients with arthrosis without using x-rays. The idea was that even if most physicians believe that they are capable of diagnosing arthrosis without x-rays, they could possibly do it differently from each other, and there could be a benefit of practicing to see if there were any differences. This was balanced, however, by the benefit of the lecture being brief based on feasibility.

Even though the free discussions were perceived as helpful, it was also suggested that more structure may be warranted. Two main topics to focus on more specifically were suggested. The first one was related to discussing why one would want to do an x-ray for arthrosis for patients who were not interested in surgery. What could be the perceived benefit of ordering an unnecessary x-ray and to discuss how to handle that in a different way with the group.

The other topic was focused more on the interaction with patients who ask for an x-ray. How to understand their perspectives and based on an understanding of that how to be able to convince them that they do not need an x-ray.

A shortcoming of the feedback received during the feedback meetings was that the data were difficult to interpret. Because few patients presented with arthrosis per month at the center, it was difficult to see a clear trend. They further commented that the feedback was not precise enough to ascertain whether the reduced number of x-rays was an effect of correct or incorrect decisions. Because some x-rays are warranted for pre-surgical consultation, the data was difficult to interpret.

> "Perhaps one would have to dive deep into individual cases to check if the results were based on us not using x-rays or not using x-rays for arthrosis" (IP3).

4. Discussion

In this study, we used applied behavior analysis to identify two strategies, a lecture and feedback meetings, to address the local contingencies (antecedents, consequences, and rules) maintaining the use of LVC. The results from the evaluation of how each of the three target behaviors changed following the strategies were inconclusive. However, the findings that more patients received the arthrosis diagnosis without an x-ray and more received arthrosis diagnoses than general knee-pain diagnoses after the introduction of the strategies may indicate a behavior change in the expected direction. Such a conclusion is supported by interview data showing that participants perceived an effect in response to both strategies. Qualitative findings showed that the participants described the applied behavior analysis approach as feasible, supported the identified strategies' appropriateness, and suggested additional ways the strategies influenced the contingencies.

The strategies used in this study are consistent with the literature on de-implementation indicating that education and feedback, separate or together, are effective for de-implementation (39–41), and that feedback as a general strategy is effective in changing behaviors (42). Based on the ERIC taxonomy (43), the education and feedback strategies in this study could be sub-classified as including an educational meeting, educational outreach (the invited physiotherapist), development of educational materials (a PowerPoint presentation), and a mandate for change (the presence of the center's manager and medically responsible physician). Such sub-categorization could increase the precision with which a de-implementation effort is described. However, from the perspective of applied behavior analysis, *how* the strategies influence contingencies is more important to describe. One strategy may include several features to maximize the likelihood that the strategy targets the identified contingencies. For example, the aspiration to establish a new rule to govern LVC behaviors was taken into account in the design of the lecture. Features included in the lecture to strengthen the effect as a rule

governing behavior was how the PowerPoint presentation was designed, the presence at the lecture by the manager and the medically responsible physician, the inclusion of detailed instructions on how to diagnose arthrosis without using x-rays, that is, a replacement behavior (44), and that the presentation at the lecture was held by an expert i.e., the physiotherapist. Similarly, the discussions held during the feedback meetings aimed to allow for problem solving to influence the three-term contingencies, a strategy that has been shown to be effective in previous studies (45, 46). Therefore, whereas the ERIC taxonomy may provide more details on the available strategies, applied behavior analysis focuses on the strategies' functions—that is, how they are expected to influence behaviors (i.e., mechanisms). This way of designing strategies corresponds well with recent research in applied behavior analysis on how to match an analysis of the target behaviors with relevant strategies offering a way to bridge general knowledge on what strategies influence behaviors and how, with detailed information about a specific context (47).

The single-case data did not consistently point in one direction regarding whether the strategies influenced LVC-related behaviors. Yet, the pattern of change adds a layer to the analysis. The three single-case data together show that after the introduction of the strategies, more patients received the arthrosis diagnosis than x-rays and/or the general knee-pain diagnosis. This may indicate that more patients receive the diagnosis without an x-ray, which aligns with the aspired behavioral change. Interview data also supports this interpretation. Overall, the participants were more positive about the strategies' perceived effects. Therefore, some discrepancy arose between single-case data and interview data. One reason for this discrepancy could be the turnover rate among the physicians working at the center in combination with the use of center-level data, which meant that behaviors of physicians who were not exposed to the de-implementation strategies were included in the outcome data, which may have reduced the effect. Another explanation could be that interviewees were individuals who experiences the two strategies and therefore may be prone to promoting a positive evaluation simply to justify their time investment or social desirability (48).

Of course, it cannot be ruled out that the strategies simply were not effective. Possible reasons for that could be that the information received from the participants about possible contingencies were not sufficiently comprehensive. Those identified in this study were only a few out of several suggested in the literature (7, 10, 49). Alternative contingencies with a stronger influence on behaviors related to using x-rays could potentially have maintained unnecessary use of LVC despite the two strategies. Another explanation could be that the strategies did not target the maintaining contingencies effectively enough. The feedback intervention, in particular, could have been improved. Feedback is more effective if it is delivered individually, without delays, and if it is delivered from a person who is valued by the recipient of the feedback (42). Thus, access to individual data, more frequent feedback and feedback delivered solely by the medically responsible physician would possibly have improved the effect of the strategies.

One challenge in de-implementation of LVC is that few practices are LVC for all patients (7, 50). For example, ordering an x-ray for patients who are being referred for surgery is still appropriate. This has implications for evaluation of the effectiveness of de-implementation strategies and the design of strategies for de-implementation. From an evaluation perspective, it means that it is unclear whether the results should be interpreted because unnecessary orders of x-rays still occur. Another interpretation could be that more patients were receiving the arthrosis diagnosis than the general knee-pain diagnosis, and the number of ordered x-rays indicates that the strategies contributed to more appropriate ordering of x-rays (i.e., correct decisions). More detailed data and analysis of each patient who received an x-ray would be needed to draw such conclusions but was not available in the current case.

In addition to affecting evaluation, the need for specificity and discrimination between occasions when a practice is of value and when it is not may also influence the design of strategies. The findings from the interviews showed that even though participants confirmed that the two strategies influenced behaviors by influencing the targeted contingencies (lecture influencing rule-governing and feedback meetings influencing the three-term contingencies) and other contingencies (lecture influencing the three-term contingency and feedback influencing rule-governing), they also suggested that the feedback was not specific enough. They wanted feedback on whether the ordered x-rays were based on correct or incorrect decisions, thus pointing to the general challenge in the design of strategies for de-implementation. From a theoretical perspective, the strategies were designed to reinforce and thereby increase one behavior and, as a result, lead to a decrease in another, so-called differential reinforcement (28). Differential reinforcement has been suggested for use in de-implementation (44) but has rarely been used (50, 51). However, the participants emphasized that to target the dilemma of few LVC practices being LVC for all patients, approaches are necessary that improve a behavior's precision so it is only present during the right set of circumstances. In applied behavior analysis, this is called discrimination training (28). Reducing LVC with discrimination training would involve providing feedback on the number of correct decisions (i.e., to order an x-ray or diagnose arthrosis without an x-ray when necessary). The feedback would then improve signal detection (i.e., the ability to identify the correct signal to respond to), thereby increasing the precision with which a strategy is applied (52, 53). A similar argument has been expressed in relation to prevalence data for LVC. Most prevalent data are presented *via* so called indirect or volume measures suggesting that less is always better. However, direct measures or value measures of how many patients who should *not* receive a practice would be a more suitable way of measuring prevalence of LVC (54).

To improve how de-implementation is evaluated and strategies are designed, sufficiently precise data is therefore necessary. In our case and in many other clinical settings, such data may not always be available or would substantially increase the burden of data collection. For example, it may require a person trained in the guidelines reviewing the electronic health journals for all patients receiving an x-ray or one of the two diagnoses to determine how

often they were used correctly vs. incorrectly, a task that would be very time consuming, thus making the strategies less feasible. An alternative would be to provide a more intense training with fictive patient cases to deliver precise feedback. A third alternative would be the physicians ordering an x-ray to document whether they were referring the patient for surgery so the data could show correct vs. incorrect decisions. Based on our participants' suggestions for improvement, it may also be sufficient to improve the two strategies used in this study by strengthening their function as rules by more clearly showing how to discriminate between when the practice is valuable and when it is not or by improving the influence on the three-term contingency (more specific problem solving during the feedback meetings).

Implementation science and applied behavior analysis have similar aims, to change socially significant behaviors to create meaningful change. Implementation science has contributed with empirical studies of many different types of strategies available for both implementation and de-implementation purposes. Applied behavior analysis adds to this by using a theory of human behavior that has been applied across settings for decades, providing a way to understand which factors, out of a multitude, that need to be addressed to change behaviors as well as providing a structure for analyzing which strategies could address these factors. Thus, applied behavior analysis may provide a valuable addition to the field of implementation by offering a theoretically guided way of matching strategies to barriers.

4.1. Implications for research and practice

The study's results are inconclusive but have some implications for research and practice. The participants found the approach feasible, perceived positive results from the two strategies, and suggested further improvements of the strategies and how they could be used for other examples of LVC. This suggests that using applied behavior analysis to plan and evaluate strategies for de-implementation could be valuable. To improve the approach, knowledge from discrimination training could be used. The approach could also benefit from a continuous improvement approach by being used in several iterations in which feedback from the professionals is used to improve the strategies, which are tested again and improved based on feedback again, making them more precise in their influence on the targeted behaviors [similar to, e.g. (55),]. Similar steps as those taken in this study could be taken in practice to tailor strategies to local contexts and evaluate their effects. "Perfect" data is rarely available in practice but could be good enough to be used for improvements in health care (56).

4.2. Methodological considerations

The study has some limitations that need to be recognized when one interprets the findings. This is a small study of one primary care center, which limits our ability to draw firm conclusions and generalize results. However, the combination of quantitative and qualitative data enabled a comprehensive investigation of the process and the two strategies, including their perceived strengths and limitations.

Furthermore, the COVID-19 pandemic may have impacted the results. The general belief at the center was that patients were returning to a more normal level of help seeking during the time of the study. However, if patients had waited to seek help during the pandemic, this may have resulted in increased symptom severity. This could indicate a higher likelihood of patients needing an x-ray for referral to knee surgery. As the patient population gradually returned to normal, a decrease in the number of patients needing x-rays would be natural. We tried to compensate for that by examining a longer period for the data (see APPENDIX 1 in the **Supplementary Material**) and subjectively evaluating the development of patient visits to the center in general to decide on a reasonable time frame for the baseline data and the study.

Another limitation of the study was the lack of individual-level data. The administrative system did not allow us to extract data on the individual physician level, which may have influenced the results because the number of physicians at the center can influence the number of patients who could be referred for an x-ray. It was also not possible to extract only data regarding the physicians who had participated in the lecture and the feedback meetings, which diluted the strategy's effect. However, the two strategies could also have influenced the entire center even though not everyone participated. The physicians likely discussed the study topic with colleagues and other professions outside of the meeting. The lack of individual-level data also made the feedback component less effective because the feedback never included information on whether each decision had been right or wrong. In theory, a decision not to use an x-ray could have been the wrong decision, and the decision to use an x-ray could have been right. We tried to control for this by also providing feedback on how many patients received the arthrosis diagnosis during the same time frame under the assumption that the more confident the physicians would be in diagnosing patients with arthrosis, the more patients would receive the diagnosis in relation to the number of patients who received an x-ray.

The study also has several strengths. It provides a theoretical approach to de-implementation that makes it possible to analyze influencing factors related to the use of LVC and the mechanism underlying strategies for de-implementation. Our detailed analysis also makes it possible to understand how the same types of strategies can work differently depending on how they manage to influence the targeted contingencies. It also shows that different strategies can work in the same way, by influencing the same contingencies.

5. Conclusions

The findings illustrate how applied behavior analysis can be used to analyze contingencies related to the use of LVC and to design strategies for de-implementation. It also shows an effect of

the targeted behaviors even though the quantitative results are inconclusive. The conclusion from the qualitative analysis widens the understanding of how different strategies influence existing contingencies related to the use of LVC. The strategies used in this study could be further improved to target the contingencies better by structuring the feedback meetings better and including more precise feedback.

Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

Ethics statement

The studies involving human participants were reviewed and approved by the Swedish Ethical Review Authority (Ref no. 2021-03529). The patients/participants provided their written informed consent to participate in this study.

Author contributions

SI, IS, PN, HH, HA and UvTS participated in designing the study. SI recruited the primary care center. SI and HH met with the center to inform about the study, discuss possible LVC to focus on and gather input on possible strategies. SI then continued with the planning of the strategies, participated as an observer at the lecture, collected and presented to data for the feedback-meetings and observed the discussions during those meeting. SI also conducted the interviews and transcribed them. SI and IS did the first analyses of the data and the results was discussed several times with all authors. SI drafted the first version of the article with assistance from UvTS. SI, IS, PN, HH, HA and UvTS discussed the draft, revised it and approved the final manuscript. All authors contributed to the article and approved the submitted version.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Publisher's note

Supplementary material

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/frhs.2023.1099538/full#supplementary-material.

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Repeated measures of implementation variables

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It is commonly acknowledged that implementation work is long-term and contextual in nature and often takes years to accomplish. Repeated measures are needed to study the trajectory of implementation variables over time. To be useful in typical practice settings, measures that are relevant, sensitive, consequential, and practical are needed to inform planning and action. If implementation independent variables and implementation dependent variables are to contribute to a science of implementation, then measures that meet these criteria must be established. This exploratory review was undertaken to "see what is being done" to evaluate implementation variables and processes repeatedly in situations where achieving outcomes was the goal (i.e., more likely to be consequential). No judgement was made about the adequacy of the measure (e.g., psychometric properties) in the review. The search process resulted in 32 articles that met the criteria for a repeated measure of an implementation variable. 23 different implementation variables were the subject of repeated measures. The broad spectrum of implementation variables identified in the review included innovation fidelity, sustainability, organization change, and scaling along with training, implementation teams, and implementation fidelity. Given the long-term complexities involved in providing implementation supports to achieve the full and effective use of innovations, repeated measurements of relevant variables are needed to promote a more complete understanding of implementation processes and outcomes. Longitudinal studies employing repeated measures that are relevant, sensitive, consequential, and practical should become common if the complexities involved in implementation are to be understood.

KEYWORDS

implementation, scaling, measurement, validity, replication

Introduction

Measurement of implementation variables in practice has been a challenge because of the complexities in human service environments, the novelties encountered in different domains (e.g., education, child welfare, global public health, pharmacy), and the ongoing development of implementation as a profession and as a science.

Greenhalgh et al. (1) conducted an extensive review of the diffusion and dissemination literature. They reflected a commonly held view when they concluded: "Context and "confounders" lie at the very heart of the diffusion, dissemination, and implementation of complex innovations. They are not extraneous to the object of study; they are an integral part of it. The multiple (and often unpredictable) interactions that arise in particular contexts and settings are precisely what determine the success or failure of a dissemination initiative." For a science of implementation to develop, measures of implementation-specific independent and dependent variables must be established and used in multiple studies. Those variables and measures must be usable across the "multiple (and often unpredictable)" situations Greenhalgh et al. described.

Implementation is viewed by many as a process that takes time and planned activities at multiple levels so that innovations can be used fully and effectively and at scale (2). Yet, studies labeled as "implementation science" predominately use unique measures and one-time assessments of something of interest to the investigator (3, 4). Currently, avid readers of the "implementation science" literature are hard pressed to find a measure of an implementation-specific independent or dependent variable. Even when one is found, one data point at one point in time is a poor fit with the complexity of implementation as described in the literature. For example, Allen et al. (4) reviewed the literature related to the "inner setting" of organizations as defined by the Consolidated Framework for Implementation Research (CFIR). Consistent with previous findings from a review and synthesis of the implementation evaluation literature (3), Allen et al. found only one measure that was used in more than one study and noted that the definitions of constructs with the same name varied widely across the measures.

Repeated measures of multiple variables are needed to match the complexity of the practice, organization, and system environments in which changes must occur to support the full and effective uses of innovations in practice. Researchers have documented the years typically required to accomplish implementation goals (5, 6) even when skilled implementation teams are available (7). To advance a science of implementation, repeated measures and methods must be well suited to cope with research in applied settings where there are too few cases, too many variables, and too little control over multi-level variables that may impact outcomes (8, 9).

Implementation specialists and researchers who are doing the work of implementation and studying the results over time continually deal with complexity and confounders to accomplish their implementation practice and science aims (10). In their description of implementation practice and science, Fixsen et al. (10, chapter 16) proposed criteria for "action evaluation" measures that can be used to inform action planning and monitor progress toward full and effective use of innovations. Action evaluation measures are: (1) *relevant* and include items that are indicators of key leverage points for improving practices, organization routines, and system functioning, (2) *sensitive* to changes in capacity to perform with scores that increase as capacity is developed and decrease when setbacks occur, (3) *consequential* in that the items are important to the respondents and users and scores inform prompt action planning; repeated assessments each year monitor progress of action planning as capacity develops and outcomes are produced, and (4) *practical* with modest time required to learn how to administer assessments with fidelity to the protocol, and modest time required of staff to respond to rate the items or prepare for an observation visit.

While the lack of assessment of psychometric properties has been cited as a deficiency (11–13), what is missing from nearly all of the existing implementation-related measures is a test of consequential validity (14). That is, evidence that the variable under study, and the information generated by the measure of the variable, is highly related to using an innovation with fidelity and related to producing intended outcomes to benefit a population of recipients. Given that implementation practice and science are mission-driven (15), consequential validity is an essential test of any measure, an approach that favors external validity over internal validity (16, 17).

Galea (18), working in a health context, stated the problem and the solution clearly:

> A consequentialist approach is centrally concerned with maximizing desired outcomes, and a consequentialist epidemiology would be centrally concerned with improving health outcomes. We would be much more concerned with maximizing the good that can be achieved by our studies and by our approaches than we are by our approaches themselves. A consequentialist epidemiology inducts new trainees not around canonical learning but rather around our goals. Our purpose would be defined around health optimization and disease reduction, with our methods as tools, convenient only insofar as they help us get there. Therefore, our papers would emphasize our outcomes with the intention of identifying how we may improve them.

By thinking of "our methods as tools, convenient only insofar as they help us get there" psychometric properties may be the last concern, not the first (and too often, only) question to be answered. The consequential validity question is "so what?" Once there is a measure of a variable it is incumbent on the researcher (the measure developer) to provide data that demonstrates how knowing that information "helps us get there." Once a measure of a variable has demonstrated consequential validity then it is worth investing in establishing its psychometric properties to fine tune the measure. It is worth it because the variable matters and the measure detects its presence and strength.

This exploratory review was undertaken to "see what is being done" to measure implementation variables and processes in situations where achieving outcomes was the goal (i.e., more likely to be consequential). The interest is in measures that are relevant, sensitive, consequential, and practical. In particular, given the long-term and contextual nature of implementation work that often takes years to accomplish, the search is for studies that have used repeated measures to study the trajectory of implementation variables over time. For this review, a measure that has been used more than once in a study is an indication that the measure is relevant to the variable under study, sensitive to change in the variable from one data point to the next, consequential with respect to informing planning for change, and practical by virtue of being able to be used two or more times to study a variable.

Materials and methods

The review was conducted within the Active Implementation Research Network (AIRN) EndNotes data base. The AIRN EndNotes data base contains 3,950 references (March 20, 2021)

that pertain to implementation with a bias toward implementation evaluation and quantitative data articles. The oldest reference relates to detecting and evaluating the core components of independent variables (19). The most recent article describes over 10 years of work to scale up innovations in a large state system (20).

In 2003 the AIRN EndNotes data base was initiated by entering citations from the boxes of paper copies of articles accumulated by the authors since 1971, the year of the first implementation failure experienced by the first author (21). Beginning in 2003 AIRN EndNotes was expanded with references produced from literature searches conducted through university library services (3). Since 2006, articles routinely have been added through Google Scholar searches. Weekly lists of articles identified with the implementation-related search terms are scanned and relevant citations, abstracts (when available), and PDFs (when available) are downloaded into AIRN EndNotes. For inclusion in the database, articles reporting quantitative data are favored over qualitative studies or opinion pieces. Reflecting the universal relevance of implementation factors, the data base includes a wide variety of articles from multiple fields and many points of view. About 2/3 of the articles in AIRN EndNotes were published in 2000–2021.

The majority of articles in AIRN EndNotes published since 2000 include the Abstract and/or a PDF, and the full text of about half of all the articles has been reviewed by the authors and their colleagues. The reviewer of an article enters information in the "Notes" section of EndNotes regarding concepts and terms that relate to the evidence-based Active Implementation Frameworks as they are defined, operationalized, evaluated, and revised (3, 7, 15, 22–27). Given the lack of clarity in the implementation field, the Notes provide common concepts and common language that facilitate searches of the AIRN EndNotes data base.

For this study, the AIRN EndNotes data base was searched for articles that used repeated measures of one or more implementation variables. Using the search function in EndNotes, "Any Field" (i.e., title, abstract, keywords, notes) in the data base was searched using the word "measure" *and* the term "repeated," or "longitudinal," or "pattern," or "stepped wedge." The search returned 260 references. Because searches of the literature were less systematic in the pre-internet days, references published prior to the year 2000 were eliminated leaving 213 references. The title and abstract of each of the 213 articles was reviewed and those with apparent repeated measures of an implementation variable were retained ($n = 58$).

The full text of the remaining 58 references was reviewed. For the full text review, "repeated" was defined as two or more uses and "measure" was defined as the same method (observation, record review, survey, systematic interview) with the same content used at Time 1, Time 2, etc. No judgement was made about the adequacy of the measure or time frames. Thus, psychometric properties of a measure were not considered in the review. "Implementation" was defined as any specific support (e.g., training, coaching, leadership, organization changes) for the full and effective use of an identified innovation.

The full text review eliminated 26 articles. The reasons for elimination are provided in Table 1. For example, 13 articles were eliminated because the repeated measure concerned an intervention and not an implementation variable and 7 were eliminated because the same measure was not repeated from one time period to the next.

TABLE 1 Articles eliminated after full text review.

Reason for Eliminating an Article	Number of Articles
Intervention variables only - not a study of implementation	13
Same measure was not repeated	7
Measure development with a convenience sample	2
An open-ended interview - not a measure	1
Qualitative study - no measures	1
Reprint of an evaluation already included for study	1
Implementation variables identified but not measured	1

Results

The search process resulted in 32 articles that met the criteria for a "repeated" "measure" of "implementation" variables: in 17 articles 2 or more variables were measured and in 15 articles one variable was measured. Fourteen (14) of the articles were published in 2000–2010 and 18 were published in 2011–2019.

As noted in Table 2, 23 different implementation variables were the subject of repeated measures. In Table 2 the Implementation Variable names are grouped using the Active Implementation Frameworks as a guide (10). The broad spectrum of implementation variables included innovation fidelity (assessed in 17 articles), sustainability (assessed in 8 articles), organization change (assessed in 6 articles), and scaling (assessed in 5 articles). Training, implementation teams, and implementation fidelity were the subject of 2 articles each.

Table 3 details the individual articles, the assessments they reported, and the implementation variables that were studied.

Discussion

It is heartening to see the breadth of implementation-specific variables that have been measured two or more times in one or more studies. Given the long-term complexities involved in providing implementation supports to achieve the full and effective use of innovations, repeated measurements of relevant variables are needed to promote a more complete understanding of implementation processes and outcomes. Yet, this exploratory review found few examples in the literature.

It is discouraging to see so few articles reporting repeated measures. The review found only 32 articles among the 3,950 mostly implementation evaluation articles, and provide an indicator of what must be done to advance the field. Implementation practice and science would be well served by

TABLE 2 Implementation variables measured two or more times in the 32 articles.

Implementation Variable	Number of Articles
Related to Implementation Stages	
Exploration Stage	1
Community readiness	1
Organization readiness	1
Initial Implementation Stage	1
Related to Implementation Drivers	
Competency Drivers	1
Training	2
Coaching	1
Innovation fidelity	17
Organization Drivers	1
Organization change	6
Organization capacity	1
Leadership Drivers	1
Other	
Implementation Teams	2
Improvement cycles	1
Implementation capacity	1
Implementation fidelity	2
System change	1
Scaling	5
Sustainability	8
TA Collaboration	1
Attitude toward EBPs	1
Organization culture	1
Organization climate	1

investing in using and improving the measures identified in this review. The measures already have been developed and used in practice and appear to be relevant (they assess the presence and strength of an implementation-specific variable), sensitive (results showed change from one administration to the next), and practical (able to be administered repeatedly in practice). The field would benefit by using these measures in a variety of studies to establish more fully their consequential validity (does the variable being assessed impact the use and effectiveness of innovations). Meeting the criteria for action evaluations is a good start for the development of any measure.

As found in this study, there are good examples of repeated measures of implementation-specific variables in complex settings. Szulanski and Jensen (43) studied innovation fidelity and outcomes for over 3,500 franchises, each with 16 data points spanning 20 years for a total of 56,000 fidelity assessments that showed detrimental outcomes associated with lower fidelity in the early years and improved outcomes associated with lower fidelity after year 17. McIntosh et al. (35) studied innovation fidelity in 5,331 schools for 5 years, a total of 26,655 fidelity assessments that allowed the researchers to detect patterns in achieving and sustaining fidelity of the use of an evidence-based program. For 10 years Fixsen and Blase (41) studied innovation fidelity every six months for practitioners in 41 residential treatment units, a total of 820 fidelity assessments that detected positive trends among new hires as the implementation supports in the organization matured. Datta et al. (32) collected data for two years with 41 data points to track the effectiveness of continual attempts to produce improved outcomes for neonates admitted to the neonatal intensive care unit.

Innovation fidelity also has been assessed at an organization level. McGovern et al. (45) developed the Dual Diagnosis Capability in Addiction Treatment (DDCAT) to assess the dual diagnosis (substance abuse and mental health) capability of addiction treatment services. DDCAT items assess: (1) Program Structure; (2) Program Milieu; (3) Clinical Process: Assessment; (4) Clinical Process: Treatment; (5) Continuity of Care; (6) Staffing; and (7) Training. Organization dual diagnosis treatment capacity was measured at baseline and at 9-month follow-up in a cohort of 16 addiction treatment programs, 32 data points that found assessment, feedback, training, and implementation support were most effective in changing organization capacity. The DDCAT has been used in other studies by different authors to assess capacity (33, 47).

In these and other examples cited in this article, the measures of implementation variables are meaningful (relevant) and are repeated (practical) so that trends (sensitive) can be detected and corrected (if needed). Consequential validity was reported in these examples and in other articles (e.g., 43, 48, 49) and requires further study.

Innovation fidelity ($n = 17$) was the most frequent repeated measure. Innovation fidelity always is specific to the innovation under consideration. Implementation fidelity, on the other hand, refers to implementation-specific variables being used as intended. A science of implementation and assessments of implementation fidelity are intended to be universal. For example, the drivers best practices assessment (DBPA; 59, 60) measures the presence and strength of the implementation drivers (10, 15, 26, 27) that relate to (a) competency (selection, training, coaching, fidelity), (b) organization (facilitative administration, decision support data system, system intervention), and c) leadership (technical, adaptive). As shown in **Table 2**, over half of the measures ($n = 30$; **Table 2**) reported in the articles assessed one or more variables related to the implementation drivers. The DBPA has been used to assess implementation fidelity in a variety of settings and organizations, demonstrating a strong association with intended uses of evidence-based programs (61–64). As action measures are used in practice, the statistical (psychometric) properties can be assessed (61, 65).

These longitudinal studies are not typical, but they should be. After, before and after, one-time, or short-term assessments may be interesting but may add little to the science of implementation. To do something once or even a few times is interesting. To be able to do something repeatedly with useful outcomes and documented improvements over decades will produce socially significant benefits for whole populations (66). Data on the processes of implementation over time are badly needed.

There is much to be done to establish a science of implementation that has useful and reliable measures of implementation-specific independent (if…) and dependent (then…) variables. Implementation theory (67–69) can become the source of predictions (if…then) that can be tested in practice.

TABLE 3 The information in the table was sorted alphabetically based on the implementation Variable column (information regarding the implementation Variable can be found at www.activeimplementation.org).

Article	Repeated Measure	Implementation Variable
Strand et al. (28)	Each of the 6 sites selected an implementation team to carry out the initiative. Measures developed for this project included a key informant interview to assist in agency selection and an Organizational Readiness Assessment (ORA). The ORA was used across sites every 6 months. The ORA eight factors included three that aligned with the Organization driver, two factors that aligned with the Competency driver, two that aligned with the Leadership driver, and one stand-alone factor, Attitude Toward Evidence-based Treatment that consisted of one item.	Competency Drivers; Organization Drivers, Leadership Drivers; Attitude toward EBPs
Panzano et al. (29)	A longitudinal study designed to collect a range of interview, survey, and implementation outcome data in 91 agencies and relate the data from earlier stages to later stages. At 9-month intervals Panzano and colleagues followed a group of 91 agencies that had committed to and were funded to use one of several evidence-based programs in a state mental health system. The 91 agencies engaged in Exploration and Installation activities but 44 (48%) never used a selected program (i.e., did not reach the Initial Implementation Stage).	Exploration Stage; Initial Implementation Stage; Sustainability
Vernez et al. (30)	Assessed School staff commitment, Professional development, Adequacy of resources, External assistance, Internal facilitator, Feedback on instruction, and District support at 3 points: Yrs. 1–3, 4–6, 7 + using standard RAND-University of Washington principal and teacher surveys.	Implementation fidelity
Fixsen and Blase (21)	Implementation fidelity and organization sustainability measured repeatedly for 59 attempted replications of organizations using an evidence-based program with fidelity	Implementation fidelity; Sustainability
Fixsen et al. (31)	Assess implementation capacity development every six months for five years in state education systems. Measures assessed Leadership Investment (implementation roles and functions, coordination for implementation, leadership), System Alignment (implementation guidance documents, state design team), Commitment to Regional Implementation Capacity Development (resources for regional implementation capacity development, support for RIT functioning)	Implementation Teams; Scaling
Datta et al. (32)	The team set an aim of eliminating severe hypothermia and reducing moderate hypothermia by 50%. 41 data points over two years. Repeated PDSA Cycles with interventions to solve each set of problems exposed in the last cycle. Evaluated staff training (improving hand hygiene), administrative changes (team met weekly; supervised change; consistent supply of warm linen), facility changes (placement of charging leads for transportation incubators).	Improvement cycles; Organization change; Practitioner training
Lee and Cameron (33)	The Dual Diagnosis Capability in Addiction Treatment (DDCAT) index is a fidelity instrument for measuring alcohol and other drug treatment services' capacity to provide comorbidity service to clients. Measures were taken the week prior to the PsyCheck training and 6 months after the training at each site (13 sites).	Innovation fidelity
Hardeman et al. (34)	A measure of fidelity was developed and tested across practitioners. Repeated measures of four sessions.	Innovation fidelity
McIntosh et al. (35)	Assessed fidelity annually for 5,331 schools over a 5-year course of implementing school-wide positive behavioral interventions and supports (SWPBIS). Four patterns of developing and sustaining fidelity were found.	Innovation fidelity; Sustainability
Tiruneh et al. (36)	Before and after data from 134 intervention health centers were collected in April 2013 and July 2015. [27 mos.] A BEmONC implementation strength index was constructed from seven input and five process indicators measured through observation, record review, and provider interview. The BEmONC implementation strength index score ranged between zero and ten. Assessments were made pre-post tailored support (including BEmONC training to providers, mentoring and monitoring through supportive supervision, provision of equipment and supplies, strengthening referral linkages, and improving infection-prevention practice) provided in a package of interventions to 134 health centers, covering 91 rural districts of Ethiopia to ensure BEmONC care.	Innovation fidelity
Shapiro et al. (37)	During the 2011–2012 academic year, 170 teachers of prekindergarten through second grade across all 15 elementary schools in a Pennsylvania school district (targeting approximately 4,000 elementary-school students) were trained in PATHS and asked to deliver it in accordance with the curriculum manual. Two grant-supported technical-assistance providers (TAs) were hired to support PATHS implementation. The TAs worked with teachers to schedule monthly (8 times during the school year) classroom observations (eight observations of each teacher during the school year). To assess fidelity the TAs completed the 19-item PATHS Monthly Implementation Rating Form (provided by PATHS developers) during each observation. For the purposes of this study, 10 of the items were used to examine overall lesson implementation quality [innovation fidelity], specific dimensions of implementation, and teacher characteristics.	Innovation fidelity
Hoekstra et al. (38)	Evidence-informed physical activity promotion program in Dutch rehabilitation care. Fidelity scores were calculated based on annual surveys filled in by involved professionals ($n = \pm 70$). Fidelity scores of 17 organizations at three different time points. Three trajectories were identified as the following: "stable high fidelity" ($n = 9$), 'moderate and improving fidelity' ($n = 6$), and 'unstable fidelity' ($n = 2$).	Innovation fidelity
Chinman et al. (39)	Fidelity (adherence, quality of delivery, dosage) and the proximal outcomes of the youth participants (aged 10–14)—attitudes and intentions regarding cigarettes, alcohol, and marijuana use. Fidelity was assessed at all sites by observer ratings and attendance logs. Proximal outcomes were assessed *via* survey at baseline, 3, and 6 months. Fidelity was assessed at all sites by observer ratings and attendance logs. Proximal outcomes were assessed *via* survey at baseline, 3, and 6 months. A 2-year implementation support intervention. It compares 15 Boys and Girls Club sites implementing CHOICE (control group), a five-session evidence-based alcohol and drug prevention program, with 14 similar sites implementing CHOICE supported by GTO (intervention group).	Innovation fidelity
Rahman et al. (40)	In the first 3 months, functional water seals were detected in 33% (14/42) of latrines in the sanitation only arm; 35% (14/40) for the combined WSH arm; and 60% (34/57) for the combined WSH and Nutrition arm, all falling below the pre-set benchmark of 80%. Other fidelity indicators met the 65 to 80% uptake benchmarks. Rapid	Innovation fidelity

(*continued*)

TABLE 3 Continued

Article	Repeated Measure	Implementation Variable
	qualitative investigations determined that households concurrently used their own latrines with broken water seals in parallel with those provided by the trial. In consultation with the households, the authors closed pre-existing latrines without water seals, increased the CHWs' visit frequency to encourage correct maintenance of latrines with water seals, and discouraged water-seal removal or breakage. At the sixth assessment, 86% of households in sanitation-only; 92% in the combined WSH; and 93% in the combined WSH and Nutrition arms had latrines with functional water seals.	
Fixsen and Blase (41)	Innovation fidelity for practitioners in 41 units assessed every six months for 10 years. Practitioners employed for 2 years or more remained at high fidelity each year even with turnover in staffing. Over 10 years, repeated measures noted substantial improvements for practitioners in the newly hired 0–6 month group and the 7-12 month group at each data point. The fidelity scores for these less experienced practitioners increased over 10 years from around 3 to over 5 on a 7-point scale.	Innovation fidelity; Sustainability
Jensen (42); Szulanski and Jensen (43)	Monthly performance data and two types of adaptation indicators, the addition of new routines and the modification of existing ones, for a majority of the U.S. units (approx. 3,500) of a large non-food franchisor. The results indicate that despite possibly increasing fit with the local environment, adapting recommended organizational routines results in poorer performance rather than greater. 5 data points in first year then every other year or so with 16 data points up to year 20.	Innovation fidelity; Sustainability
Althabe et al. (44)	Ten hospitals were assigned to the intervention group and nine to the control group. Pre-post assessments of changes in policies regarding active management of the third stage of labor, prophylactic use of oxytocin, or episiotomy as recommended by evidence-based obstetrical practices. The outcomes were measured at baseline, at the end of the 18-month intervention, and 12 months after the end of the intervention.	Innovation fidelity
McGovern et al. (45)	The Dual Diagnosis Capability in Addiction Treatment (DDCAT) index consists of 35 items, rated on a 5-point ordinal scale. Fidelity assessed using the DDCAT at three points in time over an 18-month period.	Innovation fidelity
Parvez et al. (46)	Enabling technologies and behavior change were promoted by trained local community health workers through periodic household visits. To monitor technology and behavioral uptake, the authors conducted surveys and spot checks in 30-35 households per intervention arm per month, over a 20-month period, and structured observations in 324 intervention and 108 control households, approximately 15 months after interventions commenced.	Innovation fidelity
Chaple and Sacks (47)	On average, programs ($n = 150$) received a follow-up assessment nearly 2 years after their baseline assessment. The baseline sample consisted of 603 outpatient programs licensed to operate in New York State. A follow-up sample of 150 programs was randomly selected to evaluate the impact of technical assistance and implementation support. Assessment Tools: The DDCAT6 and DDCMHT7 indices employed in this study included 35 items organized into 7 dimensions: (1) Program Structure, four items; (2) Program Milieu, two items; (3) Clinical Process—Assessment, seven items; (4) Clinical Process—Treatment, ten items; (5) Continuity of Care, five items; (6) Staffing, five items; and (7) Training, two items. Each item was scored on a 5-point scale of Dual Diagnosis Capability with three anchor points.	Innovation fidelity; Organization change
Aladjem and Borman (48)	Four evidence-based comprehensive school reform models designed for grades K–8 were studied in 170 "model" schools: Accelerated Schools (AS), Core Knowledge (CK), Direct Instruction (DI), and Success for All (SFA). Repeated measures over 5 years of teachers' initial training, ongoing professional development, and external assistance from model developers/consultants. Assessment of the time allocated to an internal school staff member to facilitate and coordinate model implementation. The use of prescribed components of each model was assessed in each school at each time period.	Innovation Fidelity; Practitioner Training; Practitioner Coaching;
Forgatch and DeGarmo (49)	Evaluated innovation fidelity over the course of three generations of practitioners trained in PMTO. Generation 1 (G1) was trained by the PMTO developer/purveyors; Generation 2 (G2) was trained by selected G1 Norwegian trainers; and Generation 3 (G3) was trained by G1 and G2 trainers.	Innovation fidelity; Scaling
Kim et al. (50)	The authors used a cluster-randomized design with repeated cross-sectional surveys at baseline (2010, $n = 2188$), endline (2014, $n = 2001$), and follow-up (2016, $n = 2400$) in the same communities, among households with children 0–23.9 mo of age. Intervention exposure was measured by maternal recall of home visits (by BRAC frontline workers) received in the last 6 mo, number of times visited, attendance at a CM activity in the last 1 yr. and recall of ever having seen the A&T TV spots.	Innovation fidelity; Sustainability; Scaling
Litaker et al. (51)	In the setting of an intervention to increase preventive service delivery (PSD), the authors assessed practice capacity for change by rating motivation to change and instrumental ability to change on a one to four scale. After combining these ratings into a single score, random effects models tested its association with change in PSD rates from baseline to immediately after intervention completion and 12 months later.	Organization capacity
Parker (52)	Used established measures of job autonomy, skill utilization, participation in decision making, role overload to assess pre-post introduction of 3 lean production practices: lean teams, assembly lines, and workflow formalization. 4 groups surveyed over 3 yr period	Organization change
Jetten et al. (53)	Organization identification, Changing identity, Uncertainty, and Affect were assessed using an existing questionnaire. Administered about a month before and again about a month after a planned restructuring of work teams.	Organization change
Das et al. (54)	The facility assessment (readiness) tool focused on the infrastructure, training facilities, workforce, service delivery related to delivery and newborn care, practices, protocols, guidelines followed, communication, supplies, referral, and transport facility, documentation and reporting, and monitoring and supervision at the facilities. The authors used 26 maternal and newborn care signal function indicators, focusing on delivery, and postnatal care for assessing the readiness of the facilities for both routine and emergency care in health facilities. These 26 signal functions included general services and facilities (4 functions), routine obstetric care (3 functions), basic	Organization change; Organization readiness

(*continued*)

TABLE 3 Continued

Article	Repeated Measure	Implementation Variable
	emergency obstetric care (5 functions), comprehensive obstetric care (2 functions), routine newborn care (3 functions), basic emergency newborn care (6 + 1 function), and comprehensive emergency newborn care (2 functions). Pre-post intervention assessment.	
Ryan Jackson et al. (55)	Measuring implementation capacity at every level of the system for full and effective use of a practice that benefits all students is critical to alignment and cohesion of implementation efforts. Over 40 months, capacity is measured every 6 months using the State Capacity Assessment (SCA: Fixsen et al. (70)), Regional Capacity Assessment (RCA: St. Martin et al. (71)), District Capacity Assessment (DCA: Ward et al. (72)), and the school level, Drivers Best Practice Assessment (DBPA: Fixsen et al. (73)).	Organization change; system change; scaling; implementation teams; implementation capacity
Smith et al. (56)	Evaluate the comparative effectiveness of the Immediate vs. Delayed Enhanced REP sequences in 89 VA sites. Organization culture or climate measure at 6 and 12 months post-randomization. Organizational culture and climate measures came from the 2012 VA All Employee Survey (AES), a national survey of employees focused on organizational culture and climate distributed anonymously on a yearly basis.	Organization culture; Organization climate
Fixsen et al. (7, 22)	Assess the number of attempted replications of an evidence-based program over 10 years. Proximity discriminated early failures from successes (the group homes closer to the training staff got more personal, on-site observation and feedback). Given this, the focus shifted to developing Teaching-Family Sites instead of individual group homes. Longer term data showed that this had a large impact on sustainability (about 17% of the individual homes lasted 6 + years while over 80% of the group homes associated with a Teaching-Family Site lasted 6 + years).	Scaling; Sustainability
Massatti et al. (57)	IDARP is a longitudinal study with data gathered at approximately 9-month intervals. This analysis uses data gathered from the first three contact points. To collect information at each interval, a trained two-person team conducted confidential semi-structured interviews with multiple key informants. For organizations that discontinued their chosen evidence-based program, researchers asked key informants during the open-ended portion of the interview to provide the primary reasons for de-adoption.	Sustainability
Chilenski et al. (58)	PROSPER project intervention communities ($n = 14$) in Pennsylvania and Iowa composed the sample. Assessed TA collaboration (7 items); community readiness (15 items); Substance use norms (six items). 14 data points over 4.5 years.	TA Collaboration; Community readiness

In this way, like any science, a science of implementation can be cumulative and "crowdsourced" globally as theory-based predictions are tested and theory itself is improved or discarded.

Limitations

In the current study, the AIRN EndNotes data base provided a convenient sample for the search that was conducted. Thus, the results of the search offer an indication regarding repeated measures of implementation variables. An exhaustive search of all available sources may produce a different view of the field.

Data availability statement

The original contributions presented in the study are included in the article/Supplementary Material, further inquiries can be directed to the corresponding author/s.

Ethics statement

Ethical review and approval was not required for this study in accordance with the local legislation and institutional requirements.

Author contributions

All authors contributed to the article and approved the submitted version.

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Conflict of interest

All the authors were employed by Active Implementation Research Network, Inc.

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Theorizing is for everybody: Advancing the process of theorizing in implementation science

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There has been a call to shift from treating theories as static products to engaging in a process of theorizing that develops, modifies, and advances implementation theory through the accumulation of knowledge. Stimulating theoretical advances is necessary to improve our understanding of the causal processes that influence implementation and to enhance the value of existing theory. We argue that a primary reason that existing theory has lacked iteration and evolution is that the process for theorizing is obscure and daunting. We present recommendations for advancing the process of theorizing in implementation science to draw more people in the process of developing and advancing theory.

KEYWORDS

theorizing, determinant prioritization, mechanisms, implementation science, causality

1. Introduction

Theories and frameworks (i.e., theoretical products) bring clarity to complex systems within which implementation occurs (1) and provide explicit assumptions that can be collectively tested, validated, or refined (2) (see **Table 1** for definitions). As such, they support efficiency in generalizing knowledge across contexts (3). Determinant frameworks commonly describe *what* is likely to impact implementation by defining and organizing determinants while implementation theories often provide explanations for *how* change is believed to occur (2). Theoretical products are often used deductively to guide empirical enquiry, yet we fail to inductively modify theory based on findings (1, 4, 5). In doing so, we miss opportunities to advance theory in light of accumulating evidence, leaving implementation science susceptible to stagnation.

There has been a call to shift from treating theories as static products to engaging in a process of theorizing that *draws on empirical data* to develop, validate, modify or expand theoretical explanations in implementation science (4). Theorizing, as described here, includes the development of new explanations, but also the refinement of existing theoretical explanations. Everyone has the potential to contribute to theorizing, but many do not explicitly do so. This is partly due to two reasons. First, our understanding of what constitutes a theory is too grand. Others have outlined the characteristics of strong theory, such as clarity in relationships between concepts, explanatory power, and generalizability (6). These characteristics are the aspirational endpoint of good theories, not the starting point.

TABLE 1 Terminology.

Terminology	Description
Postulate	A proposition or explanation to be investigated.
Concept	A theoretical entity used in a postulate.
Hypothesis	Data statements that form the basis for testing a postulate.
Theory	"An organized, heuristic, coherent, and systematic set of statements related to significant questions that are communicated in a meaningful whole." (12)
Determinant framework	Articulate determinants that act as barriers and facilitators that influence implementation outcomes.
Grand theories	Broad theories made up of abstract concepts and postulates. Grand theories tend to be general enough to be widely applicable across contexts.
Middle-range theories	Theories with a narrower scope, less abstract, and have a higher degree of contextualization than grand theories. They fall between working hypotheses and all-inclusive grand theories. Their lower level of generalizability can allow for greater accuracy.
Micro-theory	Narrow scope theories that tend to focus on explaining a specific phenomenon within a particular context or population. These narrow scope theories can include a theory of the problem, such as explaining how determinants jointly impede implementation in a particular context or a theory of the solution, such as a program theory that provides an explanation about how a specific policy, intervention, or project is believed to function.
Theorizing	A process that draws on empirical data to develop, validate, modify or expand theoretical explanations.
Multiple working hypotheses	A process of proposing multiple competing hypotheses that can be tested within a single study.

Second, many do not engage in theorizing due to a failure to recognize opportunities for research to contribute to advancing, refining, or (in)validating theory. When findings conflict with theory, authors rarely question the theory's validity, but rather consider explanations such as weaknesses in study design (7). Researchers should be empowered to challenge theory, regardless of its popularity, prestige, or longevity when warranted by evidence.

Increasing explicit engagement in theorizing will require that researchers are equipped with tools to support theorizing. Inspired by writers like bell hooks who sought to communicate feminist thinking in a way that was accessible to everyone (8), we strive to make clear how theorizing is for everybody. To facilitate this, we draw on the building blocks of theory (9, 10) to describe how empirical research can advance the parsimony and comprehensiveness of theory, and elucidate the boundary conditions under which theory is most accurate. We illustrate how these building blocks can be used to develop micro-theories that provide explanations for how implementation determinants influence implementation. Lastly, we discuss how adopting multiple working hypotheses can discourage the calcification and reification of premature theories by arbitrating between multiple tenable explanations for a phenomenon (11).

2. Theorizing in implementation science

2.1. Sources for theorizing

Theorizing can be inspired by direct observation or vicariously through the synthesis of existing knowledge. Existing theoretical products in implementation science have stemmed from developers' experience, synthesis of empirical evidence, and drawing on or synthesizing existing theories and frameworks (2). Micro, middle-range, and grand theories can have reciprocal influences on one another. For instance, lower-order theories can be inspired by focusing on a narrow element of a grand theory or, conversely, higher order theories can emerge from synthesis of narrower middle-range and micro theories (13). Whether developing a novel micro-theory from limited empirical observations or modifying a middle-range theory through synthesizing numerous studies, such theorizing can have implications for the full ladder of theories.

2.2. Building blocks of theory

The building blocks of theory construction have previously been outlined to describe the attributes of a well-formed comprehensive theory (9, 10). We draw on them to demonstrate how research and reasoning that addresses *any one of these questions* can contribute to advancing theory.

What refers to concepts and constructs relevant in explaining a phenomenon. Research can inform the sufficiency and parsimony of middle-range theoretical products by answering the questions *what is missing from the explanation of this phenomenon* and *what is not contributing to explaining this phenomenon?* While implementation science must not stop at classifying determinants (14), determinant frameworks are critical in organizing the science. They influence study questions, hypotheses, measurement, and implementation targets (2, 15). Determinant frameworks were informed by varying degrees of evidence (2), so assessing the validity of their postulated determinants to inform their refinement is important. Within implementation science, evidence syntheses are beginning to answer the question *what is missing* (16–18), proposing key concepts, such as the health systems' architecture, previously overlooked in frameworks (16). These questions can advance existing theory as well. For instance, studies have provided evidence that additional constructs may improve the explanatory power of the Theory of Planned Behavior (19, 20). They suggest that constructs such as self-identity and past behavior may improve the prediction of behavior (21). By asking these questions, everyone can contribute to advancing existing theoretical products.

How refers to explanations of causes, consequences, mechanisms, and conditions. Theoretical products describing *what* have outpaced explanations of *how* in implementation science, as evidenced by numerous determinant frameworks but fewer explanatory theories

(22). However, empirical enquiries often attempt to establish causes and consequences and, more recently, mechanisms (23–25). Evidence syntheses can assess the evidence for postulates in existing middle-range theories or propose novel theoretical explanations based on evidence. For instance, Meza and colleagues synthesized evidence for the relationship between first-level leadership and inner-context and implementation outcomes (26). They found support for some postulates in existing leadership theory, such as the positive influence of first-level leadership on organizational and implementation climate (27). But also identified limited and inconsistent evidence supporting the commonly regarded postulate that first-level leadership influences implementation outcomes. Individual studies can also contribute to explanations of *how* by directly testing the postulates of theory to evaluate their validity. For instance, Williams and colleagues designed a study to test several postulates of the theory of strategic implementation leadership and articulated how their findings would support or challenge the validity of those postulates (24).

Individual studies can also develop novel explanations of *how* using situation-specific micro-theories. Micro-theories can begin with "cheap" theorizing, formulating tentative and narrow postulates to be evaluated and refined by research. Supported postulates can be maintained and their generalizability further tested, while unsupported postulates discarded or refined. Through such a process, micro-theories can inform middle-range theories with greater generalizability.

Developing novel causal explanations can seem daunting. But researchers and stakeholders can contribute to causal explanations. Humans naturally organize events into causes and consequences. Simple tools can support causal thinking. Qualitative interviewing can elicit implicit causal explanations and coding can characterize those relationships. Linguistic expressions, such as *because* and *since,* shed light on causal conceptualizations (28). The word *because* helps to differentiate a central concept from its determinants. "*I knew that administering the screener (central concept) was a priority because its administration was being measured (determinant*)." Stakeholders can participate in reasoning exercises to clarify their causal thinking. For instance, through counterfactual reasoning, stakeholders can imagine what could have or what may have happened during implementation. This provides answers to questions such as, "*how would implementation have been different if there was consumer demand for the innovation?*" Drawing on direct experience or observations, if-then statements can organize causal thinking. "*If a mandate is instated (cause), then the screening will be administered (effect), but only if screening materials are available (necessary condition).*" We illustrate the application of these tools to prioritize determinants.

Who, where, and when refer to boundaries of a theory's generalizability. Theoretical products are developed within limited contexts and their generalizability is tested when applied outside of that context (29). Empirical research can inform how broadly theories should be applied. Boundary conditions, such as conditions of time and space (30), describe the limits of the generalizability of theoretical assumptions (9). Theorizing about boundary conditions can move us beyond selecting familiar theories, to those best suited to a context. Testing moderators of theoretical postulates can also inform boundary conditions. For instance, implementation theories suggest that implementation climate is a driver of innovation use (31–33). Williams and colleagues found the relationship between implementation climate and evidence-based practice use was contingent on a positive molar climate, suggesting that positive molar climates may be a boundary condition under which implementation climate has the strongest effects (34). Applying theory in research outside of the original context in which it was developed can also elucidate boundary conditions. For instance, research can speak to whether the postulates of COM-B (Capability, Opportunity, Motivation and Behavior) (35) hold true across diverse populations, types of behaviors, and in novel contexts. In instances where these postulates are not supported, researchers are encouraged to speculate about potential theoretical boundaries to advance the precision by which we select and apply theory.

3. Theorizing about implementation determinants

Efforts to identify implementation determinants frequently surface dozens (36), producing a formidable task of deciding which to target. Existing methods, such as prioritizing determinants deemed important and feasible to address (37, 38), treat determinants as independent, ignoring their complex relationships that may inform their importance. An overly simplistic understanding of how intervention characteristics, implementer activities, and the contextual conditions jointly influence implementation limits our understanding of the key (clusters of) determinants to prioritize. Developing a micro-theory of how determinants unfold can help to organize these complex relationships.

Figure 1 provides an illustration of a micro-theory of how determinants influence school and teacher adoption of a group-based intervention, informed by the questions what, how, who, where and when. We illustrate our approach to stimulate theorizing, not to suggest it be followed as a recipe. We drew on qualitative interviews with stakeholders (teachers and principals) from schools following a phase of implementation-as-usual. Originally, qualitative interviews were used to identify all determinants, stakeholders prioritized determinants based on feasibility and importance, and strategies were aligned with those determinants. Here, we reapproach that process to prioritize determinants based on their causal functioning.

3.1. What determinants and IPPs influenced adoption?

Using qualitative interviews, we identified the presence of determinants and implementation policies and practices (IPPs) that schools used to support adoption (39). We inductively coded concepts that emerged, and when aligned, used a combination of determinant frameworks and the theory of organizational determinants of effective implementation (39) to

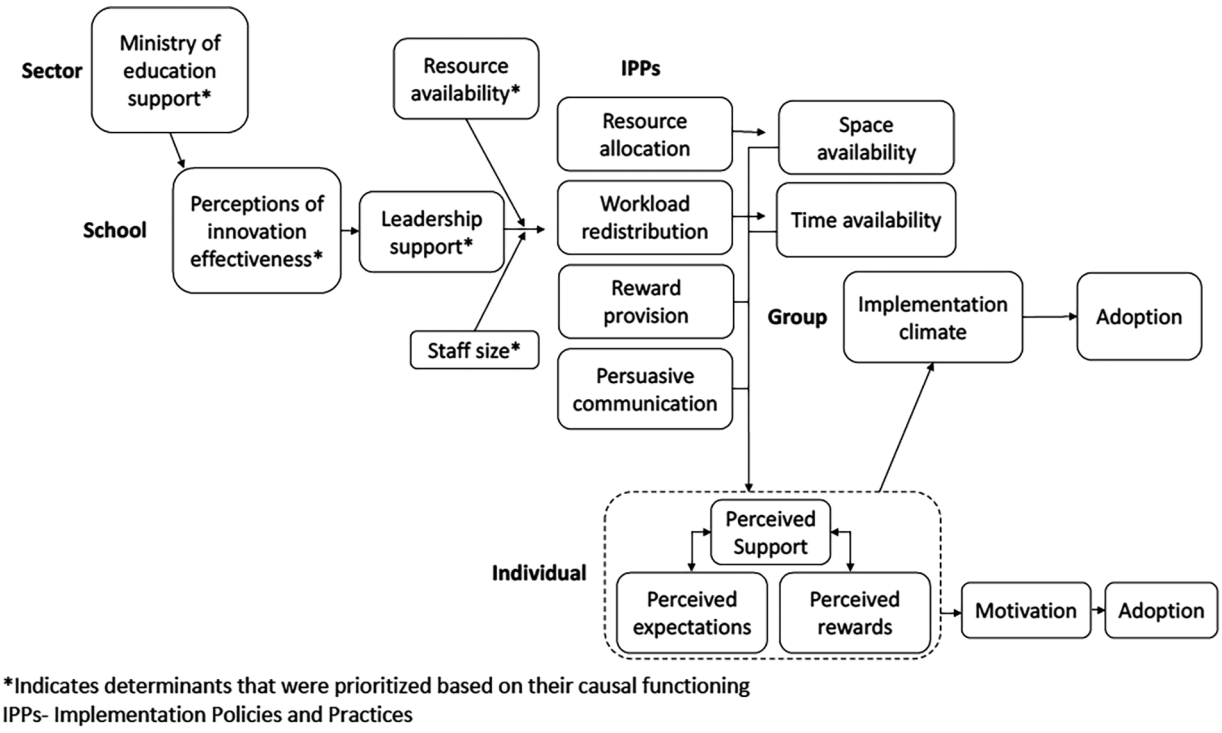

FIGURE 1
A micro-theory of implementation determinants.

provide a common terminology and conceptual clarity to emergent concepts.

3.2. How did determinants and IPPs unfold to influence adoption?

We examined transcripts for linguistic expressions that described the nature of relationships between concepts. If using this approach *a priori*, interviews could be designed to ask about causal explanations. In our post-hoc approach, we looked for terms like *since* and *because* to indicate causal explanations (e.g., I had time to attend the training because our principal asked the deputy teacher to cover my class). This produced many antecedent–outcome linkages (e.g., workload adjustment provided teachers with time for intervention activities) and pointed to moderators (e.g., supportive leaders allocated space for delivery, but only when classrooms were available).

Qualitative responses will undoubtedly lack precision in the chain-of-events that occur between antecedents and outcomes. For instance, rewards were described as influential for adoption, without explanation. To expand on these, the research team constructed if-then statements based on impressions from observations (e.g., if a counselor was recognized by their principal (reward), then this would enhance their motivation (motivation), and increase their likelihood of delivering the intervention (adoption). We used counterfactual reasoning to theorize about the effect of events that did not happen to identify necessary conditions [e.g., if the ministry of education had not signaled support (*necessary condition*), leaders in each school would not have engaged].

We drew on existing theoretical postulates to inform the integration of antecedent–outcome linkages. For instance, interviews suggested several linkages between different IPPs and the perception that implementation was expected, supported, and rewarded (i.e., implementation climate). Drawing on theory (31, 39), we conceptualized IPPs as having an additive effect (i.e., the more IPPs present, the stronger the influence on adoption) and a compensatory effect (i.e., the presence of some high quality IPPs can compensate for the absence or low-quality use of others).

A participatory approach could be used throughout these steps. For instance, initial antecedent-outcome linkages could be presented to stakeholders for member-checking and stakeholders could co-develop if-then statements and engage in counterfactual reasoning [e.g., if X had (not) happened, what do you think would result?] to expand on gaps in the causal chain-of-events.

3.3. For whom, where, and when do postulates apply?

A primary function of considering boundary conditions of a situation-specific micro-theory is ensuring its applicability across the contexts it is applied. Including extreme cases is one way to do this. We purposively sampled from schools with varied characteristics (e.g., small and large staff sizes) to surface explanations across diverse characteristics. We modified explanations to be valid in schools with the most extreme

characteristics. For instance, we added staff size as a moderator because leadership support only led to workload redistribution in schools with a moderate-to-large staff size. A micro-theory will inherently be bounded within a narrower context. As their postulates are empirically supported in new contexts or refined, they can inform middle-range theories.

3.4. Prioritizing determinants based on functioning

Determinants can be prioritized based on their theorized influence (see **Figure 1**). For instance, we may prioritize those occurring early in the causal chain of events that have a cascading influence (e.g., perceptions of innovation effectiveness), moderators that could diminish the effects of other targeted determinants (e.g., resource availability), or necessary determinants that would preclude successful implementation (e.g., Ministry of Education support).

4. Using multiple working hypotheses to support theoretically informative research

The tools discussed so far can be used to leverage empirical research to develop novel theory or refine existing theory. An equally important part of theorizing is validating existing theory. Validating theory should push us toward strong theory, while its invalidation should push us to move away from or refine existing theory. With over one hundred theoretical products available (40), their utility must be tested to lead the field toward high value theories. While a couple of theoretical products are most commonly used, the criteria for selecting them is inconsistent (15). The lack of information on the value of theories may maintain the use of familiar theories "without thought or reflection." (4) We argue, as has been argued for decades before us, that leveraging multiple working hypotheses can produce research that guides the field toward high value theories (11, 41).

Hypotheses are driven by the postulates of theory, whether that theory is explicit or implicit. Platt argued the most rapid scientific advances can be made using multiple hypothesis generation followed by careful experimental design that arbitrates between hypotheses (41). With a single hypothesis, we can only affirm and refine a single theory that may or may not be a reasonable approximation of reality. Imagine the scientific process as a tree diagram with a single path to follow. We might be able to meander down various smaller paths, but we leave other branches unexplored. If, instead, we introduce multiple plausible hypotheses we open all branches we can generate. Good experiments will produce findings consistent with some families of hypotheses, but more importantly, they provide results inconsistent with others. An iterative process of this kind is more efficient in pushing the field toward theories with greater explanatory power and protect against uncritical and superficial theory application. The existence of multiple competing hypotheses in the literature is a sign of health for the field.

Modern statistical analyses have provided tools to evaluate the plausibility of multiple competing hypotheses or models through approaches such as structural equation model fit comparisons and Bayesian alternatives to null hypothesis significance testing. For instance, Bayesian statistical approaches can be used to estimate the posterior probabilities of several competing models given the data, and models with the greatest probabilities can then be selected as the starting point for additional model development. Unfortunately, even moderately complex models may require large sample sizes ($N > 500$) to correctly reach a true model among competing options (42).

As the field responds to growing calls for mechanism-based explanations (43, 44), this will be an important place to adopt multiple hypotheses. Among behavior change theories, there are numerous postulated pathways through which behavior change occurs. For instance, COM-B proposes that capability, opportunity and motivation produce behavior, which in turn influences these components (35). In contrast, the Theory of Planned Behavior posits that attitude toward a behavior, subjective norms, and perceived behavioral control, together shape an individual's behavioral intentions, which, in turn, shapes behavior (19). Rather than proposing hypotheses intended to test the postulates of a single theory, we can compare the explanatory power of each theory in a single study. This approach can also be used to pit multiple novel competing theoretical explanations that emerge through theorizing against one another. This allows for "cheap" theorizing in which we produce many explanations and allow evidence to push us towards those of value. Above all, theorists should feel empowered to readily eliminate unsupported hypothesized determinants or poorly fitting theories.

5. Discussion

Complexity is the rule, not the exception, in the change efforts we undertake in implementation science. The classification and organization of constructs into frameworks, delineation of concepts, and theories that explain and predict implementation processes have contributed to creating order and clarity within this complexity (1). Many have argued for the relevance of theory to even the most practical among us who undertake change efforts (45). We agree and also argue that everyone can play a part in advancing theory. All research is related to theory and relevant for pushing theory forward. While many implementation scientists may not identify as philosophers of implementation science, we all play a direct role in theory advancement.

We offer three recommendations for increasing engagement in theorizing. First, articulate the contribution a study can make to advancing or modifying existing theory. To do so, studies must be designed to *question* the postulates of existing theory (i.e., what, how, who, where, when) and findings interpreted in terms of their support for, *or against,* those postulates. Second, engage in novel, "cheap", micro-theory development. The field is increasingly moving towards articulating causal pathways to open the "black box" of implementation (14, 46, 47). This will require greater engagement in developing theories of the problem (e.g., how

determinants unfold to influence implementation) and of the solution (e.g., how strategies can address determinants). We advocate for "cheap" theorizing, in which researchers are empowered to draw on empirical evidence to formulate tentative and narrow postulates to be evaluated and refined by research. As these micro-theories are tested and refined through empirical enquiry, they can inform the foundation of generalizable middle-range theory. Third, to continue advancing existing and novel theories forward, researchers should adopt multiple working hypotheses that pit competing explanations against one another. This approach ensures that our theories do not stay stagnant in their nascent and tentative forms and pushes the field towards high value theories.

One barrier to theorizing that we do not address is funder's expectation for studies to adopt existing theory. The popularity of particular theories, despite a lack of strong empirical support has long been an issue (11). Therefore, we urge that theory not be judged on its longevity or popularity, but on its empirical foundation. If theories developed "in-house" have a strong empirical basis and are being advanced by additional empirical enquiry, this is a benefit to the field. Theory development is never done.

We have sought to clarify how theorizing is for everybody and to demonstrate how the questions we ask and hypotheses we test contribute to theoretically informative research that advances theory. Drawing more people into the process of theorizing is precisely how we push our field towards the advancement and elevation of good theories.

Data availability statement

The original contributions presented in the study are included in the article/Supplementary Material, further inquiries can be directed to the corresponding author.

Ethics statement

Ethical review and approval was not required for this study in accordance with the local legislation and institutional requirements.

Author contributions

RDM, BJW, CCL, PK and MDP: contributed to the conception of the manuscript. RDM: wrote the first draft of the manuscript. JCM and MDP: contributed to sections of the manuscript. All authors contributed to the article and approved the submitted version.

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Co-designing, measuring, and optimizing innovations and solutions within complex adaptive health systems

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Objective: To introduce, describe, and demonstrate the emergence and testing of an evaluation method that combines different logics for co-designing, measuring, and optimizing innovations and solutions within complex adaptive health systems.
Method: We describe the development and preliminary testing of a framework to evaluate new ways of using and implementing knowledge (innovations) and technological solutions to solve problems *via* co-design methods and measurable approaches such as data science. The framework is called PROLIFERATE; it is initially located within the ecological logic: complexity science, by investigating the evolving and emergent properties of systems, but also embraces the mechanistic logic of implementation science (IS) (i.e., getting evidence-based interventions into practice); and the social logic, as the study of individuals, groups, and organizations. Integral to this logic mixture is measuring person-centered parameters (i.e., comprehension, emotional responses, barriers, motivations, and optimization strategies) concerning any evaluated matter across the micro, meso, and macro levels of systems. We embrace the principles of Nilsen's taxonomy to demonstrate its adaptability by comparing and encompassing the normalization process theory, the 2 × 2 conceptual map of influence on behaviors, and PROLIFERATE.
Results: Snapshots of ongoing research in different healthcare settings within Australia are offered to demonstrate how PROLIFERATE can be used for co-designing innovations, tracking their optimization process, and evaluating their impacts. The exemplification involves the evaluation of Health2Go (the design and implementation of an innovative procedure: interdisciplinary learning within an allied health service—community-based) and RAPIDx_AI (an artificial intelligence randomized clinical trial being tested to improve the cardiac care of patients within emergency departments—tertiary care).
Conclusion: PROLIFERATE is one of the first frameworks to combine ecological, mechanistic, and social logic models to co-design, track, and evaluate complex interventions while operationalizing an innovative complexity science approach: the knowledge translation complexity network model (KT-cnm). It adds a novel perspective to the importance of stakeholders' agency in the system by considering their sociodemographic characteristics and experiences within different healthcare settings (e.g., procedural innovations such as "interdisciplinary learning" for Health2Go, and tech-enabled solutions such as RAPIDx_AI). Its structured facilitation processes engage stakeholders in dynamic and productive ways while measuring and optimizing innovation within the complexities of health systems.

KEYWORDS

complex systems, implementation, evaluation, knowledge translation, digital health, healthcare, transdisciplinary co-design

Background

Globally, health systems are under pressure due to increased healthcare utilization and its associated demands. Limited access to health services is rising because of the increasing number of people living with more than one chronic condition and non-communicable diseases (NCDs), such as heart disease, cancer, diabetes, and others (1–7). Apart from NCDs and the rising demands around caring for aging populations (4, 5), the existing COVID-19 pandemic has demonstrated that the ramifications of a single communicable disease have far-reaching effects in terms of accentuating preexisting inequalities in healthcare (1–3, 6, 8). Although, between 1990 and 2019, the Healthcare Access and Quality (HAQ) index increased overall (19.6 points, 95% uncertainty interval 17.9–21.3), particularly in the young age group, it also indicates that healthcare access and quality are lagging among those belonging to lower levels of social and economic development (i.e., those of working age (15–64 years) and post-working age (65+ years)) (9).

Addressing current healthcare access and quality trends and responding to demands around better health services for patients with multimorbidity or populations affected by communicable diseases requires the implementation of changes in the health system *via* innovations and or solutions; these concepts refer to using either new knowledge or discovering new ways of using existing knowledge (innovations) and technology (knowledge activated by some technological solution) to solve health problems; for example, developing vaccines, devices, and diagnostics, new drugs, as well as new techniques or processes for designing, engineering, or manufacturing health products, treatments, healthcare management approaches, software, policies, and services (8, 10, 11). However, the implementation of any of these innovations requires a good understanding of the health system and their impact within so that the innovations can be accepted and utilized (i.e., uptake) across time (i.e., sustainability) or modified to work according to changes (i.e., optimized) or de-implemented when necessary. To that end, according to the WHO, "*a health system is most simply described as being made up of component parts (e.g., stakeholders and organizations), and interactions (e.g., functions) that promote, restore and maintain health and that, taken together, form a unified whole*" (1, p. 3).

As COVID-19 demonstrates (1–3, 6, 8), implementing innovations within ever-changing health system environments requires collecting and interpreting data about the *whole health system structure, functions, and parts*; this is done by gathering large datasets analyzed with computational methods (a procedure referred to as big data) (12, 13). Such approaches—collecting data about engaging people, their connection with each other and their environment (organizations), and their respective views—represent, for many businesses and technological sectors, a fundamental condition for assessing the impact of new knowledge in the shape of innovation (12–15). In this context, a crucial step for delivering person-centered healthcare services, policy, research projects, and programs is evaluating data with the contribution of such stakeholders (people affected by the innovation being implemented) (14, 15). Yet, working with stakeholders and their data involves a paradigm shift. For example, the transition requires, among other changes, moving away from a single disease model toward a more holistic one, in which the totality of the personal experience can provide essential insight about a solution relevant to the person and the health system; this refers to the evaluation of the effect and impact that the introduced solution may have, could have, or is having in light of its users' feedback (9, 16, 17).

A lack of engagement with relevant stakeholders or their exclusion from analyzing information concerning their personal experience may bring negative consequences. For example, despite an overall increase in evidence-based resource allocation over the last decade, the distribution of such resources has mainly been determined by population-based surveys on risk factors and the existing scope of health and medical research, which is focused on disease- or discipline-specific outcomes (9, 16). A more holistic view of the health system can come from working with all groups affected by the change or innovation we are planning to introduce; yet, a clear gap in knowledge and practice has been identified concerning such attempts (1–3, 8, 18, 19). For example, the understanding and utilization of co-design methods for research, implementation, and evaluation purposes is often referred to as poor when co-design is understood as the meaningful involvement of users of innovation or solution across all discovery phases (1–3, 8, 18, 19). In this way, there is an increasing demand for shepherding the data collection and analysis of big data to guarantee that their interpretation reflects the issues of relevance for patients, families, communities, and other stakeholders. This is still an issue for decision-makers, academics, and practitioners as more data are increasingly collected and analyzed from a limited or partial perspective that needs to reflect the dynamics of the health system, its functions, and its parts (1–3, 8, 9, 16, 18, 19).

In the context of co-design, meaningful involvement means the non-tokenistic participation of stakeholders. Their roles and contributions must be explicitly described, defined, and auditable across all processes of a project; this means that their tasks and functions confer them influential voices and decision-power (14, 15, 19). This type of democratization of research, implementation, and development processes permit the capturing of important insights on the attributes and connections between people and groups and eventually incentivize change (i.e., better knowledge uptake and health) (1–3, 8, 18, 19). For example, today, the investigation of the health system through the lens of people's experiences, may capture information about climate change and war. These subjects may seem separate from implementing a health solution. Still, those events cause injuries and illnesses within many populations and disrupt the operation of healthcare facilities and health due to migration, poverty, food insecurity, racism, and other socioeconomic issues (1–3, 8, 18, 19). These connections between topics and sectors that initially seem disconnected from implementing health innovations demonstrate that implementing change within health systems extends beyond the health sector. Therefore, implementing changes for better delivery and access to healthcare services

broadens to considering the social determinants of health (e.g., biological, socioeconomic, political, and psychological factors affecting individuals and the promotion or restoration of their health) (1).

The poor engagement of stakeholders from different sectors may limit the ability of researchers and decision-makers to capture important information and the capacity to interpret people's experiences concerning innovation (14, 15, 19). For instance, when implementing and evaluating a new treatment, failing to engage stakeholders can limit the researchers' interpretation of data patterns on the behavior of organizations; e.g., hospitals and communities, and their functions (e.g., healthcare services and their utilization) concerning the treatment's positive and negative implications according to its different users (e.g., clinicians delivering the treatment) or other end-users (e.g., patients, family members, and their reported changes on their roles and behaviors as a result of the treatment implementation).

A systematic review and meta-analysis of consumer engagement in healthcare policy, research, and services has come to the same conclusions as studies addressing longitudinal solutions around urban development and community health (14, 15). Both studies recommend using participatory methods such as co-design and quantifiable approaches (e.g., big data). Their commonality appreciates the importance of measuring engagement for the sustainability of the implementation of innovations and their uptake; this refers to the scale-up or the adoption of the behaviors that the innovation requires from its different users (14, 15, 19). These strategies are relevant to facilitate a better distribution of power and expertise throughout the discovery, implementation, and evaluation processes because they result in innovations informed by insights from experts and the knowledge gained through people's lived experiences across all relevant sectors involved (14, 15, 19).

Research objective

The presented background concerning healthcare utilization, innovation, co-design, and its relevance for implementing and influencing change within the health system coincides with other studies that suggest tapping into different logics or methods to achieve better implementation uptake and health (5, 20–22). Those studies imply that implementation and its uptake within health systems is not only about bringing evidence-based interventions into practice (known as mechanistic logic). It requires considering the evolving and emergent properties of the person's networks (identified as the ecological logic) and the study of the social organizations, groups, and individuals (covered by the social logic) (20, 22). Mixing or integrating these logics and their most relevant methods could help to recognize effective implementation processes for innovations and the best approaches for their sustainability and optimization (or not) considering their relevant contexts and settings within the health system (5, 20–22):

1. *Ecological logic*: complexity science, the field investigating the evolving and emergent properties of systems (15).
2. *Social logic*: social science, which concentrates on the social study of individuals, groups, and organizations (15).
3. *Mechanistic logic*: implementation science as the field bringing evidence-based interventions into practice (15).

As introduced in the background, a practical combination of ecological, mechanistic, and social logic is required, focusing on co-design and measurable approaches. This need is reflected in reviews demonstrating that millions of dollars are lost yearly in implementing health innovations that still need to achieve their expected uptake despite being backed up by robust evidence of their benefits (19, 20, 22). Consequently, responding to the need for such a methodological integration, this manuscript introduces, describes, and demonstrates the emergence and testing of an evaluation method that combines those logics for co-designing, measuring, and optimizing (or not) innovations and solutions within complex adaptive health systems.

Methodology

Initially, the task of combining different logics was triggered by evaluating the impact of a video on stakeholders' perceptions of frailty, described elsewhere (23). The video was co-designed with health consumers, e.g., patients and their carers, health researchers, and clinicians (this aspect of the video is consistent with social logic objectives). However, the video was created to disseminate and facilitate the utilization of evidence-based information for managing frailty (objective aligned with mechanistic logic) by reflecting on consumers' experiences and priorities (which also reflects the characteristics of the ecological logic) (23). Evaluating this combination of aspects from the perspectives of the video's stakeholders (i.e., users such as health promoters and partitioners and end-users such as patients) was essential to understanding and measuring its impact. Therefore, a group was created to integrate a practical way of evaluating the video. The group involved many stakeholders who were not involved in the video creation team (23) but with the representation of different sectors (areas of knowledge) associated with the audiovisual resource:

- clinicians from different disciplines;
- artists;
- a mass communicator;
- health researchers; and
- health consumer advocates.

This group of stakeholders decided to work using a transdisciplinary approach; this means incorporating the knowledge from their different disciplines and experiences to produce an evaluation that transcends the boundaries of their various fields. This transcendence aspect means moving their contributions to areas beyond their personal experiences/disciplines to create, together, a new way of evaluating the impact of the video, considering its different aspects/logic (24–27). The resulting video evaluation procedure is summarized in **Figure 1** and explained in **Table 1**.

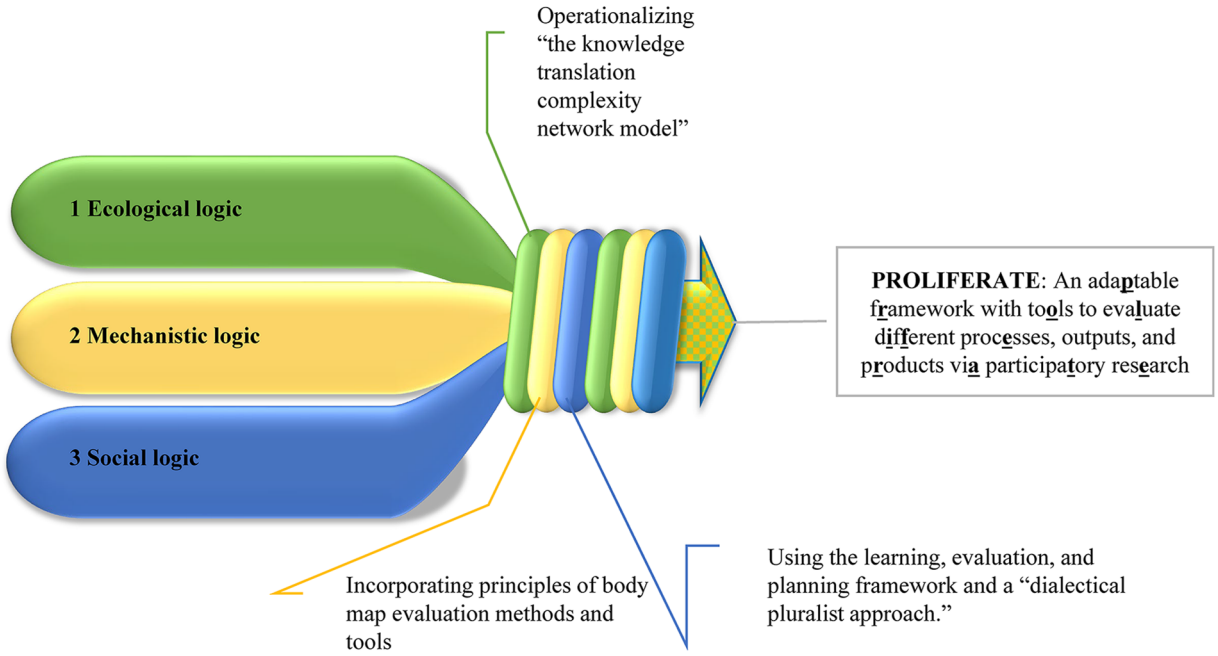

FIGURE 1
Development of the PROLIFERATE framework. The transdisciplinary group has been working together for 3 years, on which COVID-19 changed the operative dynamics toward online communications and meetings. Benefitting mostly from iterative online discussions and presentations to peers, health consumer advocates, and health practitioners, the group inductively integrated the combination of logic presented in Figure 1 and Table 2 (24, 28–30). The mixture of their personal and methodological experiences, skills, reasoning, and areas of research resulted in a high-level combination of procedures and methods to evaluate different processes, outputs, and products *via* participatory research: PROLIFERATE. It is required to gain familiarity with the evaluation methods, mixed-methods research approaches for achieving spread, and scale-up of innovation explained in Tables 1 and 2 and illustrated across all figures of this manuscript to comprehend the PROLIFERATE framework, its focus, procedure, and its operationalization.

The multi-logic combination of Table 1 was eventually adapted, modified, and applied to other projects evaluating different innovations and involving their respective transdisciplinary groups. These iterations resulted in a combination of the methods reflected in Figure 2 and used in the exemplar cases presented in the "Results" section of this manuscript (24, 28–30).

PROLIFERATE ecological logic: the basis of the evaluation

Comprehending Table 1 and Figure 2 involves understanding the knowledge translation complexity network model (KT-cnm), which is defined as a network that optimizes the effective, appropriate, and timely creation and movement of knowledge to those who need it to improve what they do (31). The model is a core component of PROLIFERATE because, by operationalizing it, evaluators can identify ways to identify the movement, adaptation, and acceptance of innovations within complex and adaptable processes; this is because they are dependent upon the decisions and actions of individuals and teams, and their connections across and between multiple networks (31). The KT-cnm is based on the concepts and definitions presented in Table 2 (replicated with authorization (31)).

The KT-cnm (31) brings the ecologic basis of PROLIFERATE (defined in Table 1 and illustrated in Figure 3). Having the KT-cnm as a foundational component of PROLIFERATE is of interest to the field of IS because it means operationalizing a novel way of considering the evolving and emergent properties of the health systems and developing, identifying, implementing, and evaluating solutions that attempt to respond to the challenges presented in the introduction (22, 31, 37).

PROLIFERATE was designed to help to identify relevant stakeholders (nodes, hubs, clusters, and networks) represented in the five sectors of Figure 3 (Governments; Community including Industry; Health, Education, and Research) and aims to view and measure how those sectors function dynamically in space and time as clusters that differ in frequency of interaction and goals across the KT stages/processes (Problem identification, Knowledge creation, Knowledge synthesis, Implementation, and Evaluation) (see Figure 3 and explanations in Table 1) (31).

The measuring objectives of the PROLIFERATE evaluation framework given the KT-cnm also take a mechanistic logic (as per Table 1) and therefore are compatible with IS broader methodological objectives because PROLIFERATE aims to (21):

1. describe/guide the process of translating research into practice *via* process models (21);
2. understand/explain what influences implementation *via* determinant frameworks, classic theories, and implementation theories (21); and
3. evaluate implementation *via* evaluation frameworks (21).

TABLE 1 The combination of logic that integrates the introduced evaluation framework (table adapted from Greenhalgh and Papoutsi, 2019) (22).

Logics	Focus	Contribution	Core processes of spread and scale-up of innovation	Key methods for achieving spread and scale-up of innovation	Key methods for researching spread and scale-up of innovation	Measures and metrics	Evaluation approaches combined to create PROLIFERATE
Ecological: Complexity science	The evolving and emergent properties of systems	Emphasizes the system's inherent complexity and need for adaptive change at multiple interacting levels	Emergent properties of an interacting system—self-organization, management of interdependencies, and sense-making	Achieve a rich understanding of the case context. Use multiple methods flexibly and adaptively. Assumes surprises and manages them inventively. Builds on individuals and organizations to be creative and resilient	Case study approach using multiple qualitative and quantitative methods. Narrative can be used as a synthesizing tool to capture complex chains of relationships and structures	Conjugated narrative about what changed and why including (where relevant) how the intervention was adapted or abandoned	The knowledge translation complexity network model (KT-cnm)—explained in Table 2 and Figure 3—whose objective is to initiate new ways of thinking, engaging with complex problems and generating relevant solutions that can become the accepted standard (31). It helps to identify users/adopters represented in the five sectors (Governments; Community, including Industry; Health; Education; and Research) that function dynamically in space and time as networks/clusters that differ in frequency of interaction and goals across the KT stages/processes (Problem identification, Knowledge creation, Knowledge synthesis, Implementation, and Evaluation) (31).
Mechanistic: Implementation science	Evidence-based interventions in practice	Provides concrete and planned approaches to the delivery and study of spread and scale-up	Uncertainty reduction, emphasis on fidelity, and contextual influences	Use structured, programmatic approaches to develop and replicate a complex intervention across multiple settings	Metrics for measuring improvement (quantitatively) and systematic approach to exploring processes and mechanisms (qualitatively)	Replication of a particular service model or approach in multiple contexts ("fidelity")	Body map evaluation tools—illustrated in Figure 4—which tend to be used to investigate and measure people's perceptions, opinions, beliefs, and attitudes, by capturing evidence from those with limited literacy or language differences, involving people while exploring complex processes, capturing many opinions and views efficiently; gathering impressions of progress or outcomes and providing evidence of unexpected outcomes (32, 33)
Social: Social science	Social study of organizations, groups, and individuals	Focuses on patterns of social behavior and interaction, professional beliefs and values, and organizational routines and structures	Social, professional, and organizational influences that shape (and are influenced by) individual and collective action	Develop and apply theories of how individuals' behaviors and actions are influenced by interpersonal, material, organizational, professional, and other factors	Ethnography, interview-based methods, and case narratives to provide insights into social interactions and contexts	Theoretically informed and empirically justified explanations about human and organizational behavior	The learning, evaluation, and planning framework (LEAP) (34), which is a resource used by those involved in promoting health and well-being in community settings, whether in community projects, primary care, clinical practice, health promotion, or public health. It is designed to assist projects and programs that focus on enabling people to develop and maintain their health on a day-to-day basis through individual and participatory community action research (35). This method was combined with *a dialectical pluralist approach*, which refers to the acceptance and expectancy of differences in every aspect of the evaluation by facing them with a dialogical attitude thriving on differences and intellectual tensions (36)

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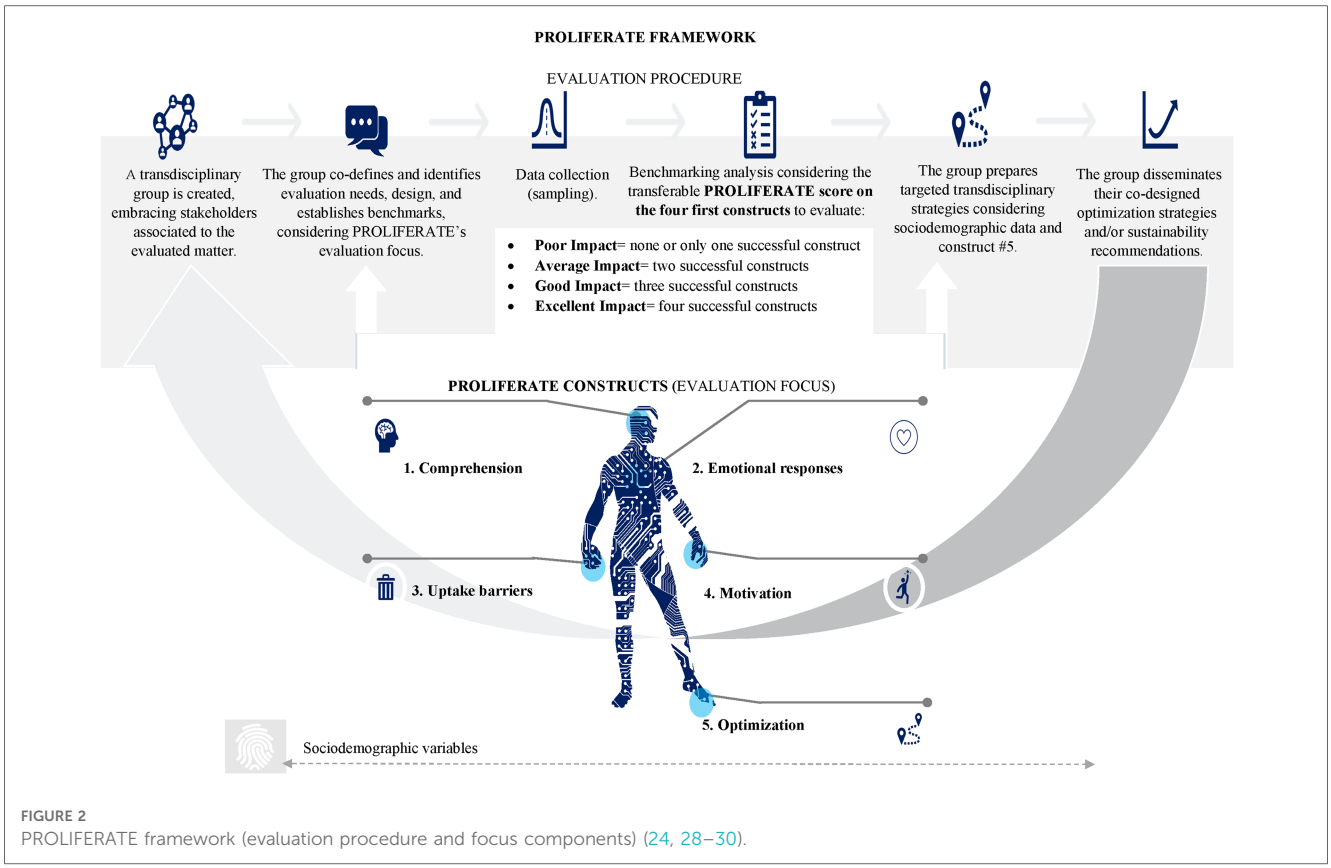

FIGURE 2
PROLIFERATE framework (evaluation procedure and focus components) (24, 28–30).

TABLE 2 The nomenclature used and working definitions of the knowledge transition (KT) complexity network elements (31).

Term	Explanation
Node	A single agent (individual, process, or virtual system) that interacts with other single agents (nodes)
Hub	A single agent that interacts more extensively with other nodes and becomes the champion for collective actions, within and between clusters
Cluster	A subnetwork made up of nodes and hubs. The sub-network comprises a number of nodes, some of which act as hubs, pursuing the same goals
	A cluster may be a subnetwork involved with key areas of activity (such as PI) or a subnetwork within a sector (such as a university health science research group)
Network	A collection of nodes, hubs, clusters, and the connections between them
Problem identification (PI)	The process by which societal challenges, issues, or problems are formulated, defined, and constructed to proceed to systematic investigation
Knowledge creation (KC)	Describes what is traditionally termed basic, clinical, pre-clinical, epidemiological, health services, and population health research approaches to answering health related problems
Knowledge synthesis (KS)	The rigorous and systematic generation of evidence-based products (patents, materials, tools, programs, and guidelines) for application in policy and practice
Implementation (I)	The rigorous application of new knowledge into policy and practice in a theory informed and reflective way
Evaluation (E)	The explicit and systematic review of key processes of KT and broader objectives within and across a range of complex and interconnected sectors and networks
Complex adaptive system (CAS)	Complex systems (e.g., within research institutions, health systems) and KT processes (e.g., PI, KC) that are a collection of diverse connected nodes or parts with interdependent actions. The behavior of a CAS is generated by the adaptive interactions of its components
KT complexity network	The umbrella term that describes the components of the overall network that connect and interplay in order for KT to occur. Different stakeholders collaborate within a dynamic discursive space to ensure that appropriate information is being developed, refined, and mobilized throughout the network to the appropriate nodes, hubs, clusters and sectors

Research into IS methods and practice indicates that methods combining the above objectives tend to be too general (lacking details in their how-to components) or too specific, needing more transferability (21). Therefore, the PROLIFERATE design tries to bring balance between such extremes (i.e., becoming too general or too specific) by using the principles of body map evaluation tools (see Table 1) (32, 33), to establish constructs (i.e., person-centered parameters) that can capture the stakeholders' comprehension, emotional responses, barriers, motivations, and optimization strategies concerning any evaluated matter (32, 33), while evaluating stakeholders' sociodemographic characteristics to assess their interactions with their context and grouping them (see Figures 2 and 4).

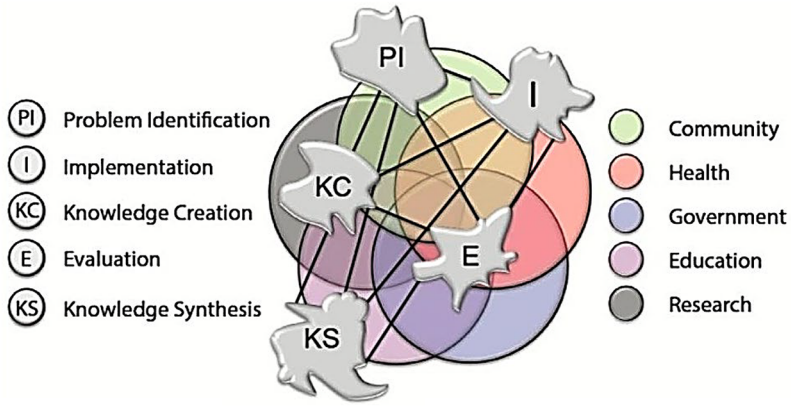

FIGURE 3
The knowledge translation complexity network model (KT-cnm) (31). The overlapping of lines (connection between KT stages) and colors (different sectors) represent the complexities of the ever-changing conditions of a complex adaptive system (CAS).

PROLIFERATE mechanistic logic: the focus of the evaluation

Figure 4 provides a simplified view of the five non-hierarchical person-centered parameters of PROLIFERATE called constructs; they were included in the PROLIFERATE design as the focus of the evaluation (as per Figure 2) to explore the person construction of meaning or their perceptions concerning any evaluated matter. Evaluating these constructs in combination with the person's sociodemographic characteristics (or variables) is essential, as such variables play a similar role to the social determinants of health mentioned in the background of this manuscript (1). To that end, the constructs can help to capture and measure the multiple interacting social structures and

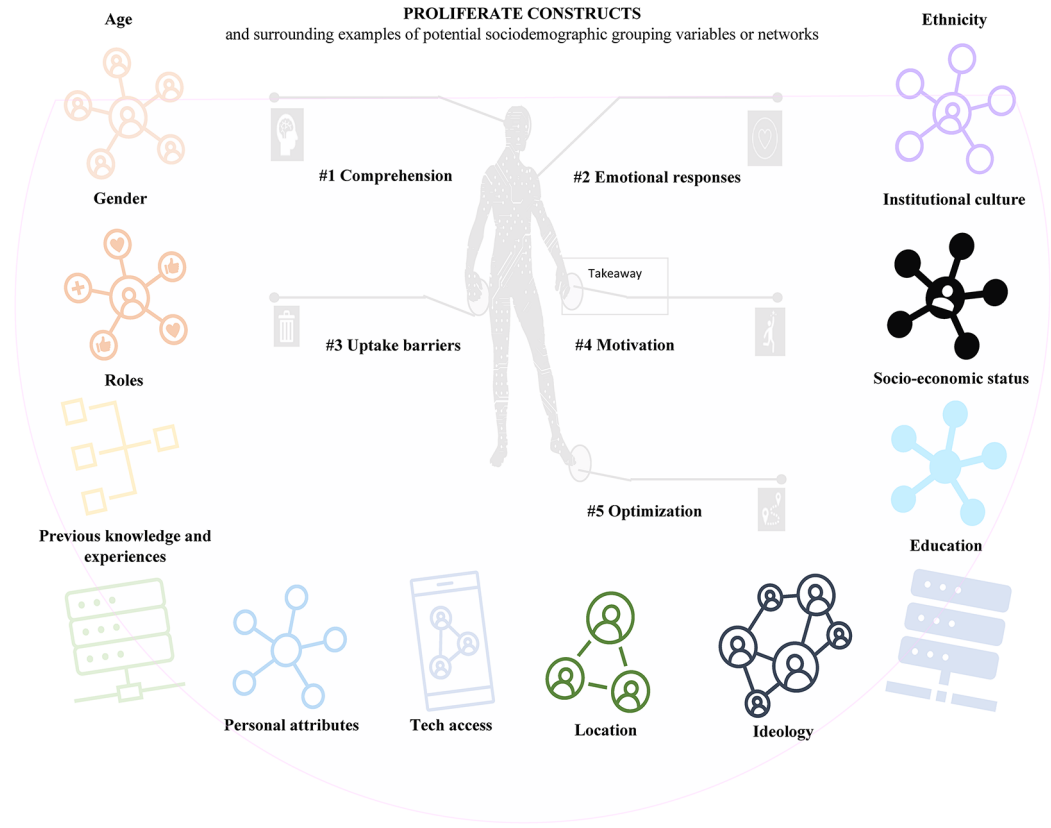

FIGURE 4
PROLIFERATE's five non-hierarchical constructs and the person's sociodemographic characteristics (i.e., examples of variables for creating possible affiliation networks—grouping—to map multilevel social networks).

ecological networks by identifying the stakeholders' functions within the KT-cnm sectors of the health system.

Ideas around the constructs' measurement and their mapping *via* network structures (grouping) were imported by members of the PROLIFERATE transdisciplinary group and their in-depth explorations of fundamental care (31, 38, 39). Their work quantifies and maps a network structure considering the micro, meso, and macro dimensions of care as explained elsewhere (38, 39). The parallelism between PROLIFERATE and such measurement of fundamental care is based on the analysis of networking data about the personal experience of patients, clinicians, and care administrators, to eventually develop interventions through a thorough investigation of the intersections of 38 fundamental care elements, which are similar to the five person-centered constructs in the context of the individual sociodemographic characteristics as variables (**Figure 4**). The combination of constructs and variables in the described PROLIFERATE evaluation focus (presented in **Figure 4**) unites the ecological and social logics of **Table 1** to capture and measure (*via* a mechanistic logic) different stakeholders' views/perceptions and their networking position and functions within the health system—they can be policymakers, implementers, community members, managers, providers, and other types of innovation users/roles (1, 31, 38–41).

The non-hierarchical focus that PROLIFERATE constructs have allows for the creation of a simple and transferable scoring system, which permits to evaluate and track the stakeholders "software": the agency that shapes human behavior, ideas, interests, values, norms, and/or the conscious and unconscious drivers impacting on innovation spread and scale-up, e.g., by incorporating experiments about human perception and behavioral responses around the constructs concerning an innovation (1, 42). This scoring system is designed to analyze results according to the pre-established benchmarks (quantifiable measures of success) that the transdisciplinary group sets for each construct at the beginning of the evaluation (see in **Figure 2**, the PROLIFERATE procedure, and the evaluation focus being united by the scoring system).

The score introduced in **Figure 2** helps the transdisciplinary group determine conclusions about the quality, merit, or worth of the evaluated matter irrespective of the analytical methods utilized to benchmark the success of each of the four first constructs of PROLIFERATE (e.g., qualitative, quantitative, and mixed methods). The score identifies the innovation impact as follows:

- *poor impact*: none or only one of the first four constructs presents data above the pre-established benchmark on success (hypothesized responses/behaviors toward innovation uptake, spread, and scale-up);
- *average impact*: two of the first four constructs resulted in data going above their pre-established benchmark;
- *good impact*: three of the first four constructs resulted in data going above their pre-established benchmark; and
- *excellent impact*: the first four constructs resulted in data going above their pre-established benchmark.

The framework's fifth construct (#5) refers to "optimization" and is designed to capture the person's qualitative feedback on improving or modifying the evaluated innovation. This design facilitates a more meaningful interpretation of the score. The transdisciplinary group uses the score to determine if the implementation of the innovation needs to utilize optimization strategies to move the data obtained about the constructs above the pre-established benchmark (e.g., behavioral interventions, education *via* communication or campaigning, using creative, artistic, or empowerment activities, utilizing facilitation techniques, generating health interventions, re-design or re-engineering technology, etc.). For example, work on optimization strategies is required when the score results in poor, average, or good impact. If the score reflects excellent impact, sustainability strategies are necessary (i.e., activities that facilitate the maintenance of the status quo), as well as their monitoring across time.

Construct #5 can also be used (in combination with the sociodemographic variables) to assess the de-implementation of an innovation or a solution; to this end, the standardization of assessments that the score provides could help compare different evaluated matters across their sectors/users. Using the described network approach and benchmarking stakeholder feedback concerning the constructs and the person's sociodemographic variables can help to navigate across these levels of health systems by exploring their dynamics, i.e., cross-scale components (as presented in **Figure 5**) (1, 31, 38–41):

- The micro level refers to the personal and perceptional drivers of human behaviors (the five person-centered constructs).
- The meso level implies the connection of different people according to their characteristics and social organization (networks and their sociodemographic characteristics).
- The cross-scale components reflect the structural patterns of multiple interactions and connections of multilevel social networks, which can facilitate or limit the uptake, spread, and scale-up of new knowledge in the form of innovations and/or solutions and change.
- The macro level is about the broader context, norms, and legislations that govern different networks' interactions (multilevel networks).

Figure 5 implies that the PROLIFERATE constructs and the person's sociodemographic characteristics (possible grouping variables of **Figure 4**) provide information about the system, contexts, and settings from which different stakeholders perceived any innovation (26, 33–36). To illustrate how the PROLIFERATE cross-scale components can be considered/captured *via* sampling procedures (e.g., survey), **Figure 6** (28) shows a general view of the triangulation structure between possible survey items or questions concerning the following:

1. sociodemographic variables;
2. constructs #1, #2, #3, and #4; and
3. potential open questions around optimization (construct #5, to be utilized and triangulated with and by the insight of the transdisciplinary group).

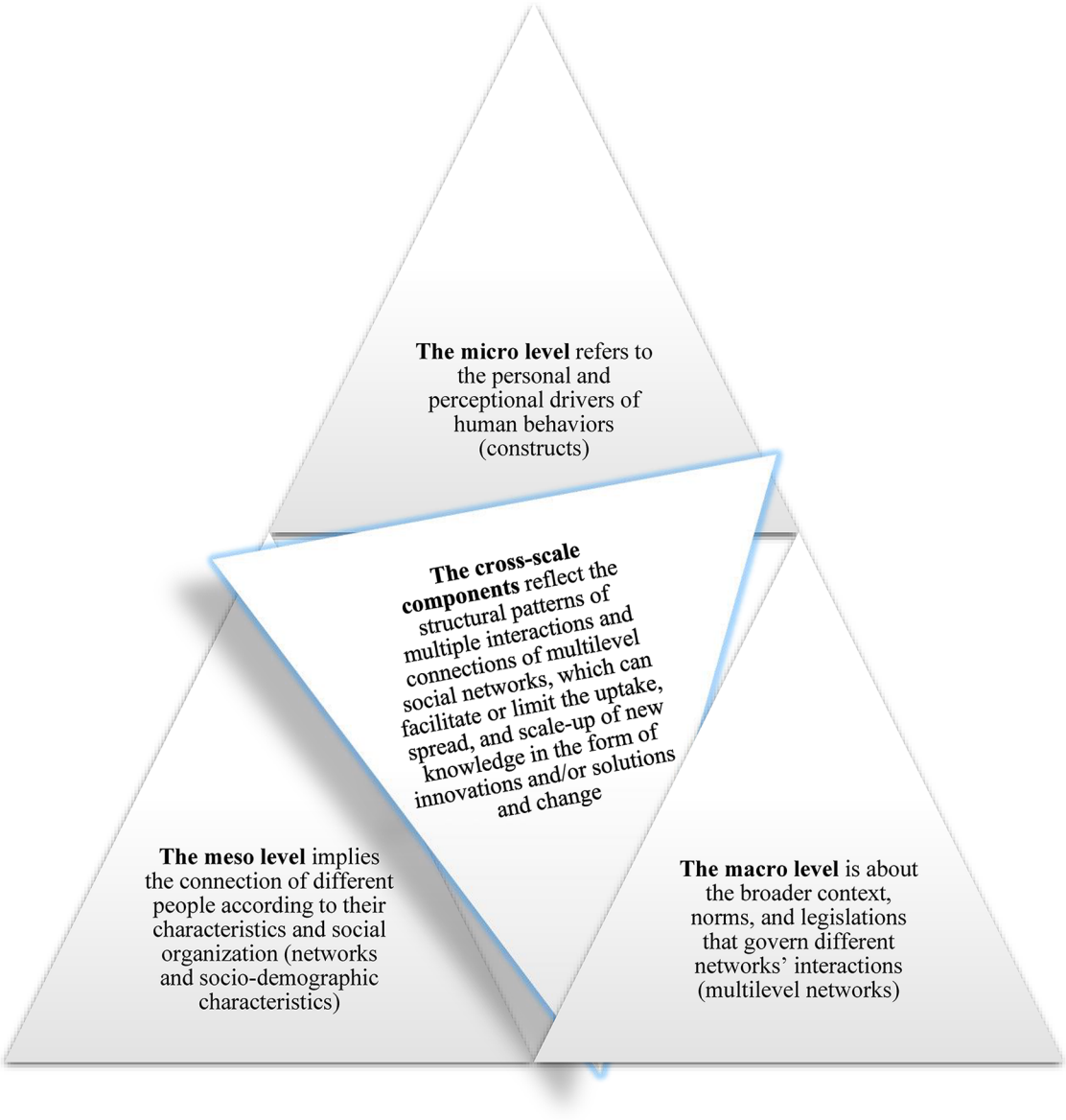

FIGURE 5
PROLIFERATE multi-logic is centered on the cross-scale components of health systems.

PROLIFERATE can be used longitudinally or cross-sectionally; this evaluation focus is implied in the bottom part of Figure 2, which shows an arrow that connects the last step of the procedure to its beginning, represents an iterative optimization cycle that improves and maintains an ongoing application of the framework if necessary. This quality and sustainability cycle assumes the implementation and de-implementation of interventions, procedures, and technologies as a natural process that requires measuring the tracking/scoring/benchmarking of the four first constructs and optimizing innovations (considering construct #5) within complex adaptive systems. A description or mapping of the cross-scale components can be done by examining the structural patterns, frequencies of interactions/networks, or structures of social relations and/or their types of connections and occurrence (17, 31, 38, 39).

PROLIFERATE social logic: guiding procedure of the evaluation

The explained focus of the PROLIFERATE evaluation is guided by a procedure imported from the social logic of "the learning, evaluation, and planning framework" (LEAP) (34) (see Table 1 and the top part of Figure 2). The LEAP uses a co-design approach that steers the evaluation of PROLIFERATE constructs according to this general checklist (depicted in the top part of Figure 2):

- forming a transdisciplinary group with users of the evaluated matter and learning about the PROLIFERATE evaluation method;

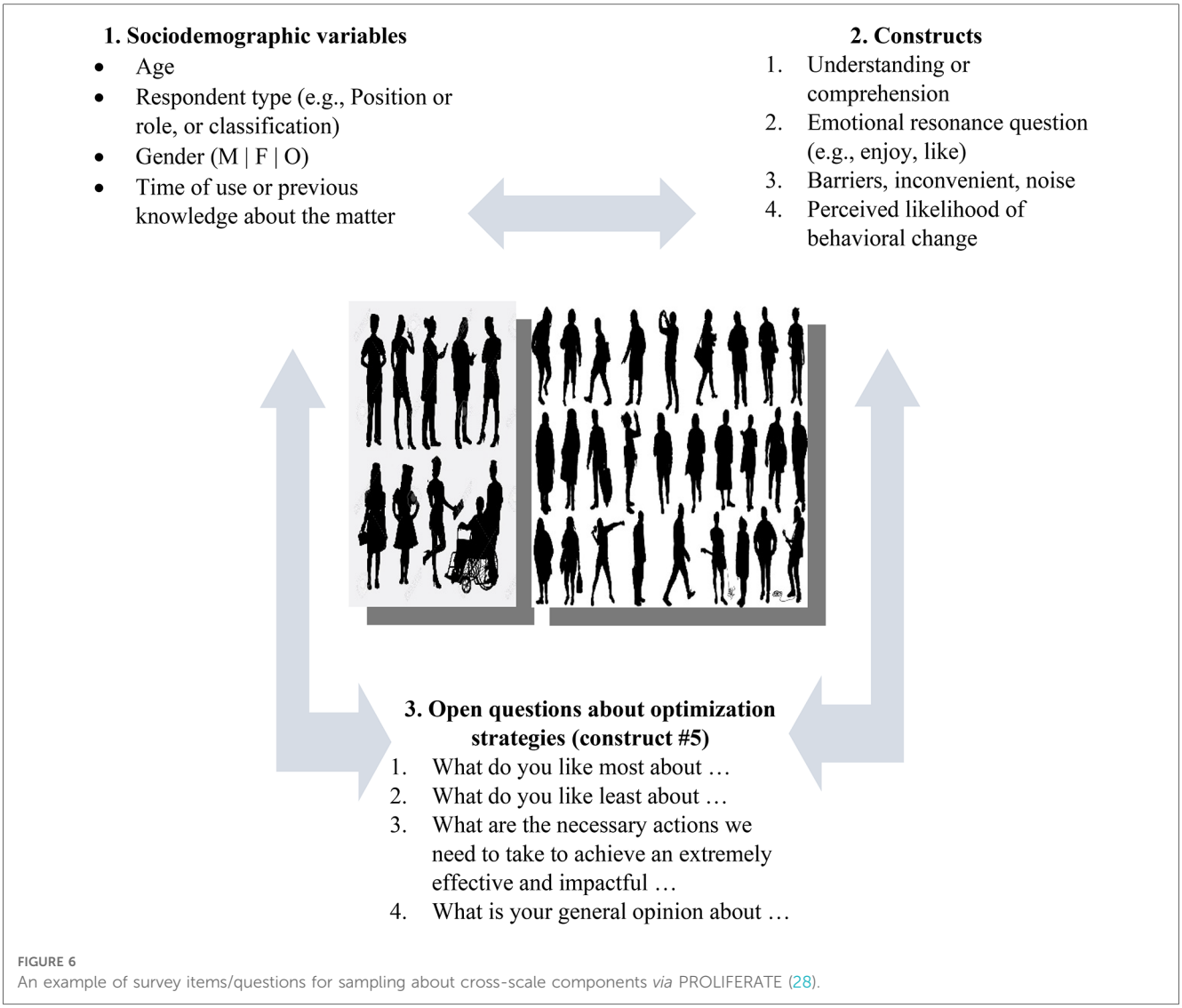

FIGURE 6
An example of survey items/questions for sampling about cross-scale components *via* PROLIFERATE (28).

- agreeing on the outcomes to be evaluated: goals and assumptions of the group, including the populations that they may be representing (e.g., KT-cnm sectors) and from which they will collect data to test their hypotheses; this means benchmarking (i.e., establishing measurable success indicators) concerning PROLIFERATE's constructs;
- actioning a planning process on making a difference about the most appropriate methods for collecting (sampling) and analyzing data about the innovation/solution, considering the constructs and the stakeholders' sociodemographic characteristics as variables (as per **Figures 3** and **6**);
- tracking constructs to measure the innovation impact longitudinally or cross-sectionally; this means evaluating the difference made using PROLIFERATE scoring system and considering the optimization data (construct #5);
- creating targeted strategies for better uptake or optimization, considering each type of user (e.g., their KT-cnm sectors and their positioning according to the KT-cnm's stages (31)); and
- disseminating the lessons learned to each stakeholder group/type (i.e., targeted strategies developed from the data analysis) to facilitate the scale-up and sustainability of the evaluated matter (34, 35).

The whole procedure of PROLIFERATE is based on and supported by two enabling values from the social logic (36):

1. value 1: "pluralism" as the acceptance and expectancy of difference in transdisciplinary co-design environments (36); and
2. value 2: "dialectical" is the operative process of dialogical nature in which all positions have a voice and vote in the co-design table (36).

This "dialectical pluralism" component of PROLIFERATE is visible in **Figure 2** (procedure). It is highlighted because of the need for proper co-design in the innovation process and the interpretation and evaluation of data and big data per stakeholders' requirements. Therefore, all stakeholders, including the facilitators and evaluators, must work as peers with equitable expertise and authority to run this procedure. This enabling factor may allow researchers, practitioners, clients, policymakers,

the community, and other stakeholders to co-design, track, influence, or optimize sustainable innovations or adaptable solutions accounting for their agreements, frictions, compressions, and tensions (36, 43, 44).

PROLIFERATE as an adaptable evaluation framework

In making a case around the multi-logic of PROLIFERATE and demonstrating why it expands the body of knowledge to inform IS, we embrace the principles of Nilsen's taxonomy (around the characteristics of IS frameworks) (21). This is done by tabling a broad comparison of different IS approaches (**Table 3**). This comparison helps the reader identify *what* is required and/or *how* each method reaches its objectives. **Table 4** facilitates a testing or comparison exercise intending to demonstrate the complementary nature between the different logics, approaches, designs, and capabilities of:

1. the normalization process theory (NPT) (45, 46);
2. the 2 × 2 conceptual map of influence on behaviors (42); and
3. PROLIFERATE (24, 30).

The comparison of approaches in **Table 3** presents the NPT level of complexity (45, 46) mostly around the social logic; the 2 × 2 conceptual map of influence on behaviors (42) as a tool consistent with the mechanistic logic; and PROLIFERATE as a multi-logic evaluation approach that can help prioritize and make sense of the elements of importance for stakeholders per their positioning within KT-cnm sectors and processes (24, 28–30). The embracement of PROLIFERATE toward different types of logic is observed in **Table 3**, as each descending row does not prevent predecessors' approaches from occurring and being used in subsequent rows. In this way, the last row location of PROLIFERATE implies that it may, in a non-exclusive manner, absorb and mix the strategies of other methods in adaptable ways. Further, we provide snapshots of ongoing research in different healthcare settings within Australia to demonstrate how PROLIFERATE is being used while embracing different methodologies to evaluate various innovations.

Results

To introduce the results, we return to **Figure 1** and PROLIFERATE's multi-logic approach because its mixture of logics may result in several concepts and terms being interpreted differently depending on the reader's background. To facilitate a common language across logics within this manuscript, we created a glossary of critical terms in **Table 4** to unify understandings around some of the ideas presented in the background and explored in the coming case exemplars.

To demonstrate PROLIFERATE's adaptability, in **Table 5**, we display snapshots of ongoing research in different healthcare settings within Australia; it exemplifies how PROLIFERATE is utilized within:

1. A community-based service: the innovation implemented is an interprofessional learning procedure within an allied health service (Health2GO). In this work, the transdisciplinary group ($n = 96$, across several sessions) co-designed the interprofessional learning procedure during focus groups that involved researchers, students, and teaching specialists from hearing, speech pathology, physiotherapy, vision, and health research areas (43).
2. A tertiary care service: the innovation is an Artificial Intelligence (AI) driven technology (RAPIDx_AI), which is implemented/tested *via* a randomized controlled trial (RCT), in which PROLIFERATE is evaluating its end-users' feedback and integration within hospital workflows (24, 28, 30, 53). This adaptation of PROLIFERATE involves the creation of a transdisciplinary group ($n = 15$) to test the integration of the AI tool within hospital emergency departments. The group comprises experts in Bayesian models and statistical analyses; ethical and legal considerations; KT-cnm; medicine; RCTs; co-design; project management; cognitive sciences; behavior and health research; experimental design and big data; evaluation methods; science communication, health promotion, and marketing science; digital technologies and artificial intelligence; community representation and advocacy; non-profit organizations; psychology; social sciences and art; and nursing and clinical practice (24, 28, 30, 53).

The Snapshots' comparison of two PROLIFERATE adaptations (**Table 5**) exemplifies *what* is required and/or *how* PROLIFERATE methodological adaptations are becoming fit for purpose within two different innovations and objectives. For instance, in adaptation 1 (Health2Go), the evaluation detected a lack of motivation leading to a score of "good impact" because of more passive than promoters' responses in construct #4 (motivation to change); to address this issue, data from construct #5 (optimization) informed the transdisciplinary group about potential ways to change this situation: offering stakeholders insight, according to each type of learners and their interactions with others; developing solutions targeting better times for interprofessional learning; delivering better schedules; and providing space to focus on the process (43).

In RAPIDx_AI, the transdisciplinary group pre-established a success benchmark of 50% for each end-user type (i.e., clinicians and community, as per **Table 6**). The idea of this simulation is to demonstrate that based on that information (big data approach), the transdisciplinary group can co-design KT activities, interventions, and solutions to move constructs above the benchmark for clinicians and the community concerning the undesirable predictions (in the lower level of the credible interval) about the motivations and emotions concerning RAPIDx_AI potential impact (see **Table 1**) (24, 28, 30, 53).

The prediction of RAPIDx_AI's impact unveiled this PROLIFERATE score: "average impact"; because it found only two successful constructs (over the 50% benchmark, including the credibility intervals): comprehension—construct #1—and uptake barriers—construct #3, and identified the other two (motivation—construct #4, and emotion—construct #2) below the agreed benchmark (**Table 6**). Qualitative data analysis from the assessment of construct #5 (optimization) must be considered to create KT strategies around the constructs, according to

TABLE 3 Comparison of approaches (based on the principles of Nilsen's taxonomy around the characteristics of IS frameworks (21)).

Approaches	Objectives	What is the investigative focus of the implementation approach	How users/adopters (e.g., clinicians) are addressed in the approach	How end-users are investigated or considered (e.g., patients) in the approach	How is the implementation context considered in the approach	How or what are the means of facilitating the implementation process
Normalization process theory (NPT) (45, 46)	Describing how the intervention and its components change and how practices are operationalized, enacted, and reproduced (Intervention performance, Relational restructuring, Normative restructuring, Sustainment – normalization)	Constructs (Coherence-building, Cognitive participation, Collective action, Reflexive monitoring) and mechanisms of purposive social action behind health techniques, technologies, and other complex interventions	Detecting the mechanisms of purposive social action that require an investment of personal and group resources	They are interpreted chiefly from the users'/adopters' (e.g., clinicians) feedback	Qualifying patterns of social relations and structures (Strategic intentions, Adaptive execution, Negotiating capacity, Reframing organizational logic) that unfold over time and across settings and create the implementation environment	Identifying, characterizing, and explaining the Context-Mechanism-Outcome configuration to qualify and organize inductive and/or deductive implementation studies
2 × 2 conceptual map of influence on behaviors (42)	Guiding about the type of theory, model, or framework that might be most relevant for understanding and facilitating behavior change	Individual-level and collective-level influences on behaviors directed by conscious cognitive processes or non-conscious processing	Identifying the conditions regarding what influences practitioners' behaviors	They are interpreted chiefly from the users'/adopters' (e.g., clinicians) feedback	Using mixed-method research that responds to the types of influences on the behaviors that need to be changed	Accounting for whether behaviors are deliberate or automatically performed and under what circumstances they operate
PROLIFERATE (24, 30)	Co-designing, measuring, and optimizing innovations and solutions within complex adaptive health systems	Constructs around stakeholders, users, and end-users behaviors (Comprehension or understanding, Resonance or Emotional responses, Uptake barriers, Motivation associated with behavior change, and Optimization suggestions or opinions), and the person's sociodemographic characteristics as reflections of KT-cnm's networks/clusters/dynamics (i.e., PROLIFERATE: cross-scale components)	Co-designing: identifying, engaging, and sampling/testing/falsifying the dynamic interactions (in space and time) of the sample and their personal experience/expertise concerning their constructs, networks/clusters per sociodemographic characteristics across the KT-cnm processes/sectors and goals (i.e., PROLIFERATE: cross-scale components and insights from the transdisciplinary group)	Co-designing: identifying, engaging, and sampling/testing/falsifying the dynamic interactions (in space and time) of the sample and their personal experience/expertise concerning their constructs, networks/clusters per sociodemographic characteristics across the KT-cnm processes/sectors and goals (i.e., PROLIFERATE: cross-scale components and insights from the transdisciplinary group)	Using mixed methods to locate, track, and respond to complex adaptive interaction, interconnections, and links between the sectors (adopters, users, and end-users) and the processes and stages of KT, given the person's sociodemographic characteristics and evaluated constructs in time/frequencies/occurrences (i.e., PROLIFERATE: cross-scale components and insights from the transdisciplinary group)	Using dialectical pluralism for co-designing adaptable mixed-method approaches/solutions *via* transdisciplinary and participatory action research methods that triangulate findings from: 1. the PROLIFERATE score and the cross-scale components; 2. the optimization construct (#5; and 3. the insights from the transdisciplinary group

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TABLE 4 Terms defined according to the emerging adaptable framework: PROLIFERATE.

Term	Explanation
Big data (47)	Digital data (a considerable amount) captured *via* technological devices that require processing using computational or algorithmic procedures to draw responses to diverse research questions
Bayesian statistics and prediction modeling	Bayesian techniques are based on mathematical statistics to test and offer inferences about a matter of interest *via* Bayes' theorem (48). In such a theorem, investigators update the probability of a hypothesis (*prior distribution*) by taking more evidence into its assessment (*posterior distribution*) (48). This Bayesian approach is fundamental to informing decision-makers. The method is used in medicine, quantum physics, biology, and the investment industries because of its prediction modeling capacities: estimating probability distributions of potential outcomes and allowing for random variation in inputs (i.e., stochastic changes) concerning the matters of interest (30, 48)
De-implementation (49)	A procedure of identifying and removing or substituting unsafe, irrelevant, and/or low-value practices, technologies, and/or processes (partially or entirely) *via* their empirical and evidenced-based evaluation; this includes developing unlearning methods to support and sustain the required behavioral, procedural, social, and/or contextual change
Falsifiability (50)	The condition of acknowledging falsification (e.g., disconfirmability or refutability): the logical possibility that a hypothesis, assertion, or theory can be revealed to be false through observation or an experiment (a test)
Transdisciplinary (24–27, 51)	The incorporation of knowledge—coming from different cultures, values, capabilities, and rationalities—from and with diverse stakeholders (experts and/or users) with interests to produce solutions that transcend the boundaries of their various fields and personal experiences
Net Promoter Score (52)	A method to evaluate and track the customer-centric value of products and/or services across large samples in a quantitative and replicable manner. It calculates the number of respondents expressing positive views about a product or service ("Promoters"), minus those with opposing views ("Detractors"), ignoring neutral responses ("Passive")

the sociodemographic variables and the identified KT-cnm sectors and stages concerning clinicians and community members (24, 28, 30, 53).

These examples of using the PROLIFERATE scoring system are collected in both studies *via* an online survey to investigate the triangulation behind the PROLIFERATE cross-scale components (as described in **Figures 4–6**). In both case exemplars (Health2Go and RAPIDx_AI), each sector's sociodemographic characteristics and responses to construct #5 (optimization) should have been considered against the transdisciplinary group's insights; such triangulation would have determined the best KT approach that addresses cross-scale findings. However, these examples reflect incipient studies that need more progress to share such experiences.

A takeaway from the current status of PROLIFERATE is that within the case examples presented, the transdisciplinary team cross-pollinated ideas based on their experiential learning, aiming to acquire, utilize, or master individual and/or collective skills and capabilities for collaborative research (51) (Box 1).

Embarking on this journey to inform the nature and body of work requires commitment and support, alongside investment of time and effort—most often to absorb the backlash due to power dynamics and deeply entrenched "resistance to change." The development of the PROLIFERATE framework tried to bring a conglomerate of knowledge and wisdom (like a snowball) collectively by collaborating and undertaking research projects within the domain of applied KT, IS, and health systems research. This shared experience (history or collaboration projects) is enriching, despite differing views, methods, cultures, or perspectives. However, it implies that all participants, co-authors, and partakers have a vision that is based on the listed core values, so they all gain something relevant by reaching toward it. Most studies of this transdisciplinary nature refer to the high cost behind such collaborative activities, mainly referring to involving non-academic peers; we believed that their budgeted and supported involvement is an ethical imperative that must always be part of any multistakeholder design (14, 15, 19).

BOX 1 These capabilities underpinned core values that were explicitly put forward and explored with each PROLIFERATE adaptation (see co-design evaluation procedure and Figure 2).

- to undertake research that crosses disciplinary boundaries (51);
- to develop and apply tools and frameworks in new situations (51);
- to sustain an appreciation for the importance of the particular or granular aspects of problems (51);
- to utilize and understand pluralism (51);
- to acknowledge and communicate complexity effectively (51);
- to understand and utilize reflexivity (51);
- to actively empower collective leadership centered around the core values while navigating the power dynamics (51);
- to reimagine and work toward sustaining research livelihood (51);
- to manage/work with and for a research team beyond institutional boundaries and projects (51);
- to establish trust in collaboration (51);
- to be egalitarian (51);
- to be humble (51); and
- to build societal capacity for democratic struggle (51).

Those interested in applying an adaptation of the PROLIFERATE framework to their programs, projects, products, or procedures must consider the framework flexibility; this means their investments (cost, skills, and time) would depend on the context and matter to be evaluated while forming a transdisciplinary group, fomenting the core values, so that they

TABLE 5 A snapshot comparison of two PROLIFERATE adaptations.

PROLIFERATE adaptations	Background	Objective	Methods	Findings/results	Conclusion
Health2Go study called: "Un-siloing allied health practice and interprofessional learning" (43)	An interprofessional service involves multiple professionals/caregivers collaborating to deliver quality care and comprehensive health services to clients. Leveraging the combined skills and perspectives in collaborative care improves client outcomes, saves time, and facilitates managing and coordinating chronic conditions. However, learning to coordinate different care stakeholders to manage multiple healthcare issues requires shifting power structures and embracing diversity to teach and apply such procedures	To co-design and evaluate interprofessional learning within a student-led clinic that offers optometry, audiology, physiotherapy, speech pathology, exercise physiology, occupational therapy, and nursing services to a diverse population (>50% born overseas). We intended to identify the challenges/opportunities to improve the sustainability of quality care *via* interprofessional learning	The interprofessional co-creation involved three co-design sessions, $n = 32$ people each, and a posterior sampling procedure. Ethics approval (No. 1858) and consent were received to apply: PROLIFERATE (**Figure 2**). After an initial implementation phase, the transdisciplinary group agreed on testing PROLIFERATE constructs using Net Promoting Score principles (see 52) *via* an anonymized online survey. Such principles measured the innovation's promoters, passive, and detractors of "Interprofessional learning (IL)." The passing or success of each construct (i.e., benchmark) was established considering the percentage of promoters in constructs #1, #2, and #4 (or the responses against detractors concerning construct #3). Construct #5 was assessed qualitatively by interpreting open answers to optimization questions	The results of the co-design sessions facilitated the implementation of IL *via* clinical learning activities outside the participant's discipline through observation and follow-up discussions. The online evaluation survey captured 15 survey respondents in the areas of hearing (20%), speech pathology (27%), physiotherapy (13%), vision (20%), and other (20%). Each PROLIFERATE construct (**Figure 3**) unveiled: 1. comprehension: promoters (47%), passive (40%), detractors (13%); 2. emotional responses: promoters (53%), passive (33%), detractors (13%); 3. barriers: responses provided against detractors (80%), promoters (13%), passive (7%); 4. motivation: promoters (40%), passive (47%), detractors (13%); and 5. Optimization: people requested targeted time or better scheduling and space to focus on IL	The design and implementation received a PROLIFERATE score of "Good Impact" and captured essential planning strategies for overcoming the motivation barriers around IL in allied health practices. Further investigation should incorporate the optimization suggestions and construct results in light of sociodemographics to longitudinally test IL using a bigger sample. This study brings evidence and methods for supporting the WHO's recommendation on developing a "collaborative practice-ready" health workforce that embraces differences around expertise and personal characteristics (culture, ethnicity, age, etc.) to improve healthcare
RAPIDx_AI (24, 28, 30, 53): a computer simulation study evaluating (predicting) the impact of AI implementation. Study called: "Predicting the implementation impact of RAPIDx_AI in South Australian (SA) emergency departments" (54)	There were 75,900 presentations to Australian public hospital emergency departments (EDs), with a principal diagnosis of coronary heart disease in 2020–2021. RAPIDx_AI is tested within a randomized controlled trial to test whether computer algorithms in hospital EDs can help doctors provide better care for patients by receiving guidance about diagnosing and treating patients with symptoms that may be due to their heart	To test a PROLIFERATE adaptation for predicting and measuring stakeholders' perspectives about the implementation impact of RAPIDx_AI. This methodological adaptation was necessary because person-centered healthcare services require effective technology integration within clinical workflows to provide better patient care while considering the needs of all end-users involved and affected by AI or similar tech/practices/service changes	We introduced PROLIFERATE and incorporated Bayesian statistics as our data analysis method to benchmark the constructs. We created a protocol for this adaptation and modeled data (i.e., produced computer-simulated results) to demonstrate the evaluation and prediction capabilities of the method concerning the impact of RAPIDx_AI in simulated clinicians and communities (patients and their families). PROLIFERATE constructs were benchmarked at a 50% prediction concerning the 95% probability prediction intervals and credible intervals (2.50–97.50)—PROLIFERATE AI algorithm and data analysis were produced in R (software), $n = 60$ simulated scenarios	Our methodological innovation (protocol) is informed by 95% probability prediction and credible intervals on these domains of stakeholders' perspectives: Comprehension, Emotional response; Uptake barriers; Motivation, and Optimization. Computer-simulated responses to a PROLIFERATE online survey predicted (**Table 6**) an Average Impact for RAPIDx_AI. The simulation results imply that the transdisciplinary group must implement motivational and emotional knowledge translation strategies for clinicians and the community to improve the perceived impact of RAPIDx_AI and its sustainability. Ethical approval for using PROLIFERATE (non-simulated evaluation) in 12 SA hospitals was granted by the Southern Adelaide Human Research Ethics Committee (SACHREC) (OfR no.272.20)	This AI adaptation of PROLIFERATE considers the non-linear characteristics of complex and adaptive workflows of acute care environments from an end-user perspective; it can monitor real-world clinical settings, research outcomes, and technological products by assessing their fitness *via* person-centered parameters and a co-designed transdisciplinary approach, which will be used to test and evaluate the RAPIDx_AI integration within clinical workflows to provide better patient care in SA

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agreed on goals, and benchmarking methods. This process could be articulated into a straightforward and rapid project or could become a prolonged sustainability cycle; from our point of view, it promises returns on investment because it measures and can optimize innovations and solutions considering their context complexity while delivering adaptive strategies. This perspective comes from our own longitudinal and transdisciplinary co-design journey concerning these evaluation endeavors. They have been powered and moved by long-term aims that feed into one or several research programs. This process requires a longstanding plan, including envisioning, thought leadership, and appropriate investments. We have benefited from the ingenuity of articulating different projects into a programmatic and impactful vision in which all part-takers gain something in the long run.

To illustrate the navigation process and the associated complexities of our long-term evaluation design, we mapped the networks of collaboration from which the PROLIFERATE framework is emerging. Usually, a more extensive view of the network exists in real-world scenarios as it involves more than one investigator and stakeholders representing several institutions and groups. However, in this paper, for simplification purposes, we presented the lead author's (investigator's) network because it gives us a sense of the least we can capture empirically (as best as we can with the current measurement tools) through her published works (from the period 2019 until the present, 2023). This network represents the internal and external stakeholders (academic and non-academic; health and non-health; practice and policy), influencing implicitly, explicitly, directly, or indirectly the development of PROLIFERATE and its emerging iterations or adaptations.

Figure 7 presents a PROLIFERATE co-creation network as a growing connectivity structure empowered with similar core values and the long-term goals underpinning KT and IS approaches. For example, generalizing some of our experiences around transdisciplinary goals, researchers on this network wanted to co-create the framework because of their investigative and academic interest in co-design and translation in a real-world setting. Health consumers wanted to influence healthcare services and research procedures and make their voices heard and influential within the discovery and implementation processes. Clinicians needed to demonstrate the effect and

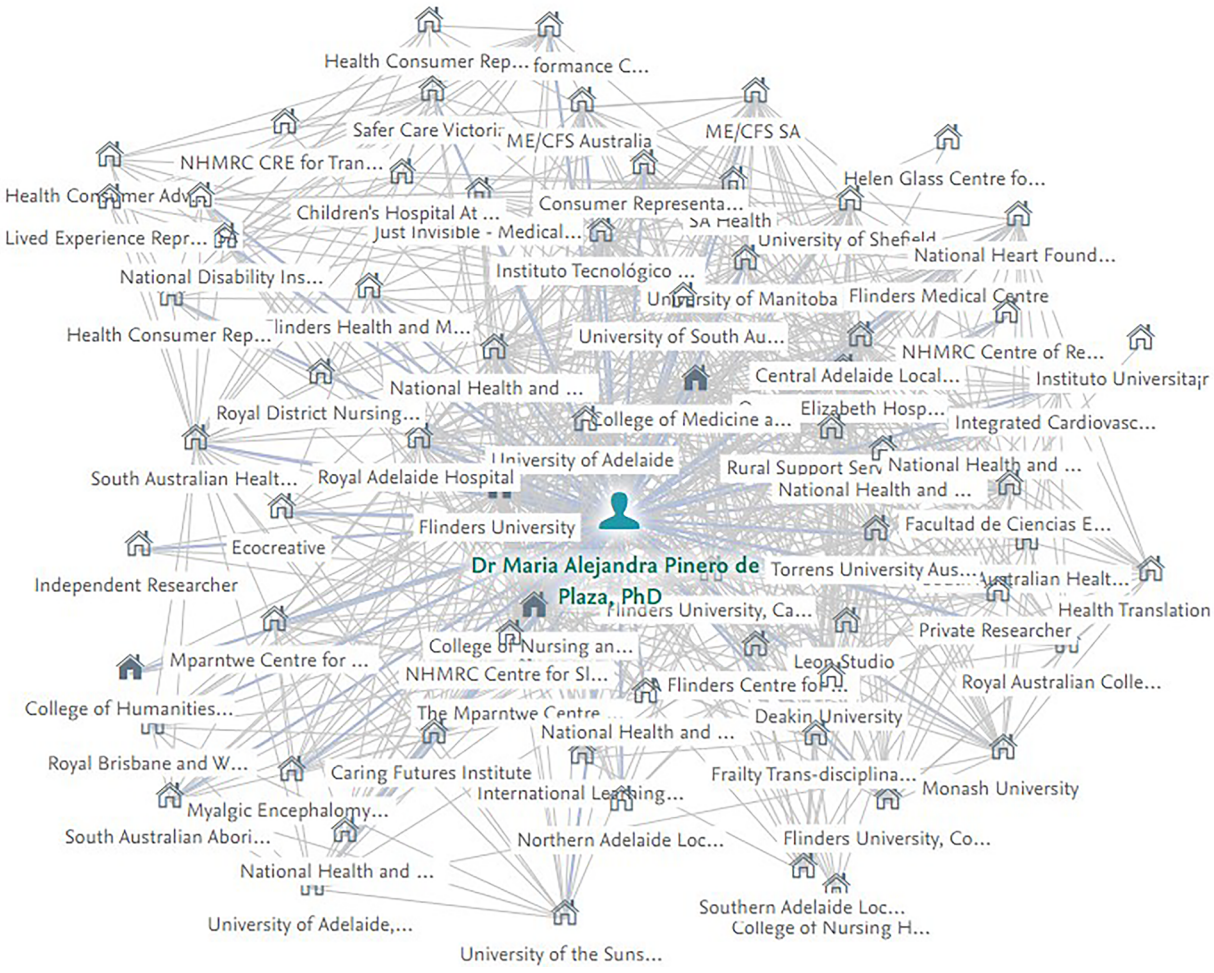

FIGURE 7
Lead author emerging PROLIFERATE network—developing and maturing over time (2019–2023). Data are based on the published work and co-authorship networks generated by the "ResearchNow" open online platform of Flinders University.

TABLE 6 The predictive result from RAPIDx_AI modeling via Bayesian statistics in R (24, 28, 30, 53).

Intervention Group	Prior	Mean	0.025	0.975
Clinicians	Uptake barriers	0.86	0.68	0.97
	Comprehension	0.81	0.60	0.95
	Emotion	0.60	0.40	0.79
	Motivation	0.66	0.44	0.85
	Optimization	0.76	0.56	0.91
Community	Uptake barriers	0.86	0.70	0.97
	Comprehension	0.81	0.62	0.94
	Emotion	0.62	0.40	0.81
	Motivation	0.66	0.44	0.82
	Optimization	0.77	0.56	0.93

impact of their interventions to improve care and attract and justify funding. Artists wanted to demonstrate how their methods could generate an impact and social change, and industry wanted to be backed up by evidence-based research. This win-win scenario for the network does not end after achieving a single objective or a specific endpoint but intends to continue in the journey while learning its lessons. Each stakeholder or person collaborating and participating in any adaptation of PROLIFERATE or its associated KT studies is willingly a part of a transdisciplinary program to which they bring their own networks, knowledge, and agendas/interests. In this democratic process, they seem to organically (and eventually, after induction, intentionally) recognize the intersecting spaces (per the KT-cnm) in which synergy and dialectical relationships seem beneficial strategies to attain, maintain, or gain their respective long-term goal.

Discussion

PROLIFERATE allows and promotes the utilization of metrics (e.g., measurable strategies such as data science) to help the transdisciplinary group falsify or test their assumptions about the dynamics of the health systems and the stakeholders they represent (17, 43, 44, 55). PROLIFERATE's adaptable nature and its transferable scoring system can be used to compare and measure by how much of a difference an innovation or a solution has impacted; this ability extends to predictive models of such impacts (24, 28, 30, 53). However, further iterations and longitudinal analyses must elucidate PROLIFERATE's utility and relevance across time and with bigger sample sizes. Its emerging status demonstrates the method's applicability and flexibility. However, the case examples are still in progress and not mature enough to:

1. illustrate the PROLIFERATE process in the long run, its obstacles, benefits, or the effects of the final steps of its procedure concerning implementing the strategies recommended by the transdisciplinary group and their impact; and
2. map or describe the cross-scale components that reflect the structural patterns of multiple interactions and connections of multilevel social networks to facilitate or limit the uptake, spread, and scale-up of new knowledge in the form of innovations and/or solutions and change.

A call to utilize and test PROLIFERATE is extended so that peers can evaluate its advantages and limitations within other healthcare services, products, procedures, and challenges. Such iterations may decant and percolate the dialectical pluralist approach and the multi-logic attributes enabling sustainable change or obstructing it. Peers could test the re-orientation of networks to facilitate the implementation of change by promoting effective connectivity between the five KT-cnm processes; this can be explored in future research by introducing tools such as the 2×2 conceptual map of influence on behaviors (42) and its mapping capabilities. They may enhance the recommendations and strategies of the transdisciplinary group by tailoring the KT-cnm structures *via* influencing conscious or unconscious behaviors (42).

A challenge around agreeing on implementing optimization strategies can emerge despite the dialectical pluralist approach. Even when inclusiveness should guide PROLIFERATE's co-design work, the transdisciplinary group can be seen as a miniature representation of the whole health system. Therefore, to diminish ideological and many other differences, the group's attention to cross-scale findings must be their focus to inform decisions and recommendations (an evidence-based emphasis) (31, 38–40). Yet, the difference between members' agendas is expected. Therefore, other avenues may point to research projects adapting PROLIFERATE to gaming frameworks, such as the Octalysis Framework. This could help direct behaviors, as done with game players, toward certain activities or decisions (56). Such a combination could help the transdisciplinary group testing if behavioral drivers that move game players can influence and benefit behavioral change and KT and IS. For example, the first driver of the Octalysis Framework is called "epic, meaning and calling"; it involves activities in which the person's motivation is acting safely and responsibly for a cause greater than themselves (56). These activities may induce change from not-for-profit stakeholders associated with a particular innovation.

In contrast, the fifth driver of the Octalysis Framework—"social influence and relatedness"—incorporates social elements that motivate the person to function *via* mentorship, social acceptance, and considering other influences such as competition and envy (56). This driver may influence behavioral change in health practitioners, industry sectors, or academics. Similar methods around stimulating drivers, triggers, and motivators of behavior have been used by members of the transdisciplinary group that created PROLIFERATE; they were applied in marketing studies to identify buyers and users of luxury items (57) and in health promotion to identify patterns of healthy and unhealthy dietary habits (55). Consequently, future iterations and adaptation of the PROLIFERATE evaluation framework could allow testing such techniques and their abilities to improve the co-designing, measuring, and optimizing of innovations and solutions within complex adaptive health systems.

Conclusion

An essential requirement to face today's health challenges is taking a complex view of the impacts or effects of solutions and innovation within the health systems. Such approaches need further research around multi-logic methods because they invite crossing traditional scientific boundaries to bring new ways of understanding our human physical, biological, ecological, and social dimensions (17, 43, 44, 44, 58). Consistently, we share PROLIFERATE as one of the first frameworks operationalizing the KT-cnm. This operationalization adds a novel perspective to the individual's agency in the system by considering their responses to innovations, including tech-enabled solutions within different healthcare settings. This work provides structured co-design and co-facilitation processes that help engage multiple stakeholders in dynamic and productive ways by measuring and optimizing behavioral patterns around innovation, considering the complexities of their uptake, spread, and scale-up.

Data availability statement

The original contributions presented in the study are included in the article, further inquiries can be directed to the corresponding author.

Ethics statement

The three projects that generated the integration of this methodological study received Ethics approval in South Australia, Australia, as follows:

1. Concerning the frailty, video evaluation codesign, and engagement study: Ethic approval was received from the Flinders University Human Research Ethics Committee - Project No. 8557.
2. Concerning the Health2Go study: Ethic approval was received from Flinders University Human Research Ethics Committee - Project (No 1858).
3. Concerning the RAPIDx_AI study: Ethics approval was received from the Southern Adelaide Clinical Human Research Ethics Committee (SAC HREC): OfR no.272.20.

Author contributions

AK provided significant intellectual contributions to the framework creation, guidance, and mentorship throughout its emergent development. LY reviewed the manuscript and provided important recommendations to communicate and sharpen concepts, data, and ideas. MAPdP created the methods and projects about PROLIFERATE in collaboration with different transdisciplinary groups; among them are important co-authors of the ideas previously presented or published elsewhere and referenced in the manuscript. They are Carlos Javier Barrera Causil, Fernando Marmolejo Ramos, Kristina Lambrakis, Alline Beleigoli, Michael Lawless, Derek Chew, Mandy Archibald, Alexandra Mudd, Penelope McMillan, Erin Morton, Rachel Ambagtsheer, Ehsan Khan, Robyn Clark, David Jacobs, Lucy Chipchase, Renuka Visvanathan, and the NHMRC CHAP Project Team. All authors contributed to the article and approved the submitted version.

Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Designing implementation strategies to improve identification, cascade testing, and management of families with familial hypercholesterolemia: An intervention mapping approach

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Introduction: Familial hypercholesterolemia (FH) is a common inherited cholesterol disorder that, without early intervention, leads to premature cardiovascular disease. Multilevel strategies that target all components of FH care including identification, cascade testing, and management are needed to address gaps that exist in FH care. We utilized intervention mapping, a systematic implementation science approach, to identify and match strategies to existing barriers and develop programs to improve FH care.

Methods: Data were collected utilizing two methods: a scoping review of published literature, related to any component of FH care, and a parallel mixed method study using interviews and surveys. The scientific literature was searched using key words including "barriers" or "facilitators" and "familial hypercholesterolemia" from inception to December 1, 2021. The parallel mixed method study recruited individuals and families with FH to participate in either dyadic interviews ($N = 11$ dyads/22 individuals) or online surveys ($N = 98$ respondents). Data generated from the scoping review, dyadic interviews, and online surveys were used in the 6-step intervention mapping process. Steps 1–3 included a needs assessment, development of program outcomes and creation of evidence-based implementation strategies. Steps 4–6 included program development, implementation, and evaluation of implementation strategies.

Results: In steps 1–3, a needs assessment found barriers to FH care included underdiagnosis of the condition which led to suboptimal management due to a myriad of determinants including knowledge gaps, negative attitudes, and risk misperceptions by individuals with FH and clinicians. Literature review

highlighted barriers to FH care at the health system level, notably the relative lack of genetic testing resources and infrastructure needed to support FH diagnosis and treatment. Examples of strategies to overcome identified barriers included development of multidisciplinary care teams and educational programs. In steps 4–6, an NHLBI-funded study, the Collaborative Approach to Reach Everyone with FH (CARE-FH), deployed strategies that focused on improving identification of FH in primary care settings. The CARE-FH study is used as an example to describe program development, implementation, and evaluation techniques of implementation strategies.

Conclusion: The development and deployment of evidence-based implementation strategies that address barriers to FH care are important next steps to improve identification, cascade testing, and management.

KEYWORDS

familial hypercholesterolemia, implementation science, intervention mapping, identification, cascade testing, treatment, management, cholesterol

1. Introduction

Familial hypercholesterolemia (FH) is a common inherited cholesterol disorder (prevalence 1 in 250) which leads to premature cardiovascular disease when left untreated (1, 2). Patients with a pathogenic variant in an FH gene have triple the risk for atherosclerotic cardiovascular disease (ASCVD) when compared to those without a genetic variant at any low-density lipoprotein-cholesterol (LDL-C) level, due to lifelong exposure (3). Diagnosis is often made in middle-aged adults, after experiencing premature ASCVD (4). Event rates for an FH patient with prevalent ASCVD are 5-fold higher compared to those with no prior ASCVD (5). Treatment beginning in adolescence lowers the risk for ASCVD before age 40 years from about 25% to <1% (6, 7). Although diagnostic criteria and treatment guidelines exist, data from patient registries show that FH remains underdiagnosed and undertreated for decades (4, 8, 9).

Since FH is a disease that runs in families, it is imperative that family communication and cascade testing occur so that at-risk family members are notified of their risk and have the option to undergo testing for FH. Preliminary data from the MyCode Genomic Screening and Counseling Program at Geisinger showed that probands who received FH results had approximately three living at-risk first-degree relatives that should be notified of this diagnosis and their risk; however, cascade testing had only occurred for approximately 3.5% of those relatives. Strategies have been deployed in practice to address barriers for each component of FH care: identification, cascade testing, and management (10, 11). Such efforts include improving data monitoring, sending electronic notifications to clinicians, development of new clinical teams, etc. However, in the United States the identification gap has only been improved from 10% to 30% of people being diagnosed with FH and cascade testing efforts have been suboptimal (12, 13).

To date, a systematic implementation approach has not been taken to improve FH care. One method to systematically develop implementation strategies uses both intervention (14) and implementation mapping (15), and includes diverse stakeholder perspectives to inform and improve care (14, 16). The six-steps of intervention mapping build toward developing an intervention and its evaluation (14). The six-steps are: (1) needs assessment, (2) specifying change objectives, (3) selecting theory-based intervention methods and practical applications, (4) producing the program, (5) specifying implementation plans, and (6) generating an evaluation plan (14). Implementation mapping expands upon intervention mapping to add strategies to improve adoption, implementation, and maintenance. When a systematic approach has been applied in other health contexts, such as depression, there has been improvement in care (17, 18). In this paper, we describe a systematic adapted intervention (19) and implementation mapping approach, to identify and match implementation strategies to barriers to improve FH care.

2. Materials and methods

2.1. FH care

A comprehensive care approach for individuals and families with FH involves three components: identification of patients, cascade testing of at-risk family members, and effective lipid management of the affected individuals. Identification occurs when a patient meets clinical diagnostic criteria and/or has an identified disease-causing variant in one of the genes associated with FH. Cascade testing includes risk notification and testing of at-risk relatives for FH. Management is the clinical care path established by the clinicians and an individual patient with FH to reduce their cardiovascular event risk. Management is based on the application of evidence-based guidelines (1).

2.2. Data collection

Data on key determinants of FH care related to identification, cascade testing, and management including barriers and facilitators, attitudes, and perspectives were collected using two methods: (1) a scoping review of published literature, and (2) a mixed methods study using interviews and surveys.

TABLE 1 PubMed search strategy for scoping review.

"barrier"[All Fields] OR "barriers"[All Fields] OR "facilitator"[All Fields] OR "facilitators"[All Fields] OR "enabler"[All Fields] OR "enablers"[All fields]	AND	"Hyperlipoproteinemia Type II"[Mesh] OR "familial hypercholesterolemia"[All Fields] OR "hyperlipoproteinemia type ii"[Mesh] OR ("hyperlipoproteinemia"[All Fields] AND "type"[All Fields] AND "ii"[All Fields]) OR "hyperlipoproteinemia type ii"[All Fields] OR ("familial"[All Fields] AND "hypercholesterolemia"[All Fields]) OR "familial hypercholesterolemia"[All Fields]

2.2.1. Scoping review

A scoping review was performed to identify published literature related to any component of FH care. PubMed was searched using key words including "barriers" or "facilitators" and "familial hypercholesterolemia" from inception to December 1, 2021 (Table 1). Articles were excluded if they were not relevant to FH, not relevant to a component of FH care including identification, cascade testing, or management, or if the publication type was a narrative review, commentary, protocol-only, nonhuman, or were not published in the English language. This initial search resulted in a total of 86 potential articles; 25 articles were included in the analysis after the exclusion criteria were applied during abstract and full-text review (Figure 1). Articles were then categorized by component of FH care.

2.2.2. Interviews and surveys

The mixed methods study recruited individuals and families with FH from Geisinger and the Family Heart Foundation to participate in either dyadic interviews ($n = 11$ dyads/22 individuals) or online surveys ($n = 98$ respondents). FH diagnosis was assigned by self-report or confirmed by genetic testing for those that participated in the MyCode Community Health Initiative at Geisinger (20). Two spouses participated in the dyadic interviews because they were the FH patient's caregiver and active in their care as well as communication with the family about FH. Dyadic phone interviews included the participant with an FH diagnosis and the family member they recruited to take part in the in-depth interview. Participants who completed interviews received a $20 Amazon gift card. Invitations to complete the online survey were sent *via* email to individuals identified through Geisinger and the Family Heart Foundation's databases, as well as *via* social media posts to the Family Heart Foundation's private groups. Snowball sampling was

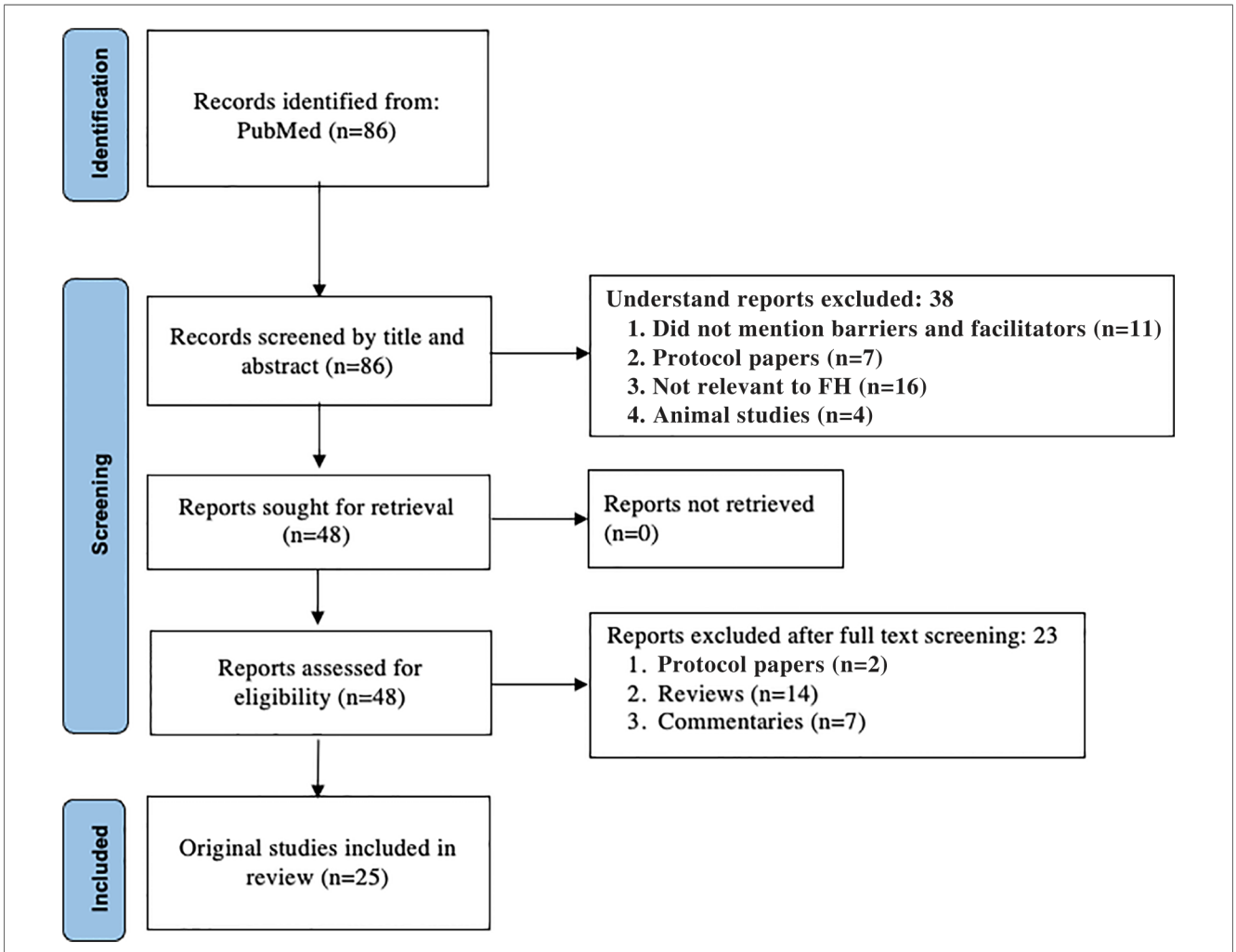

FIGURE 1
PRISMA diagram for scoping review.

TABLE 2 Adapted intervention mapping steps for this study.

Step	Title	Description of activity	Data sources
1	Conduct a needs assessment	• Describe the problem of identifying and managing individuals with FH. • List factors which influence the identification, cascade testing, and management of individuals with FH. • Describe the target groups that influence FH care.	• Scoping review • Interviews/surveys
2	Program outcomes	• Define which behaviors and environmental conditions need to be changed to improve FH care • Describe who should make those changes and when. • Define the outcomes and make sure that they are specific, measurable, achievable, realistic, and designate a time frame to complete them.	
3	Theory and evidence-based strategies	• List barriers and facilitators which can be mapped to implementation strategies from existing evidence-based compilations	
4	Program development	• Develop an FH program that involves input from key stakeholders including persons with FH, family members, clinicians, health systems, researchers, advocacy organizations, and healthcare payers	• Published protocol paper
5	Implementation	• Develop an implementation plan. • Specify implementation outcomes of interest.	
6	Evaluation	• Develop an evaluation plan. • Decide which measurement tools exist to measure the program	

utilized by allowing survey respondents to invite their family members to complete a separate but similar version of the online survey. Survey participants were asked if they were the first person to be diagnosed with FH in their family. Survey respondents recruited from Geisinger were entered into a raffle to win one of five $50 Amazon gift cards. This recruitment strategy enabled us to have a sample of participants representing diverse diagnostic odysseys (i.e., journey to identification) and clinical experiences related to FH.

The interview guide and survey questions were developed through study team collaboration with the intent to elicit responses from participants about their experiences communicating about FH within their family (e.g., how did your family learn about FH? How does your family talk about FH?) (21, 22). Before interviews, participants were asked to review three family communication strategies and share their feedback on how to (re)design these strategies during the interviews (e.g., How can we improve the family letter? How would you want us to reach out to family members for a direct contact program?). Surveys were broken into three sections in which examples or additional information for each of the three family communication strategies was displayed and participants were asked open-ended questions about each strategy (e.g., How can we improve the family letter? How can we improve the chatbot? How would you want us to reach out to family members for a direct contact program?). The interview guide was tested with one dyad, iterated upon, and then deployed for all interviews thereafter (**Supplementary File S1**). Three separate versions of the survey were created for individuals with FH from Geisinger, individuals with FH from the Family Heart Foundation, and family members (**Supplementary Files S2–S4**). The combination of methods enabled triangulation of qualitative findings to capture the breadth and depth of experiences (23).

Audio-recorded dyadic phone interviews were transcribed, de-identified, and checked for accuracy before analysis. Open-ended survey responses were exported from the survey platform, de-identified, and checked for accuracy by ensuring there was only one IP address per response before inclusion in the full data set.

2.3. Procedures

This study deployed a modified version of intervention and implementation mapping (**Table 2**).

2.3.1. Steps 1–3

Data generated from the scoping review, dyadic interviews, and online surveys were used to inform intervention mapping steps 1–3 (19). A scoping review was conducted to perform a needs assessment and uncovered reported barriers and facilitators to FH care in the literature for step 1. Two medical students and a senior researcher evaluated inclusion of the articles in abstract and full text screening in duplicate. Data from the scoping review was compared to conducted dyadic interviews (interviews with individuals with FH and their families) and online surveys to create a complete list of barriers and facilitators (step 1). Data from step 1 was used to develop program outcomes (step 2). In step 2, behaviors that promote better FH care were analyzed at the individual, clinician, and health system level. Determinants of those behaviors were extracted and ranked based on their changeability and importance. The ranking was performed by sending a survey to the study team that consists of FH researchers, advocates, and individuals with FH. Step 3 deviated from the original steps of intervention mapping, in that instead of selecting behavioral change interventions, implementation strategies were selected. This change occurred because evidence-based guidelines for FH care exist, and the purpose of the study was to improve guideline translation, so development of implementation strategies was necessary. Results from steps 1–2 were mapped to the Expert Recommendations for Implementing Change (ERIC), a compilation of evidence-based implementation

TABLE 3 Original research studies identified from the scoping review of the literature.

Study	Year published	FH care category			Study population	Barriers ($n = 25$)	Facilitators ($n = 15$)
		Identification ($n = 12$)	Cascade testing ($n = 8$)	Management ($n = 16$)			
Baldry, E. et al. (25)	2021		X		Adults with FH	X	X
Block, R. C. et al. (26)	2021	X	X	X	Clinicians	X	
Mszar, R. et al. (27)	2021	X		X	Adults with FH	X	X
Soukup, J. et al. (28)	2021	X			Clinicians	X	X
Wong, N.D. et al. (29)	2021			X	Clinicians	X	
Allen-Tice, C. et al. (30)	2020	X			Children with FH	X	
Gidding, S. S. et al. (31)	2020	X	X		Adults with FH	X	X
Jackson, C. L. et al. (32)	2020	X		X	Adults with FH	X	
Jones, L. K. et al. (10)	2020			X	Adults with FH & Clinicians	X	X
Kinnear, F. J. et al. (33)	2020			X	Adults with FH	X	X
McCormick, D. et al. (34)	2020			X	Clinicians & Payers	X	
Unim, B. et al. (35)	2020	X			Clinicians	X	X
Kinnear, F. J. et al. (11)	2019			X	Adults with FH	X	X
Zimmerman, J. et al. (36)	2019	X			Clinicians	X	X
Yamashita, S. et al. (37)	2019			X	Clinicians	X	
Farwati, M. et al. (38)	2018	X		X	Adults with FH & Clinicians	X	X
van El, C. G. et al. (39)	2018		X		Clinicians & other stakeholders	X	X
Wurtmann, E. et al. (40)	2018		X		Parents of children with FH	X	X
Zafrir, B. et al. (41)	2018			X	Adults with FH	X	X
Campbell, M. et al. (42)	2017	X	X		Adults with FH	X	
Cohen, J. D. et al. (43)	2017			X	Clinicians	X	X
Benson, G. et al. (44)	2016		X	X	Women with FH	X	
Hardcastle, S. J. et al. (45)	2015	X	X	X	Adults with FH	X	X
Frich, J. C. et al. (46)	2006	X		X	Women with FH	X	
Whayne, T. F. et al. (47)	2002			X	Patients eligible for lipid apheresis	X	

strategies generated by implementation experts (step 3) (24). The ERIC compilation was chosen because the concepts from steps 1 and 2 more closely aligned with this list of strategies.

2.3.2. Steps 4–6

To demonstrate steps 4–6 that include program development, implementation and evaluation, we provide an example of an FH program that was developed from the data generated in steps 1–3. This example includes a description of a funded study that is deploying implementation strategies to improve identification of FH in primary care.

3. Results

3.1. Demographics

3.1.1. Data from the scoping review

A total of 25 studies were included from a scoping review of the literature (Table 3). These studies were published between 2002 and 2021 and mention at least one component of FH care: 12 referenced identification, 8 referenced cascade testing, and 16 referenced management with several addressing more than one component. Only two studies addressed all three components of care (26, 45). Most studies reported on barriers and facilitators to FH care.

3.1.2. Data from interviews and surveys

A total of 120 participants completed a dyadic interview or survey. Eleven family dyads ($n = 22$ individuals) were interviewed between July and August 2020. Detailed demographic information is available in Table 4.

3.2. Step 1: needs assessment

3.2.1. Summary of implementation problems identified

Data extracted from the scoping review of the literature, interviews, and surveys illuminated the barriers related to caring for individuals with FH and their families. These challenges can be categorized into three areas: identification, cascade testing, and management. Identification of FH has been a known problem worldwide with only 10%–30% of individuals estimated to have been diagnosed with FH (12, 13). Under-identification of FH has resulted in part from lack of a universally accepted definition for FH. To date, FH can be diagnosed *via* the presence of clinical criteria such as, high cholesterol levels and presence of family history with or without physical exam features. Multiple clinical screening tools exist, but there is not a gold standard. Alternatively, individuals can have a genetic diagnosis of FH by having a disease-causing variant in one of the genes associated with FH. There are also

TABLE 4 Demographics of interview and survey participants.

Total Participants ($N = 120$)	*n*	(%)
Sex		
Female	90	(75)
Male	30	(25)
FH Diagnosis/Risk Status		
Diagnosed	109	(90.8)
At-risk	6	(5)
Not at risk (spouse/caregiver)	5	(4.2)
Educational Attainment		
Some high school/high school diploma/GED	17	(14.2)
Some college or trade/technical degree	19	(15.8)
Associate's degree	8	(6.7)
Bachelor's degree	42	(35)
Post-graduate work or degree	33	(27.5)
Preferred not to answer	1	(0.8)
Dyadic Interview Participants ($n = 22$ individuals/11 dyads)	***n* individuals, *n* dyads**	**(%)**
Dyad Type		
Sisters	6, 3	(27.2)
Mother-Daughter	6, 3	(27.2)
Father-Daughter	2, 1	(9.1)
Mother-Son	4, 2	(18.2)
Spouses	4, 2	(18.2)
Survey Respondents ($n = 98$)	***n***	**(%)**
Respondent Type		
Individual with FH from Geisinger	19	(19.4)
Individual with FH from the Family Heart Foundation	72	(73.2)
Family member of an individual with FH	7	(7.1)

biological differences on how the ultimate health outcome, cardiovascular disease, presents in men as compared to women. Age-related differences in cholesterol levels exist due to the presence of other factors that affect lipid values over time, including environmental factors and diet. Limited screening during childhood has made it more difficult to prevent premature heart disease in early adulthood. Although, lipid screening in children is more discriminatory because children have not developed other risk factors thus if a high level of LDL-C is detected it is more likely to represent FH. By screening in childhood, it is also more likely to find an undiagnosed parent. Limitations due to privacy, family dynamics, geography, and other health and non-health-related concerns have presented family communication and cascade testing challenges. After identification and diagnosis, individuals with FH often receive suboptimal treatment. Women and children are less likely to be treated than adult men (48). Management of FH often requires daily combination lipid lowering therapy for life which can make adherence difficult.

3.2.2. Barriers and facilitators influencing behaviors and environmental conditions

Barriers and facilitators were categorized into three levels: individual-, clinician-, and health system-level (Table 5).

3.2.2.1. Individual level

Barriers to FH identification, cascade testing, and management at the individual level include a lack of awareness of FH, which limits patients' ability to access testing and treatments. Additionally, interview and survey participants described ambivalent attitudes as another potential barrier to FH testing and treatments. Specifically, participants discussed how they or family members believed FH was not a serious condition or diagnosis, was not distinct from elevated cholesterol due to lifestyle, and the sense that high cholesterol is "the norm" in their family and to be expected. Participants described these attitudes as potentially undermining medical information about FH and as reducing likelihood they or their family members would feel a need to identify their high cholesterol FH or change current health management for high cholesterol. Next, while the cost of genetic testing is generally decreasing, financial concerns are still cited as a barrier to patient identification and family cascade testing, including confusion around the availability of insurance coverage for all types of testing for FH. Treatment costs and insurance coverage concerns also represent barriers when it comes to treatment (47), particularly with newer (brand-only) FDA-approved treatments, such as the proprotein convertase subtilisin/kexin type 9 (PCSK9) monoclonal antibodies and use of procedures such as low-density lipoprotein (LDL) apheresis. Treatment-related side effects, especially those attributed to statins, were also reported as a barrier to FH management. Monotherapy with statins is often unable to provide sufficient LDL cholesterol (LDL-C) lowering and has been cited as a barrier in the management of FH.

Competing personal and family demands may also prevent individuals with FH from communicating with their families about cascade testing and preventing them from prioritizing their health (e.g., adhering to treatments and lifestyle modifications). Similarly, some individuals with FH report difficulty contacting family members for cascade testing due to social and intra-familial communication dynamics (e.g., patients who no longer communicate with some or all family members). Individuals with FH and their families report a fear of a loss of privacy of their genetic information if they were to be tested, or discrimination from insurance companies if they were to receive a genetic diagnosis of FH. While there are laws that protect health information and prohibit the use of genetic information by health insurers and most employers, many individuals are unaware of such protections or do not trust that these laws will protect their information.

Finally, it has also been noted that stigma and health anxiety may prevent FH patients and their families from getting tested (i.e., FH patients do not want to be diagnosed with a serious medical condition). Limited access to healthcare and lack of patient support groups have also been reported as factors that may impede FH identification, cascade testing, and management.

Participants described experiences in which clinicians gave incorrect information such as suggesting that high LDL-C levels were acceptable without further treatment options,

TABLE 5 Description of behaviors influencing FH care identified through published and unpublished literature.

	Identification	Cascade testing	Management
Individual level			
Lack of awareness	X (10, 33)*		X (33, 38)*
Cost	X (31)*	X (31, 39)*	X (29, 47)*
Insurance coverage (absence of or limited coverage)	X (38)*		X (29, 34, 38, 41)*
Non-adherence			X (33, 38, 41, 44, 45)*
Side effects			X (41, 43, 44)*
Competing family demands		X (33, 45)	X (10, 33)
Competing personal demands		X (33, 44)	X (10, 33)
Stigma & health anxiety	X (27, 45)	X (45)	
Familial communication and social dynamics	X (27, 45)	X (31, 33, 40, 42, 44, 45)*	X (11)*
Privacy concerns & discrimination	X (27, 31)	X (39)	
Not achieving goal LDL-C levels with current therapies			X (43, 47)
Access to healthcare	X (27, 31)		X (27)
Access to patient support organizations	X (40)	X (40)	
Positive relationships with and attitudes towards physicians and healthcare system	X (27)*		X (29)*
Legal concerns	X (42)	X (42)	
Clinician level			
Lack of awareness	X (10, 26, 31, 32, 35, 36, 38)	X (31)	X (26, 30, 37, 38)
Belief that there is a lack of evidence	X (10)		X (32, 34)
Perception	X (10)		X (10)
Other clinical demands	X (28, 36)	X (39)	X (10, 29)
Inadequate record keeping systems		X (32, 36)	X (32)
Insurance (poor reimbursement for FH screening, time consuming PA procedures)	X (36, 38)		X (38, 43)
Skill level and comfort with genetic disorders	X (28, 36, 38)		
Education	X (28, 35)		X (11)
Lack of awareness of women's health needs			X (46)
Health system level			
Gaps in access to care			X (10)
Genetic testing resources and associated support staff/infrastructure	X (28, 31, 35, 36)	X (10, 39, 40)	X (11, 38)
Lack of formal screening programs that emphasize shared decision making			X (27)

Number denotes published article reference.
*Denotes from surveys and interviews generated by study team.

cascade testing was not necessary for at-risk relatives, or exhibiting poor interpersonal interactions to scare individuals about their FH-related health risks. These experiences created a barrier related to trust in clinicians and the healthcare system that participants explained complicated their ability to undergo testing for FH and/or receive appropriate treatment recommendations.

3.2.2.2. Clinician level

At the clinician level, lack of awareness of FH as a specific genetic condition has also been cited as a barrier to testing in the index case, cascade testing, and management. Some clinicians believe that there is a lack of evidence to support FH identification and treatment, and a lack of FH-related education has been cited as a barrier to FH identification, cascade testing, and management among clinicians. Some clinicians (e.g., primary care clinicians) may also not feel comfortable with identifying genetic disorders in general, which hampers FH index patient identification. Clinicians may also feel that competing clinical demands (e.g., other health issues they need to cover with patients in short visits), affect their ability to initiate FH identification, cascade testing, and management. Inadequate record keeping systems also impede clinicians' ability to detect index cases with FH and initiate cascade testing. Clinicians also cite a lack of reimbursement as a limiting factor in FH identification and treatment. Finally, cascade testing is seen as difficult by some due to clinicians' legal concerns about making direct contact with a proband's family members.

3.2.2.3. Health system level

At the health system level, access to care, particularly access to specialists, has been cited as a barrier to FH management. Similarly, organized FH screening programs that would facilitate FH identification and cascade testing are lacking. Healthcare systems, in general, may not have the infrastructure and resources (e.g., lipid-management specialists, genetic counseling programs, etc.) necessary to meet the needs of the FH population.

3.2.3. Step 2: program outcomes and objectives

3.2.3.1. Behaviors that promote better FH care

3.2.3.1.1. Individual level. The level of individual patient and family knowledge of FH and its genetic basis potentially impacts FH identification. Individuals with FH felt that learning of their condition, and its specific genetic basis, is important and will prompt them to communicate the result with their at-risk relatives. They felt this would likewise prompt their relatives to undergo testing for FH and improve both their and their relatives' adherence to management recommendations. In addition, individuals can encourage screening when discussing the FH result with their at-risk relatives. Individuals who understand the importance of taking their medications as prescribed are often more willing to discuss medication-related side effects with their clinicians.

3.2.3.1.2. Clinician level. Behaviors that affect identification include knowledge and implementation of guideline recommendations to

screen for and identify FH. It is important for clinicians to understand that earlier identification is key to preventing future cardiovascular disease. Clinicians can also promote and facilitate communication between the individual with FH and their at-risk relatives. Clinicians have a key role in understanding and recommending appropriate treatment options and intensify treatment regimens.

3.2.3.1.3. Health system level. Health systems may help to improve components of FH care by implementing protocols that make screening for FH easy for both the initial patient identified and their at-risk relatives, allow clinicians including primary care clinicians, specialists, and other healthcare clinicians to share responsibilities for FH care and remove barriers to ordering of testing and medications for FH. A health system's central laboratory could adopt language on lipid results prompting the clinician to consider FH when an LDL-C is found to be over 190 mg/dl.

3.2.3.5. Determinants

Based on the barriers and facilitators identified through the mixed methods study, determinants are ranked by their ability to be addressed (changeable) and their contribution to the behavior (important) at the individual, clinician, and health system level (Table 6). The most mentioned determinants across all levels of care were knowledge, attitude, and risk perception. These determinants will serve as priority topics for development of implementation outcomes.

TABLE 6 Description of determinants identified for FH care.

Determinants	Important	Changeable
Patient level		
Knowledge	++	++
Attitude	++	+
Risk perception	++	++
Healthcare insecurity	+	+
Cost uncertainty	+	+
Self-efficacy	++	+
Social norms	+	+
Clinician level		
Knowledge	++	++
Risk perception	++	++
Skills	+	++
Attitude	++	+
Social norms	+	0
Cost uncertainty	+	+
Self-efficacy	+	++
Time	+	0
Health system level		
Value	++	++
Return on investment	++	+
Resources/processes/infrastructure	++	+
Time	+	0

Important: contribute significantly to the behavior (0, +, ++).
Changeable: ability to be changed (0, +, ++).
Co-authors that include FH experts, FH researchers, FH clinicians, and individuals with FH reviewed the determinants and ranked their importance and changeability based on their expertise and experiences.

3.2.4. Step 3: implementation strategies mapped to program outcomes and objectives

Implementation strategies that can be deployed to help translate the evidence into clinical practice are detailed in Table 7. These implementation strategies were mapped to program outcomes and objectives and were standardized using the ERIC compilation. These strategies may provide a guide that can be used to develop tailored implementation strategies for a specific component of FH care. Most of these implementation strategies can be defined to address each component of FH care.

To ensure success and sustainability after deployment of the implementation strategies, it is important to develop a plan to obtain ongoing feedback from all stakeholders involved, reexamine the implementation outcomes, and provide assistance at the level of the patient, family, and clinician up to the health system, to help improve utility of the implementation strategies. These strategies will provide information on whether the implementation should be altered based on external and internal factors.

3.3. Example of a current FH program with an implementation and evaluation plan

Steps 4–6 were satisfied by designing CARE-FH (Collaborative Approach to Reach Everyone with FH), a clinical trial of implementation strategies, is funded by National Heart Lung and Blood Institute, and based on findings from steps 1–3.The goal of CARE-FH is to improve FH identification in primary care (49).

3.3.1. Step 4: design the intervention

Steps 1–3 determined that there was a gap in translating evidence-based guidelines related to screening for FH into practice. The needs assessment found that screening for FH is recommended but not routinely performed. The decision was made that the evidence-based guidance would be based on the 2018 AHA/ACC/Multi-society Cholesterol Guidelines and the 2020 Expert Consensus Genetic Testing Statement (1, 50). These evidence-based guidelines were used to generate the diagnostic screening algorithm for clinicians to screen for FH in the study (Figure 2).

3.3.2. Step 5: create an implementation approach

The CARE-FH study team selected implementation strategies relevant to FH identification from Table 7. These implementation strategies included: conduct dynamic educational meetings and ongoing training, develop and distribute educational material, intervene and involve patients and family members to enhance uptake and adherence, remind clinicians, and facilitate relay of clinical data to clinicians. The proposed comprehensive multi-level implementation strategy package was based on the ERIC compilation (Table 8). These implementation strategies were tailored to the Geisinger primary care practice using a 1-year pre-implementation phase where surveys,

TABLE 7 Examples of implementation strategies that address determinants that relate to all components of FH care.

Determinant addressed	Level(s)	ERIC compilation implementation strategies	Definition*
Value	Health system	Alter financial incentives	Change patient cost, reimbursement fees, or other costs associated with uptake of the implementation
Resources, process, and infrastructure	Health system	Change accreditation, membership, or credentialing requirements	Change the requirements for accreditation or membership
Resources, process, and infrastructure	Health system	Change liability laws	Propose policy changes that would make implementing FH care easier
Resources, process, and infrastructure, time	Health system	Change record systems	Implement record systems to understand the impact of the implementation
Knowledge, risk perception, skills, attitude, self-efficacy, cost uncertainty	Clinician	Conduct dynamic educational meetings and ongoing training	Conduct initial and ongoing educational meetings or trainings on the implementation that are applicable to multiple learning styles
Value, Resources, process, infrastructure	Health system	Create a learning collaborative	Facilitate the formation of a group of FH clinicians or health systems focused on improving FH care
Resources, process, and infrastructure, time	Health system	Create new clinical teams or revise professional roles	Added different disciplines and skills sets or changes roles to improve uptake of the implementation
Knowledge, attitude, risk perception, skills, social norms	Clinician	Develop and distribute educational material	Develop and distribute information on how to implement better FH care
Resources, process, and infrastructure	Health system	Facilitate relay of clinical data to clinicians	Provide up-to-date data on the uptake of the implementation to clinicians
Knowledge, attitude, risk perception, skills, social norms, value	Health system, clinician, patient	Identify and prepare champions	Identify and prepare FH champions who support, market, and prompt the implementation overing barriers in the health system
Knowledge, attitude, risk perception, healthcare insecurity, cost uncertainty, self-efficacy, social norms	Patient	Intervene and involve patients and family members to enhance uptake and adherence	Engage patients and family members in the implement of FH care
Value	Health system	Mandate change	Leadership declares the implementation a priority
Knowledge, attitude, risk perception, skills, social norms	Health system, clinician	Promote network weaving	Identify and build relationships within and outside the health system to promote information sharing and collaborative problem-solving
Value, Resources, process, and infrastructure, time, return on investment	Health system	Provide ongoing consultation	Provide access to implementers to ensure smooth implementation
Resources, process, and infrastructure	Health system	Remind clinicians	Develop systems to remind clinicians to use the implementation
Knowledge, attitude, risk perception, social norms	Patient, clinician, health system	Use mass media	Use media to reach many patients, clinicians or health systems about FH care
Knowledge, attitude, risk perception, skills, social norms, value, time	Health system, clinician	Use train-the-trainer strategies	Train clinicians and health systems to deliver the implementation to others

ERIC, Expert Recommendation for Implementing Change.
*Definitions are adapted by the ERIC compilation definitions for FH care.

contextual inquiries, and pilot testing of the strategies was conducted.

3.3.3. Step 6: develop an evaluation plan

An evaluation plan was developed using the Conceptual Model for Implementation Research and included the following implementation outcomes: adoption, penetration, acceptability, feasibility, fidelity, sustainability, and cost (51, 52). The study team has adapted this model to CARE-FH (**Figure 3**). The evaluation plan also includes service and health outcomes are detailed in **Table 9**.

4. Discussion

The application of principles from implementation science to the field of FH has been discussed in many recent articles including original research, reviews, commentaries, and guidelines (53–63). By leveraging implementation science, which aims to close the large gap from knowledge generation to implementation into practice, we can improve every component of FH care.

Intervention mapping provides a systematic process for developing evidence-based implementation strategies to improve FH care. Through steps 1–3 in this process, we identified barriers and facilitators to three components of FH care: identification, cascade testing, and management. We also found that barriers and facilitators may not be one-dimensional and exist at the patient, clinician, and health system levels. To overcome these barriers, we need to develop an implementation strategy package that addresses each level and component of FH care. We have provided a list of implementation strategies specific to FH care that others can adapt to their local context. For steps 4–6, we highlighted an example of a currently funded study, CARE-FH, that is using implementation strategies based on evidence to improve FH identification. This systematic evaluation using

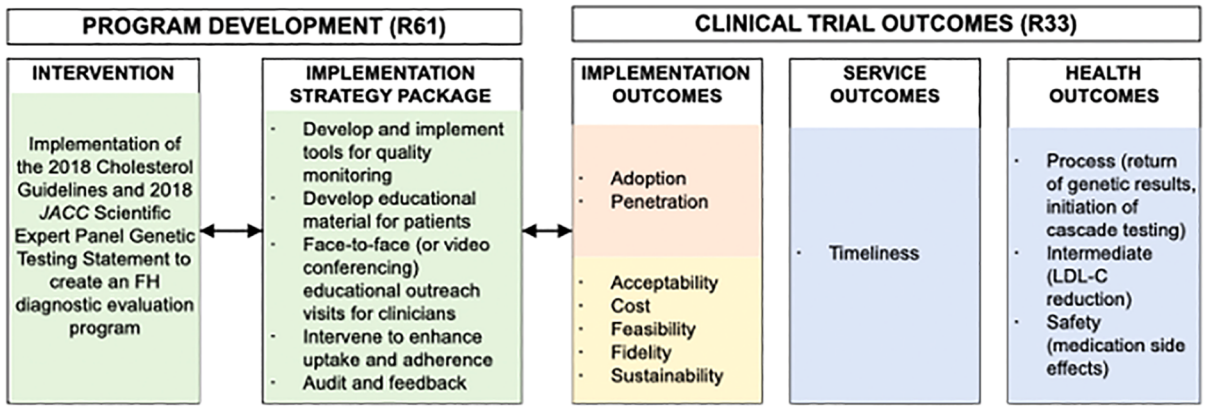

FIGURE 2
Adapted conceptual model of implementation research for the CARE-FH study. Reproduced under the CC-BY license from Jones LK et al. (49).

TABLE 8 CARE-FH study proposed multi-level implementation strategies. Reproduced under the CC-BY license from Jones LK et al. (49).

Name of strategy*	Specific study definition	Actor	Action	Action target
Develop and implement tools for quality monitoring	EHR tools to order labs, record results, and document FH care	ImpT, MedT, and InfT	Use EHR to record, order, and prescribe FH Care	Service and health outcomes
Develop educational materials	Education regarding guidelines for identification and treatment of FH	MedT and InfT	Create a CME course for clinicians about FH. Explore clinician workflow and educational needs to design novel focused educational interventions integrated within clinical workflows to support evidence-based care	MedT ready to train clinicians on FH
Conduct educational outreach visits	CME educational material for FH that is presented to each clinic	MedT and clinicians	Attend CME course on FH	Improve knowledge about FH
Intervene with patients to enhance uptake and adherence	Reach out directly to patients to recommend screening for FH	Clinicians and ImpT	Letter sent to the patient. Clinician schedules patient for appointment.	Patients diagnosed with FH from those at-risk
Identify and prepare champions	Clinical lipid champions	MedT	Identify and train lipid champions	Improved performance of study metrics, reduced costs
Stage FH care delivery model scale up	Develop the timeline for the stepped-wedge rollout to primary care	Leadership team	Notify practices of roll out and schedule education	Begin the trial
Audit and provide feedback	Provide aggregate level feedback to clinics on diagnosing FH	MedT, InfT, and clinical leadership	Report back to clinicians' aggregate level data	Improve effectiveness of the FH Diagnosis Program
Advisory board review	Clinical trial protocol	Advisory Board	Provide feedback on the clinical trial regarding protocol, generalizability and ethical issues	Protocol revision based on feedback

EHR, electronic health record; CME, continuing medical education; FH, familial hypercholesterolemia; ImpT, implementation science team; InfT, informatics and data science team; MedT, medical science team.
*Mapped to the Expert Recommendations for Implementing Change (ERIC) compilation.

intervention mapping allowed us to develop implementation strategies and allows other teams to replicate and/or adapt these strategies by other teams. The FH specific strategies that were developed in this study can be tailored by others to their specific context to improve care.

To date, there have been many explorations of barriers and facilitators to FH care, but few have developed strategies to address them that can then be implemented into practice and subsequently evaluated (10). Previous studies focused on only one component of FH care or at one level (patient, clinician, or health system) (53, 64). By addressing these barriers for components of FH care at multiple levels, we can more thoroughly address the problems faced by individuals with FH and their families.

Due to the limited evidence on implementation strategies to improve FH care, two recent review articles have retrospectively mapped interventions from previous studies to a compilation of implementation strategies (53, 65). This work has facilitated the use of a common language for naming and describing implementation strategies. By having a common nomenclature, it becomes easier to tailor implementation strategies for specific contexts such as FH care. From these two articles, we know that

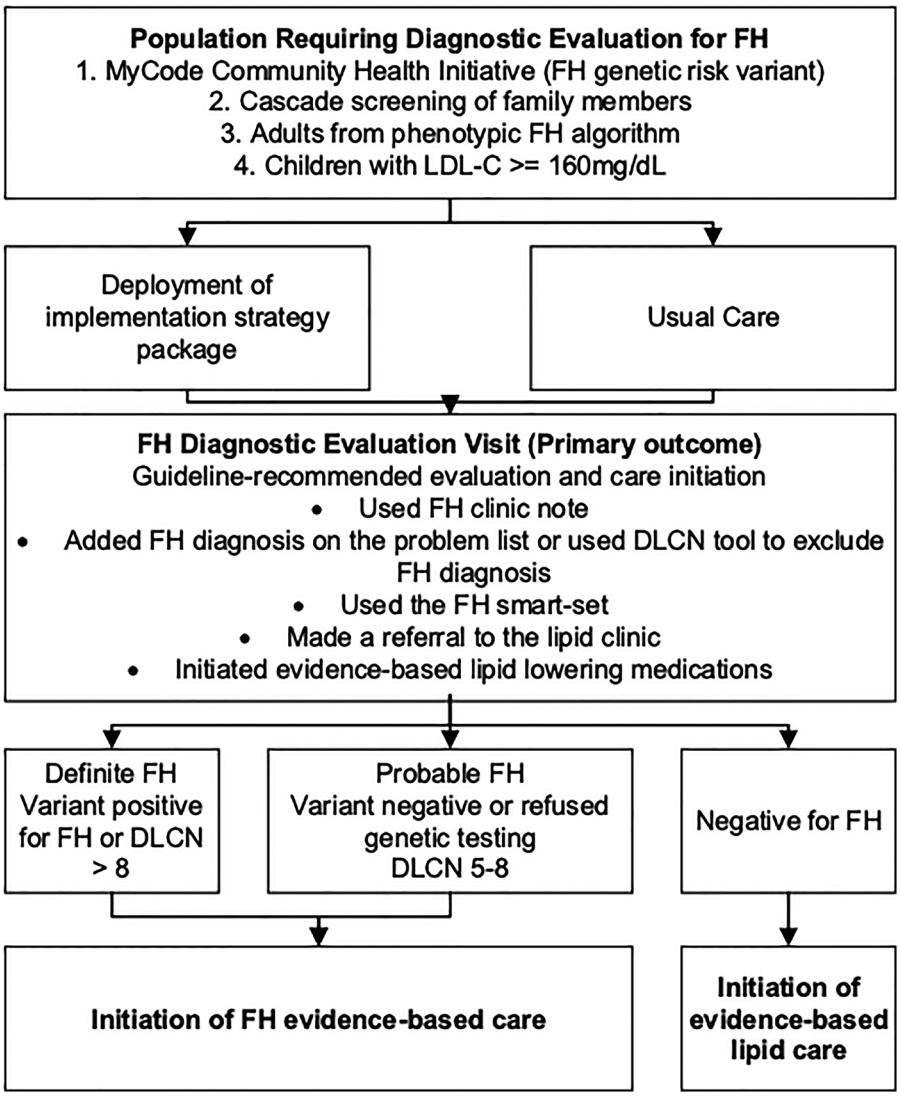

FIGURE 3
CARE-FH study diagnostic evaluation plan. Reproduced under the CC-BY license from Jones LK et al. (49).

only certain implementation strategies, including assess for readiness and identify barriers and facilitators, develop and organize quality monitoring systems, create new clinicals teams, facilitate relay of clinical data to providers, and involve patients and family members, have been tested in practice for FH care (53). There is a need to deploy other implementation strategies listed in compilations such as promote network weaving, create a learning collaborative, change liability law, among others (53, 65). In addition, implementation strategies need to be explained using a standardized reporting method so they can be replicated in the future (53, 65, 66).

Some cholesterol and FH guidelines have started to include sections on how to help improve the translation of their guidelines into practice (1, 60–63, 67). However, these guidelines are not formatted in such a way as to promote their translation and implementation in the clinic setting (54). A recent editorial provides a framework to help facilitate the translation of evidence-based recommendations with implementation recommendation to create clinical practice guidelines that can then be implemented and evaluated in local contexts (55).

4.1. Limitations

An important limitation is that not all health systems, clinicians, or patients will have the ability to implement strategies that affect multiple levels or multiple components of FH care. It will be important to identify strategies that are relevant to specific health contexts and the needs of particular health systems. This project only reported implementation strategies that we have found important for our work in our health care context, but other strategies might arise or need to be adapted. Another limitation is that this study only reported on the ERIC compilation of strategies that were relevant for the implementation phase of a study and not those that are important for pre-implementation work. Steps 1 and 2 of

TABLE 9 CARE-FH study evaluation plan. Reproduced under the CC-BY license from Jones LK et al. (51).

Domain	Aim	Outcome	Construct measured	Data source
Implementation	2	**Adoption**	**FH diagnostic evaluation defined as completed of one of the following:** - Used FH clinic note to document care - Added FH diagnosis on the problem list or used DLCN tool to exclude FH diagnosis - Used the FH smart-set (i.e., ordered a genetic test for FH) - Made a referral to the lipid clinic - Initiate evidence-based lipid lowering medications	EHR, administrative data
		Penetration	Proportion of the primary care clinicians that completed the five components of the FH diagnostic evaluation compared to those that did not use it.	
	3	Acceptability	Clinician and patient satisfaction and self-efficacy with the implementation strategy package	Semi-structured interviews
		Cost	Cost to implement the implementation strategy package	Micro-costing
		Feasibility	Clinician adoption and penetration for completion of the FH diagnostic evaluation and measured utility of implementation strategy package	Semi-structured interviews and EHR data
		Fidelity	Documentation of adaptations to the FH diagnostic evaluation program	Checklist, direct observation
		Sustainability	Potential for institutionalization	Surveys, Advisory board consultation
Service	4	Timeliness	Time to: FH screen, completion of diagnostic evaluation, medication initiation	EHR, administrative data
Health		Safety	Medication-related side effects	
		Intermediate	LDL-C reduction	
		Process	Return of genetic result	
			Initiation of cascade testing	

EHR, electronic health record; FH, familial hypercholesterolemia; LDL-C, low-density lipoprotein cholesterol.
Bolded is the primary outcome of the study.

intervention mapping include strategies relevant for pre-implementation, including conducting a needs assessment, identifying barriers and facilitators, and assessing readiness of the organization to implement the evidence-based practice. Barriers and facilitator data collected from FH patients was supplemented with the literature to account for broader perspectives. Additional pre-implementation strategies that should be considered prior to implementation include developing evaluative and iterative strategies (e.g., developing and organizing quality monitoring systems) and adapting and tailoring strategies to the local context.

5. Conclusions

Using a systematic, evidence-based, multilevel approach to the development of implementation strategies, implementation recommendations, and evaluation is imperative to success in changing practice and care for individuals with FH. This study provides an overview of one evidence-based approach to accomplish this task: intervention mapping. The implementation strategies developed as part of this report can be utilized by others to improve FH care and learnings from the highlighted study can facilitate near-term deployment into practice as well as evaluation of both clinical and implementation outcomes.

Data availability statement

The original contributions presented in the study are included in the article/Supplementary Material, further inquiries can be directed to the corresponding author.

Ethics statement

The Geisinger Institutional Review Board determined that this project was not a systematic investigation designed to develop or contribute to generalizable knowledge as defined at 45 CFR 46.102(1), and was therefore not research. All procedures performed in studies involving human participants were in accordance with the ethical standard of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Participants agreed verbally to participate in interviews and in writing to complete surveys.

Author contributions

All authors contributed to the study conception and design. Material preparation, data collection and analysis were performed by LJ, EC, GC, NW, AB, GR, MM, AR, AS. The first draft of the manuscript was written by LJ. All authors contributed to the article and approved the submitted version.

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Conflict of interest

LJ is a consultant for Novartis Corporation. SG is a consultant for Esperion. AG has received research funding from Amgen, Sanofi, Novartis, Arrowhead, IONIS, Regeneron, New Amsterdam, Esperion, and Pfizer and is a consultant for IONIS, New Amsterdam, and Regeneron. AS is an employee and has stockholder in 23andMe and an Advisor to Nest Genomics. The remaining authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Publisher's note

Supplementary material

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/frhs.2023.1104311/full#supplementary-material.

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Evidence-Based Quality Improvement (EBQI) in the pre-implementation phase: key steps and activities

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Background: Evidence-Based Quality Improvement (EBQI) involves researchers and local partners working collaboratively to support the uptake of an evidence-based intervention (EBI). To date, EBQI has not been consistently included in community-engaged dissemination and implementation literature. The purpose of this paper is to illustrate the steps, activities, and outputs of EBQI in the pre-implementation phase.
Methods: The research team applied comparative case study methods to describe key steps, activities, and outputs of EBQI across seven projects. Our approach included: (1) specification of research questions, (2) selection of cases, (3) construction of a case codebook, (4) coding of cases using the codebook, and (5) comparison of cases.
Results: The cases selected included five distinct settings (e.g., correction facilities, community pharmacies), seven EBIs (e.g., nutrition promotion curriculum, cognitive processing therapy) and five unique lead authors. Case examples include both community-embedded and clinically-oriented projects. Key steps in the EBQI process included: (1) forming a local team of partners and experts, (2) prioritizing implementation determinants based on existing literature/data, (3) selecting strategies and/or adaptations in the context of key determinants, (4) specifying selected strategies/adaptations, and (5) refining strategies/adaptations. Examples of activities are included to illustrate how each step was achieved. Outputs included prioritized determinants, EBI adaptations, and implementation strategies.

Conclusions: A primary contribution of our comparative case study is the delineation of various steps and activities of EBQI, which may contribute to the replicability of the EBQI process across other implementation research projects.

KEYWORDS

implementation science, community engagement, quality improvement, pre-implementation, implementation strategies, comparative case study

1. Introduction

Community-engaged research is "the process of working collaboratively with groups of people affiliated by geographic proximity, special interests, or similar situations concerning issues affecting their well-being"(1). The concept of engaging community partners in all aspects of research is grounded in the notion that the population impacted by the issue, condition, or situation has a unique perspective on the resolution of the issue, which is critical to ensuring the effectiveness and adequacy of health interventions in broader community settings (2, 3). Engaging community partners in health research has been proven to be significant in efforts to improve population health in areas such as diabetes, nutrition, infant mortality, cancer, obesity, dental hygiene, etc (4–8). Dissemination and implementation (D&I) science researchers began to describe the need for participatory engagement among local practitioners nearly two decades ago (9). Since that time, the field has increasingly recognized the value of involving partners to solve implementation problems and advance solutions that support equitable implementation (10, 11).

The combination of community-engaged research and D&I, termed community-engaged dissemination and implementation (CEDI) research, reflects the intersection of community-partnered research in implementation research design, methods, and dissemination (12). The overall goal of CEDI methods is to foster the translation of research findings to improve population health by the uptake of evidence-based interventions (EBIs) in communities (13). Examples of CEDI methods include implementation mapping, concept mapping, group model building, and conjoint analysis (14, 15). CEDI approaches are increasingly recognized as critical to the selection and tailoring of implementation strategies (16). Evidence-Based Quality Improvement (EBQI) (17) is another key example of a CEDI method to accomplish engagement of key community partners in the implementation process, although it has not been consistently named in CEDI or implementation literature (16, 18).

EBQI is related to but distinct from the more broadly known concept of Quality Improvement (QI). QI aims to improve local multi-level processes and outcomes by using data from the local context, local expert input and opinions, and local multi-disciplinary teams (17). A review and critical appraisal of the existing literature is not typically part of a QI process (19); thus, the addition of the term "evidence-based" to QI was made to distinguish a QI process that integrates research evidence into decisions (17). That is, EBQI expands on QI by integrating local input with the *best available research evidence* at all stages of the process, from the "diagnosis" of performance issues to the development and tailoring of implementation strategies (20), and in some cases through the process of evaluation (21). Specifically, EBQI involves implementation science researchers and local partners working as a team to adapt EBIs (i.e., programs, principles, procedures, products, policies, practices, pills) (22) and select and tailor implementation strategies designed to improve system processes for uptake of the evidence (i.e., the "how" of getting the system to use the EBI). Studies that have measured health outcomes related to the use of EBQI suggest positive effects (21).

In the literature to date, EBQI has been called a myriad of terms (21). The developers of EBQI have used terms such as method (19), multi-level approach (17), and multi-faceted implementation strategy (19). Co-authors on this paper have also referred to EBQI variably as a process, technique, and tool. Thus, the language around EBQI seems to reflect the "idiosyncratic use of … terms involving homonymy (i.e., same term has multiple meanings), synonymy (i.e., different terms have the same meanings), and instability (i.e., terms shift unpredictably over time)" (18) that has plagued implementation science in its developmental years. Drawing on an understanding of QI and EBQI's distinct features from QI, we define EBQI as a *deliberative, partnered, and evidence-driven process* to inform the selection and tailoring of implementation strategies and EBI adaptations. This definition of EBQI reflects a conceptualization that EBQI would fit under the umbrella of more global *approaches* to research (e.g., Community-Based Participatory Research, CEDI) and could be operationalized with other *methods* (e.g., network analysis, formative evaluation). We acknowledge that EBQI can be applied across all stages of implementation (20) and that engagement of community partners and key interested parties is critical at all stages of implementation. However, our attention in this perspective is more narrowly focused on the pre-implementation phase. Pre-implementation is a critical phase where key decisions are made, and input and engagement from various partners is critical for addressing contextual conditions and improving implementation success.

To date, steps in the EBQI process have included (1) the formation of local teams to consider data on barriers and facilitators to implementation and (2) drafting, iterating, and planning a locally contextualized implementation strategy to increase uptake of an EBI (20). Additionally, EBQI activities have been described as: stakeholder planning meetings using expert panel techniques to identify priorities, formative evaluation, development and training of local QI champion and team

members, practice facilitation, and review of local QI proposals (5); monthly calls to facilitate collaboration and spread of EBIs; and technical work groups to support local priorities for EBIs (23). A recent scoping review of EBQI found the most common components across 211 studies to be: use of research to select effective interventions, engagement of stakeholders (i.e., partners), iterative development, partnering with frontline implementers, and data driven evaluation (21). This illustrates variety in application of EBQI in the extant literature.

The purpose of this paper is to illustrate the steps, activities, and outputs of EBQI in the pre-implementation phase as operationalized across seven projects to illustrate common elements and variations in application of EBQI (20). This goes beyond the recent scoping review (21) to provide specifics of key case examples that illustrate common and replicable processes of EBQI. Steps are defined as components in the EBQI process; activities are the methods used to achieve those steps (20). This paper will focus specifically on the use of EBQI in the pre-implementation phase to select and tailor strategies and/or adapt EBIs. In so doing, this paper provides a multi-disciplinary exposition of the application of EBQI for advancing implementation initiatives across diverse service contexts, examining the following research questions:

(1) What steps do researchers accomplish using EBQI in practice?
(2) How do researchers accomplish the steps of EBQI? That is, what activities are used to accomplish EBQI steps?

2. Case selection

To identify key steps, activities, and outcomes of EBQI methods, we retrospectively examined a set of seven case examples of EBQI application in research projects. Specifically, our goal was to use case examples to create a holistic description of EBQI and capture how each case selected and tailored implementation strategies and/or made EBI adaptations that would be subsequently tested in a research study (24). We applied steps of comparative case study methods to achieve this goal including: (1) specification of research questions, (2) selection of cases, (3) construction of a case codebook, (4) coding of cases using the codebook, and (5) comparison of cases (21).

Natural variation and overlap in the cases were a key interest. Specially, cases were purposively included to maximize variation (24) in the EBIs to be implemented, contexts for implementation, and processes of engagement applied across known users of EBQI in our networks. Inclusion criteria for cases included: (1) explicit claim of application of EBQI processes, (2) engagement of community or clinical partners in EBQI process, (3) targeted outcome of selecting and tailoring implementation strategies or EBI adaptations through EBQI, and (4) representation of funded research among the author group. All included cases were part of IRB-approved studies from our respective institutions.

2.1. Case codebook

The research team developed a case codebook to collect a standard set of information for each case and coded each case using this codebook. This codebook included basic features of the EBQI process (e.g., number and modality of meetings, partners engaged), the progression of EBQI meetings, and activities that were used at each meeting. Using the codebook, the lead investigator for each case extracted details of their respective projects. When needed, the lead author solicited additional information or clarification from investigators. This directed template analysis approach (25) allowed for focus on the study elements most meaningful for comparison. Additionally, one study provided a meeting-by-meeting description of the EBQI process to provide greater detail on the activities of each meeting and provide illustrative examples. After extraction of this information, lead investigators on each case example met to discuss commonalities and differences across cases as well as the progression and activities of each case.

3. Case comparison

The team completed a cross-case analysis to identify similarities, differences, and the range of steps, activities, and outputs across cases. We used this comparison to generate a list of the key steps of EBQI and corresponding examples of activities to accomplish each step. **Table 1** details the targeted EBIs and contexts for implementation as well as steps, activities, partners involved, and outputs of the 7 case examples. The selected cases included 7 distinct settings (e.g., early care and education, community correction centers, hospitals), 7 EBIs (e.g., cognitive processing therapy, violence prevention program, exercise program) and 5 unique lead authors. Cases examples include both community-embedded and clinically-oriented projects. For example, Teeter and colleagues (30) deployed EBQI to adapt a pharmacist-initiated intervention for naloxone in community pharmacies, while Zielinski et al. (29) used EBQI to prioritize determinants, identify implementation strategies, and create an implementation plan for supporting uptake of cognitive processing therapy in prisons.

Cases were examined and compared for key basic features including the number of EBQI meetings held, types of partners included, and modality of meetings. Included case studies ranged in the number of meetings from 2 to 5 (26, 27, 31). On average, included cases were 4 meetings long (Median = 4). EBQI processes with greater number of meetings were observed for projects that included selecting and tailoring both adaptations and implementations, whereas projects targeting more discrete pre-implementation tasks (e.g., prioritizing determinants) met objectives in fewer meetings. Case examples included between three and seven partner sectors in the EBQI meetings (Mean = 4, Median = 3). Most projects included partners across different levels of implementation (e.g., front line implementer, leader, end user). Most (6/7) cases included end users in the process (i.e.,

TABLE 1 Case description template.

Author	Evidence-based intervention (EBI)	Context	# of Meetings	Steps[a]	Partners involved	Modality of engagement	Products/Outcomes
Swindle (26)	De-implementation of detrimental feeding practices	Early Care and Education	5	1, 2, 3, 4, 5	Teachers, parents, directors in LA; 2 EBQI peer mentors from AR	Primarily in-person with some partners joining remotely for some sessions	Package of 5 strategies
Swindle (27)	Exercise intervention for expecting women with excess weight	Community	5	1, 2, 3, 4, 5, 6	WIC, parks and Recreation, Insurance, faith leaders, trainers, mental health, mothers	Shifted to virtual after 1 session because of COVID-19	4 key adaptations and 3 implementation strategies
Lovelady (28)	Hospital-based Violence Intervention Program	Hospital & Community	2	1, 2, 3, 4	Medical providers, patients, social service orgs	In-person with one person joining *via* zoom during one session	Top 8 Barriers, Top 3 Facilitators, and Strategies for each
Zielinski (29)	Cognitive Processing Therapy, adapted for prisons (CPT-CJ)	Correction Centers	4	1, 2, 3, 4, 6	Correction center counselors, administrators, and security staff	Virtual	List of anticipated barriers and facilitators that were used to adapt materials & implementation plan; approved implementation plan
Teeter (30)	Pharmacist-initiated intervention for Prescribing and Dispensing Naloxone	Community pharmacies	4	1, 2, 3, 4, 5	Pharmacy district manager, pharmacists, community informants/ patients, pharmacists' association representative	In-Person	Patient-facing strategies to engage and educate; Pharmacist-facing strategies to train and educate, adapted to changing infrastructure
Synder/ Curran (31)	Patient-reported outcomes (PROs) in community pharmacies	Community pharmacies	5	1, 2, 3, 4, 5	Pharmacist owners/ pharmacists, pharmacy staff, patients	Virtual	Adapted PRO process and package of implementation strategies "ready to pilot"
Fortney/Curran (32)	Mental health EBPs for treatment-resistant depression/bi-polar disorder/risky drinking	FQHCs	Variable across 2 projects, minimum of 4	1,2, 3, 4, 5, 6	Site clinicians (physicians and nurses), patient representatives, EBP experts	Telephone	Selected and adapted EBPs and implementation strategies

[a]1. Form a team of local partners; 2 Prioritize determinants; 3. Select EBI adaptations/implementation strategies; 4. Specify EBI adaptions/strategies; 5. Refine EBI adaptations/strategies; 6. Make research design decisions.

TABLE 2 Activities for each EBQI step.

Steps	Activities
1. Form a team of local partners and experts.	Nomination by key informants (22–25, 28, 33); Nomination by study partners (21, 23, 33); Sector based recruitment (24, 28); Random selection from study sample (28); Inclusion of target population (21, 23–25, 33); Goal Setting (21)
2. Prioritize determinants.	Card sorting (24), Provide numeric rankings (22, 23, 28); Presentation/discussion of interview findings (23, 28, 33); Online individual brainstorming (28); Review previous research and have guided discussion (21, 23, 33)
3. Select EBI adaptations/ implementation strategies.	Concept Mapping (24, 25); Live-edit documents during presentation of previous research and guided discussion (22, 28); Online individual brainstorming (21, 28); Nominal Group Technique (33); Consensus discussion with voting (33)
4. Specify and tailor EBI adaptations/strategies.	Liberating Structures (24, 25); Nominal Group Technique (23, 25); Live-edit documents during guided discussion (22, 28); Present suggestions based on prioritized determinants and gauge reactions (21, 33)
5. Refine EBI adaptations/ strategies.	Breakout rooms with discussion questions (24); Chat probes (22, 24); Liberating Structures (24, 25); Complete implementation planning guide (22); Live-editing, Presentation of previous research and guided discussion, and group consensus (21, 28); Presentation of mid-pilot outcomes and guided discussion (22, 28)

patients, parents). The modality of meetings across cases included one example that was fully in-person; three examples that were fully virtual/remote; and 4 that included a mix of in-person and virtual strategies.

Commonalities and variations across case studies suggest basic steps that are core to EBQI in the pre-implementation phase; these are presented in Table 2 and include: (1) forming local teams of partners and experts, (2) prioritizing determinants, (3) selecting EBI adaptations and/or implementation strategies, (4) specifying and tailoring selected adaptations or implementation strategies and (5) refining EBI adaptations and/or implementation strategies. Most (7/8) cases included all these steps; three included an additional step of making research design decisions (e.g., choosing the control condition; selecting/refining measures). For the third step of selecting EBI adaptations and/or implementation strategies, all cases selected implementation strategies, while 3 also selected adaptations of the EBI (27, 29, 34).

The activities taken to achieve these steps were diverse (See Table 2). Each step had between 4 and 6 unique activities identified (Mean = 4) Commonly, cases included nomination of key informants and rapport building exercises in the first step of forming a team. Numeric rankings and guided discussions were common activities for the second step of prioritizing determinants. For the third step of selecting adaptation and implementation strategies, brainstorming and seeking consensus

were common. Presenting ideas to gauge reactions and the nominal group technique were used in multiple cases for the fourth step of specifying and tailoring strategies. Finally, guided discussion of mid-point results was the most prominent activity of refining/iterating adaptations and implementation strategies. Some activities were used across multiple steps [e.g., Liberating Structures (https://www.liberatingstructures.com/), live editing of documents], illustrating the flexibility of activities to achieve multiple purposes.

We have expanded on the Swindle (27) case to provide a meeting-by-meeting description of an EBQI process for the entirety of the pre-implementation phase, from launch to preparation for implementation. This includes the steps, activities, and outcomes of each individual meeting. (See **Supplementary**). The project described in this case study was designed to adapt a clinical exercise intervention for expecting women with excess weight for community-based delivery and establish a starting point for implementation strategies in the new setting. This process resulted in 3 key EBI adaptations (hybrid delivery, refined incentives, and post-partum support) and 3 implementation strategies (community-academic partnerships, centralized technical assistance, and involving participants' family/social support).

4. Recommendations for EBQI in the pre-implementation phase reflecting our case comparison

This perspective examined 7 case studies of the application of EBQI in the pre-implementation phase. Comparison of cases suggested 5 common steps of EBQI to prepare for implementation. These steps cut across the variety of settings and EBIs included in our case examples, which illustrates the widespread applicability of these steps. For each step, we identified several activities. That is, various activities were used across the cases to achieve each step. The diversity of activities identified illustrates how each step may be achieved depending on the context and needs of the project. Commonly, the steps identified led to prioritized determinants of implementation, adaptations for EBIs, and fully specified implementation strategies ready for testing. As such, the primary contribution of our perspective is the delineation of steps and activities of EBQI, particularly when used as a deliberative, partnered, and evidence-driven process to inform the selection and tailoring of implementation strategies and EBI adaptations prior to implementation. Thus, our work answers a recent call to provide transparency and detailed descriptions for the process of tailoring in implementation science (33).

Ultimately, the process of EBQI identified in included cases expands on steps of the EBQI model as laid out by early users (20). The 5 common steps identified were: (1) forming a local team of partners and experts, (2) prioritizing implementation barriers and facilitators (i.e., determinants) based on existing literature/data, (3) selecting and tailoring implementation strategies and/or EBI adaptations in the context of key determinants, (4) specifying selected strategies/adaptations, and (5) refining strategies/adaptations. These 5 steps tease apart and add detail to the 2 steps advanced by Curran and colleagues in 2008 (20). Notably, only some (3) of our cases included adaptations to the EBQI. We recommend the decision to adapt an EBI be driven by the prioritized determinants of implementation. That is, when fit of the EBI with the context is a barrier, adaptation is likely needed. Further, some cases involved a sixth step of making research design decisions (e.g., refining focus group questions, choosing control group, selecting measures). Each of these steps helps to prepare for a local implementation effort. Consistent with implementation science theory (28) and the spirit of CEDI (14), we view the emphasis on local knowledge and expertise as particularly important and recommend that considerations for selecting, tailoring, and iterating adaptations and strategies be made if the EBI or implementation strategy is transferred to another context. That is, by design, the ideas and priorities from one EBQI process may or may not translate to other settings with different contextual considerations.

Within each EBQI step, we identified several activities. This illustrates a non-exhaustive catalogue of options for *how* to move through EBQI in the pre-implementation phase. Key to many of our activities and an important recommendation for future application of EBQI is the inclusion of end users, which was present in 6 of our 7 cases. Other authors have made a compelling case for the importance of participatory approaches for optimizing fit of EBIs within context (35), addressing structural racism (11), and advancing equity (36). Our cases illustrate options for structuring input and balancing power with other types of partners. We acknowledge that power balance with end users (e.g., patients) and implementers (e.g., physicians) is not always possible, and some groups may choose to conduct parallel EBQI processes with implementing partners and end users as in our Snyder/Curran case study (31).

Notably, EBQI has historically been and continues to be used beyond the pre-implementation phase. Work by Hamilton and colleagues (23) illustrates that EBQI can function as an implementation strategy during the process of implementation rather than a time-limited process that ends when implementation begins. In fact, EBQI may be a "meta-strategy" during the active implementation phase through which many other strategies can be decided upon and deployed (e.g., working groups, facilitation calls, champion engagement). We believe operationalizing EBQI as an implementation strategy is most fitting when the purpose is "to enhance the adoption, implementation, and sustainability of a clinical program or practice" (37) or for "creating buy-in among stakeholders." (34) The Department of Veterans Affairs (VA) Quality Enhancement Research Initiative (QUERI) implementation road map (38) conceives of EBQI in this way and illustrates how EBQI operates during both active implementation and sustainment phases. Continuation of EBQI engagement across implementation phases allows continuation of partnerships formed in pre-implementation. Some cases included in our comparison reconvened EBQI panels after pilot tests to inform further refinement of implementation strategies and research designs as well as community expansion (27). Consistent with prior

literature (14), we believe partner engagement is critical in and beyond the pre-implementation phase. Thus, this perspective specifies the steps and activities of a specialized use of EBQI. This example may be useful for specifying steps and activities of EBQI across all phases of implementation.

We believe EBQI used at any phase of implementation is an example of quality CEDI work and fits with other recommended CEDI methods (12). However, we acknowledge this perspective is limited by over representation from one academic institution's understanding and application of EBQI. Our delineation of the steps and activities of EBQI for pre-implementation provides a basis from which others can compare and contrast their use of EBQI and other CEDI approaches and methods (e.g., implementation mapping, group model building). One promising way to advance this work is conceptualizing these CEDI approaches and methods as complex interventions and studying them using the lens and methods of functions and forms (39). Future work on EBQI can expand on both steps (e.g., which steps are pursued always vs. as-needed; which additional steps need to be considered) and activities to fulfill those steps, including developing tools and guidance for when and how to apply each step for maximum benefit. Future research may also compare EBQI as a process for selecting implementation adaptations and strategies to alternative processes (e.g., Implementation Mapping) to identify potential differences in the effectiveness of the outputs and/or partners' satisfaction with the process.

Data availability statement

The original contributions presented in the study are included in the article/**Supplementary Material**, further inquiries can be directed to the corresponding author.

Ethics statement

Ethical review and approval was not required for this study in accordance with the local legislation and institutional requirements.

Author contributions

TS led the conceptualization and writing of this manuscript, contributed two case studies, and provided the detailed case study example; JB, SJL, ABH, JLV, and MMG contributed to the writing and editing of this manuscript; NNL, MJZ, and BST contributed a case example as well as editing of the manuscript. GMC contributed to the conceptualization and writing of this manuscript and provided two case examples. All authors contributed to the article and approved the submitted version.

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Conflict of interest

SJL is a paid consultant for RAND and UTHealth Houston.

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Publisher's note

Supplementary material

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/frhs.2023.1155693/full#supplementary-material.

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The *SITS framework*: sustaining innovations in tertiary settings

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Background: To date, little attention has focused on what the determinants are and how evidence-based practices (EBPs) are sustained in tertiary settings (i.e., acute care hospitals). Current literature reveals several frameworks designed for implementation of EBPs (0–2 years), yet fewer exist for the sustainment of EBPs (>2 years) in clinical practice. Frameworks containing both phases generally list few determinants for the sustained use phase, but rather state ongoing monitoring or evaluation is necessary. Notably, a recent review identified six constructs and related strategies that facilitate sustainment, however, the pairing of determinants and how best to sustain EBPs in tertiary settings over time remains unclear. The aim of this paper is to present an evidence-informed framework, which incorporates constructs, determinants, and knowledge translation interventions (KTIs) to guide implementation practitioners and researchers in the ongoing use of EBPs over time.

Methods: We combined the results of a systematic review and theory analysis of known sustainability frameworks/models/theories (F/M/Ts) with those from a case study using mixed methods that examined the ongoing use of an organization-wide pain EBP in a tertiary care center (hospital) in Canada. Data sources included peer-reviewed sustainability frameworks ($n = 8$) related to acute care, semi-structured interviews with nurses at the department ($n = 3$) and unit ($n = 16$) level, chart audits ($n = 200$), and document review ($n = 29$). We then compared unique framework components to the evolving literature and present main observations.

Results: We present the Sustaining Innovations in Tertiary Settings (SITS) framework which consists of 7 unique constructs, 49 determinants, and 29 related KTIs that influence the sustainability of EBPs in tertiary settings. Three determinants and 8 KTIs had a continuous influence during implementation and sustained use phases. Attention to the level of application and changing conditions over time affecting determinants is required for sustainment. Use of a participatory approach to engage users in designing remedial plans and linking KTIs to target behaviors that incrementally address low adherence rates promotes sustainability.

Conclusions: The SITS framework provides a novel resource to support future practice and research aimed at sustaining EBPs in tertiary settings and improving patient outcomes. Findings confirm the concept of sustainability is a "dynamic ongoing phase".

KEYWORDS

frameworks/models/theories, sustainability, evidence-based practices, guidelines, interventions, innovations, adherence, nursing

Abbreviations

APS, Acute Pain Service; BPG, Best Practice Guideline; BPSO, Best Practice Spotlight Organization; DSF, Dynamic Sustainability Framework; EBP, Evidence Based Practices; IP, Inter Professional; KTIs, Knowledge Translation Interventions; NPP, Nursing Professional Practice; Pain P/P, Pain policy/protocol; RNAO, Registered Nurses' Association of Ontario; SITS Framework, Sustaining Innovations in Tertiary Settings Framework.

Introduction

Despite efforts among implementation practitioners and researchers a gap remains between efforts to embed evidence-based practices (EBPs), such as best practice guidelines (BPGs), in clinical practice and sustaining them over time beyond the initial implementation period (1). Ongoing discourse indicates conceptual frameworks are the best way to guide research and the implementation and sustainability of EBPs in clinical practice (2–6). To accomplish this, there are several published frameworks to choose from (4, 5). Specifically, many frameworks are designed for the implementation use phase of healthcare innovations (0–2 years) in clinical practice. However, few exist for the sustained use phase (7), especially for use within acute healthcare organizations, such as hospitals; hereafter referenced as tertiary settings. In this research, the sustained use of the evidence-based practice (EBP) change by users refers to maintaining ongoing EBP use, post an implementation period of greater than two years (i.e., >2 years) (8, 9). Distinctly, frameworks with combined implementation and sustainability constructs generally list fewer determinants for sustainability, or instead simply suggest ongoing monitoring or evaluation are necessary. As a result, practitioners and researchers alike must separately search the literature to identify sustainability determinants and related knowledge translation interventions (KTIs), (also referred to as strategies or approaches), known to influence use. Findings may or may not relate to the context of interest and often do not take into consideration the level of application (organizational verses unit level), nor the changing contextual influences over time. Measurably, this process is time consuming. This is particularly challenging to do in complex ever-changing contexts, such as in tertiary settings. There is a need for more comprehensive frameworks that combine both determinants and KTIs known to effectively facilitate the sustained use of EBPs to fill this gap in the literature and support practitioners and researchers working in clinical practice.

To date, evidence reveals the sustained use of an EBPs remains a persistent challenge in several settings (1, 10–13), and especially in tertiary settings (1, 14). In a recent empirical study that examined the determinants influencing ongoing use of EBPs in a multi-site hospital context over time, the impact of the changing underlying conditions on the determinants was revealed (15). The same study also presented insights related to the KTIs used to facilitate the sustained use of the EBP in clinical practice over time. These findings further articulated known strategies or approaches previously identified in a review by Lennox et al. (16) that included only 2 studies (out of 62) conducted in tertiary settings. These recent findings demonstrate that to promote healthcare innovation sustainability determinant identification is only part of the equation. Tailoring or linking KTIs to promote and "address specific determinants is the other critical step in the knowledge-to-action process" (2) to improve practice and related patient outcomes. This finding is not only relevant during the implementation phase but is an important component to consider during the sustained use phase for sustainability of EPBs in all contexts (17), including tertiary care settings. Currently, there are no frameworks which are explicit about the determinants and how related KTIs can be used to sustain EBPs in clinical practice during implementation (0–2 years) and sustained use phases (>2–10 years) (18) for clinical practice within tertiary settings.

The aim of this manuscript is to present a framework, which incorporates constructs, determinants, and related KTIs to guide implementation practitioners and researchers with the sustainability of EBPs, such as BPGs, in tertiary settings, namely acute care hospitals, to improve patient outcomes.

Methods

Design

To establish a framework to guide the sustainability of improved practice changes within tertiary settings, we focused our efforts on identifying relevant constructs, determinants, and related KTIs. Specifically, we combined the results of a case study using mixed methods that examined the ongoing use of an organization-wide Pain Best Practice Guideline (Pain BPG) in a hospital in Canada (15) with those from a recent systematic review and theory analysis of known sustainability frameworks/models/theories (F/M/Ts) relevant to acute care contexts (7). We compared the integrated findings with the evolving literature to confirm their inclusion in a comprehensive meta-synthesis of constructs, determinants, and related KTIs influencing sustainability for tertiary settings. The resultant '*Sustaining Innovations in Tertiary Settings (SITS) framework*' is presented herein for ease of use by practitioners and researchers alike. We present main observations related to the *SITS framework* constructs, determinants and KTIs; discuss practice implications; outline strengths and limitations; and propose future directions. In conclusion, we highlight how the *SITS framework* contributes to the current knowledge base.

Inclusion criteria

In the systematic review and theory analysis (7), and the case study (15) only concepts or constructs, determinants and KTIs from known sustainability F/M/Ts and existing peer reviewed citations related to sustainability were included. Specifically, F/M/Ts needed to address the process of sustaining healthcare innovations, such as EBPs, in an acute clinical practice setting or an unspecified healthcare organization/setting. To be eligible, citations needed to be published in English; recommended for healthcare; and in a peer-reviewed journal. A citation was excluded if the F/M/T contained an implementation and sustainability F/M/T without an explicit breakdown of related sustainability determinants. Of note, this research was not designed to examine the influence of implementation on sustainability.

Sustainability definition

We used Moore et al.'s (3) definition of sustainability which states it "is a district concept that (1) occurs after a period of

time; (2) the innovation or EBPs continues to be delivered; (3) and or individual behavior change (i.e., clinician, patient) is maintained; (4) the EBP and individual behavior change may evolve or adapt while; (5) continuing to produce benefits for individuals/systems" (3). The time period used to define the sustained use phase in this research is two years and beyond (>2 years.) which is congruent with current reviews (7–9, 14).

Data sources

We first outline constructs, determinants, and related KTIs results from two key data sources: (i) systematic review and theory analysis results derived from known sustainability frameworks for acute care contexts (7), and (ii) synthesized case study findings for three timeframes: the implementation use phase (0–2 years), the sustained use phase (>2–10 years), and at the ten-year timeframe (15).

Systematic review and theory analysis

Eight sustainability F/M/Ts for acute care contexts included in the review (7) initially generated 152 sustainability determinants. Qualitative analysis revealed 37 core determinants, which are grouped into the following seven constructs: (1) *innovation*; (2) *adopter/user*; (3) *leadership and management*; (4) *inner context* (i.e., practice setting/organization); (5) *inner processes* (i.e., infrastructure processes, methods, systems, structures or strategies); (6) *outer context* or broader system determinants; and (7) *outcomes* consisting of descriptions without defined determinants, only definitions. Sixteen out of the 37 core determinants are identified as common, occurring in four or more F/M/Ts which are highlighted by single asterix (see **Table 1**).

Case study

The case study (15) used an explanatory mixed method design to identify the 32 unique sustainability determinants and 29 related KTIs that influenced nurses ongoing use of an EBP; namely a Pain BPG, at the nursing department (an organizational perspective) and unit level (a point of care perspective) over three timeframes: (i) the implementation use phase (0–2 years), (ii) the sustained use phase over time (>2–10 years), and (iii) at the ten-year timeframe (see **Table 2**). Internal biannual audits revealed inpatient units demonstrated high to moderate adherence rates to several Pain BPG recommendations except those within the Medicine Care Department, necessitating further examination (15). Data sources included documents ($n = 29$), semi-structured interviews ($n = 19$), and inpatient chart audits ($n = 200$). Internal and external documents spanned the ten years (2007–2017). Responses from the three semi-structured department level interviews, were derived from nurses who worked across all 60 units over time. Documents and departmental findings were triangulated with unit level (subcases) quantitative results (e.g., audits) and qualitative findings (e.g., responses) derived from sixteen semi-structured unit nurse interviews.

All sustainability determinants ($N = 32$) and related KTIs ($N = 29$) influencing Pain BPG use over time were grouped into 3 constructs guided by the Dynamic Sustainability Framework (DSF) (19): the 'Innovation', 'Practice Setting', and 'Broader System' constructs. Together, department and unit level nurses identified 3 out of the 32 determinants (i.e., perceived *need*, *leadership commitment*, *external demand*) that continuously influenced sustained use over all three time periods. Notably, these three determinants were identified in different constructs: perceived *need* within the 'Innovation' construct, *leadership commitment* within the 'Practice Setting' construct, and *external demand* within the 'Broader System' construct. Department and unit nurses further identified two determinants (e.g., *stakeholder engagement*, unit level *management commitment*) that influenced ongoing use for both sustained use phase timeframes (e.g., >2–10 years, at 10 years.). Department level nurses uniquely identified eight more determinants for the sustained use phase (>2–10 years), and unit nurses uniquely identified an additional 19 determinants for the ten-year period detailed on **Table 2**.

Among the 29 KTIs identified within the case study, department and unit nurses described 8 KTIs that continuously promoted sustained Pain BPG use over all three time periods. These eight KTIs are within the DSF 'Innovation' and 'Practice Setting' constructs (19). Specifically, the first KTI: *embedding of recommendations* and *ongoing refinements* into existing forms and processes (i.e., integrating *prompts* into formal documentation processes and routine practices) facilitated high adherence rates. Second KTI: engaging *stakeholder joint collaboration* from the start, on all levels [e.g., consulting with interprofessional (IP) team members on the BPG] promoted use of EBPs among all disciplines. Third KTI: *formalizing the supervision of BPGs* within the Nursing Professional Practice (*N*PP) center and in related job descriptions for NPP leaders (e.g., BPG Coordinator and NPP department level representatives) provided an enduring centralized infrastructure to support ongoing BPG implementation, monitoring and reporting efforts over time. Fourth KTI: *obtaining buy-in* and *formalizing nursing leaders' involvement on committees* to support clinical tactics to sustain use of the innovation fostered leadership's commitment to evidence-based practice and culture among team members. Fifth KTI: *securing financial funds* externally and internally to develop a software system to monitor BPG nursing sensitive indicators at point of care facilitated BPG use beyond implementation. Sixth KTI: providing *ongoing education and training* support through formal and informal initiatives, on all levels, promoted evidence-based practice among new recruits and senior staff nurses. Seventh KTI: *educating and training champions* over time ensured access to unit level BPG expertise promoting sustained use of BPG recommendations. Eight KTI: *establishing a central reporting and monitoring structure* within the NPP department facilitated timely feedback of ongoing prevalence audit results to units and reporting of remedial action plans designed to address low adherence rates.

Additionally, department level nurses uniquely identified four KTIs for the implementation use phase (0–2 years), and fourteen KTIs for the sustained use phase (>2–10 years) (see **Table 2**). Unique implementation use phase (0–2 years.) KTIs used

TABLE 1 Synthesis of themes and determinants in known sustainability F/M/Ts for acute care (*N* = 8).

Theme /Concept	37 Core Factors	Unspecified setting Fwks					Acute care Fwks		
		1	2	3	5	6	4	7	8
Innovation (*Defined as: new process/change/ product/ practice or program, innovation, intervention)*	**Relevance/consistent with competitive strategy (need)***	✓	✓			✓		✓	
	Characteristics (scale, shape & form, age, nature, type, integrity)*	✓	✓		✓			✓	
	Perceived centrality to organizational performance /platform /services*	✓	✓		✓			✓	
	Fit with org's vision/mission, procedures/ strategies	✓		✓				✓	
	Adaptability of innovation			✓		✓		✓	
	Benefits to patient, staff, organization (cost effective, efficiency & quality of care)*		✓	✓	✓	✓		✓	
	Barrier Identification					✓			
Adopters *(Defined as: staff, stakeholder, user, adopter, actor, and or individual)*	Human resources—recruitment, processes, succession and leave planning (staffing)				✓	✓			
	Individual commitment to innovation*	✓	✓			✓		✓	
	Individual competency (skill knowledge, absorptive capacity) to perform innovation*	✓	✓		✓			✓	✓
	Internal cohesion between individual & commitment within the organization /stakeholder engagement leads to increased performance		✓					✓	✓
	Stakeholder Commitment to innovation			✓			✓		✓
	Stakeholder beliefs, attitude, perceptions, emotions, expectations towards innovation	✓		✓		✓			
	Champion presence & involvement					✓		✓	
Leadership & Management *(Defined as: style, approach, behaviors, engagement support, or feedback)*	**Management approach & engagement***	✓	✓	✓	✓			✓	✓
	Senior Leadership involvement & actions*	✓	✓	✓				✓	
Inner Context *(Defined as: context, practice setting or organization)*	**Infrastructure support- Policies & Procedures based on Innovation***	✓		✓				✓	✓
	Infrastructure support for innovation in job description with mechanism for recognizing achievement	✓		✓			✓		
	Infrastructure support-equipment & supplies for innovation*			✓			✓	✓	✓
	Organization—Absorptive capacity for innovation							✓	✓
	Cultural—Beliefs, values & perceptions to innovation	✓						✓	
	Cultural—Climate*	✓	✓		✓			✓	
	Cultural—innovation integrated into Norms (documents, protocols, manuals)	✓					✓		
	Political internal stakeholder coalition, power, influence	✓				✓		✓	
	Financial performance budgeting & measurement	✓				✓			
	Financial-internal funds & other non-financial resources of innovation					✓		✓	
Processes *(Defined as: processes, methods, systems, structures, or strategies)*	**Education & training processes***			✓	✓	✓	✓	✓	
	Processual—Planning, method, & timing of embedding innovation	✓					✓	✓	
	Processual- project structure & system to monitor/manage innovation*	✓		✓	✓		✓	✓	
	Organization—communication capacity for monitoring (reporting & feedback)*	✓	✓	✓	✓	✓	✓	✓	
	Behavioural change strategies								✓
Outer Context *(Defined as: external condition, context, system, or environment)*	Soci-economic political threats, stability	✓			✓			✓	
	External conditions, compatibility for innovation*	✓	✓		✓			✓	
	Connection to broader external context		✓			✓		✓	
	External Support for innovation from Stakeholders	✓	✓					✓	
	Political-Policy, legislation & Interests*		✓		✓	✓		✓	
	Financial-external funds & other non-financial resources of innovation							✓	
Outcomes (*Defined as: outcomes, teamwork behaviors, consequences, or continuation of benefits)*	No factors explicitly defined in frameworks for this concept	✓				✓		✓	✓

1 = Buchanan SOCF, 2 = Racine MSI, 3 = Maher NHS SM, 4 = Slaghuis FMIS WP, 5 = Chambers DSF, 6 = Fox SITF, 7 = Fleiszer SIHF, 8 = Frykmann DCOMF.
*Common Factors—occurs in 4 or more F/M/Ts (7).

included: (i) establishing an interdisciplinary Pain policy/protocol; (ii) using a framework to guide implementation and to identify barriers; (iii) securing internal financial commitment; and (iv) using a multi-modal approach to disseminate the Pain BPG across all units. During the sustain use phase (>2–10 years.) department nurses identified the following 14 unique KTIs that promoted Pain BPG use over time: (i) establishing performance evaluation indicators related to the Pain BPG for unit leaders; (ii) having unit leaders lead department and unit level pain care initiatives; (iii) encouraging unit leaders to determine EBP priorities; (iv) having unit leaders facilitate ongoing related education tailored to units; (v) implementing mandatory elearn training related to BPGs; (vi) providing unit specific training of staff based on audit remedial action plans to improve BPG

TABLE 2 Case study findings for sustainability of EBPs in a tertiary setting.

DSF Themes/ Constructs (19)	Integrated Determinants *N* = 32	*N* = 32 Unique Determinants			*N* = 29 Unique Knowledge Translation Interventions (KTIs0		
		Department RNs Implementation Determinants (0–2 years.) *n* = 3	Department RNs Sustainability Determinants (>2–10 years) *n* = 12	Unit RNs Sustainability Determinants (at 10 years) *n* = 31	Department RNs Implementation Phase (0–2 years.) KTIs (*n* = 12)	Department RNs Sustained Phase (>2–10 years.) KTIs (*n* = 22)	Unit RNs Sustained Phase (at 10 years.) KTIs (*n* = 11)
		3 ongoing Determinants			8 ongoing KTIs		
			2 + 8 Unique Determinants	2 + 19 Unique Determinants	+ 4 unique Imp KTIs	+ 14 unique Sust KTIs	+ 3 unique Sust KTIs
Innovation *(Defined as: new process/change/ product/practice or program, innovation, intervention)*	Relevance/consistent with competitive strategy (to addresses need/problem0✸	✓✸		✓✸			
	Adaptability of innovation				**Embedding of Pain P/P** into existing unit processes⁂	**Embed ongoing refinements** into existing routine practices/processes &Pain P/P⁂	**Routinize recommendations into nursing forms and practices/ processes: e**mbed prompts⁂
							Digitalized Pain P/P and forms into new eHealth record
					Pain P/P established Interdisciplinary for all disciplines		
	Benefits to patient, staff, organization (cost effective, efficiency & quality of care)			✓			
	Barrier Identification				**Use frameworks** to guide implementation and identify barriers		
Practice Setting *(Defined as inner context)*	Human resources—recruitment, processes, succession and leave planning (staffing/compliment)		✓		**Secure internal financial** commitment—time and Human resources to participate on cttees & to implement KTIs		
	Student turnover (medical)		✓				
	Individual commitment to innovation			✓			
	Individual competency (skill knowledge, absorptive capacity) to perform innovation and time management to use innovation			✓			
	expert consultants /resources			✓			
	Internal cohesion btwn individual & commitment within the organization /stakeholder engagement leads to increased performance (senior nurse mentors /influencers verses Clinical Care Leaders))			✓			**Mentorship used by senior nurses** to support Pain P/P use:
	Stakeholder Commitment to innovation (IP—interprofessional)			✓	**Joint collaboration** of human resources **from all levels of nursing** plus other disciplines to develop departmental implementation plan⁂		**Engages IP stakeholder involvement:** all professions to follow policy participate on cttees⁂
	Stakeholder beliefs, attitude, perceptions, emotions, expectations towards innovation and user motivation/resistance		✓	✓			

(*continued*)

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TABLE 2 Continued

DSF Themes/ Constructs (19)	Integrated Determinants $N = 32$	$N = 32$ Unique Determinants			$N = 29$ Unique Knowledge Translation Interventions (KTIs0		
		Department RNs Implementation Determinants (0–2 years.) $n = 3$	Department RNs Sustainability Determinants (>2–10 years) $n = 12$	Unit RNs Sustainability Determinants (at 10 years) $n = 31$	Department RNs Implementation Phase (0–2 years.) KTIs ($n = 12$)	Department RNs Sustained Phase (>2–10 years.) KTIs ($n = 22$)	Unit RNs Sustained Phase (at 10 years.) KTIs ($n = 11$)
		3 ongoing Determinants			8 ongoing KTIs		
			2 + 8 Unique Determinants	2 + 19 Unique Determinants	+ 4 unique Imp KTIs	+ 14 unique Sust KTIs	+ 3 unique Sust KTIs
	Population characteristic/needs/acuity level			✓			
	Users awareness / familiarity with innovation			✓			
Practice Setting *(Defined as inner context)*	**Leadership commitment (dept level)**✷	✓✷	✓✷	✓✷	**Formalize BPG Coordinator role**⁂	**Comparing survey results among units created a sense of competition** among leaders and users to improve⁂	**Leadership strategies**⁂ -Clinical Coordinator—dept level: (support for big issues during shifts) -Clinical Care Leaders—unit level (get involved in unit level issues to support ongoing improvements) -Unit Managers—unit level (get involved in unit wide issues, help with remedial action plans to reinforce target behaviors, review incidents, encourages education training)
	Management approach & engagement (commitment unit level)		✓	✓			
	Senior Leadership involvement & actions		✓				
Practice Setting *(Defined as inner context)*	Infrastructure support- Policies & Procedures based on Innovation (i.e., cttees, key people in nursing dept– i.e. educators, champions, NPP reps)			✓			
	Infrastructure support for innovation in job description with mechanism for recognizing achievement					**Performance Evaluation indicators** for monitoring rt innovation = leaders, managers, and staff	
	Infrastructure support-equipment & supplies for innovation (and resources = pamphlets)			✓			
	Physical layout/structure of wards			✓			
	Competing corporate priorities		✓				
	Cultural—Beliefs, values & perceptions to innovation			✓			
	Cultural—Climate (doing research)			✓			
	Cultural—innovation integrated into Norms (documents, protocols, manuals)			✓		**Unit leaders lead dept and unit level patient centered initiatives for pain care based on unit**	

(*continued*)

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TABLE 2 Continued

DSF Themes/ Constructs (19)	Integrated Determinants $N = 32$	$N = 32$ Unique Determinants			$N = 29$ Unique Knowledge Translation Interventions (KTIs0		
		Department RNs Implementation Determinants (0–2 years.) $n = 3$	Department RNs Sustainability Determinants (>2–10 years) $n = 12$	Unit RNs Sustainability Determinants (at 10 years) $n = 31$	Department RNs Implementation Phase (0–2 years.) KTIs ($n = 12$)	Department RNs Sustained Phase (>2–10 years.) KTIs ($n = 22$)	Unit RNs Sustained Phase (at 10 years.) KTIs ($n = 11$)
		3 ongoing Determinants			8 ongoing KTIs		
			2 + 8 Unique Determinants	2 + 19 Unique Determinants	+ 4 unique Imp KTIs	+ 14 unique Sust KTIs	+ 3 unique Sust KTIs
						routine practices -with adoption of EBP care	
	Team culture embraces innovation			✓	**Obtaining buy-in and Formalize nurse leaders' involvement** on Steering Cttee⁂	**Corporate level Internal cttees' support ongoing review of clinical tactics** support sustained use ie Patient Experience Steering cttee and Accreditation workgroup⁂	**Fostering an IP and EBP culture** among IP team to support Pain P/P use:⁂
	Political internal stakeholder coalition, power, influence					**Dept determine EBP priorities**	
	Financial performance budgeting & measurement				**Secure external funds**⁂ a) RNAO PBSO—secure operating funds for initial training and resource s to build capacity b) secure capital external financial support—for point of care surveying system	**Development of an electronic monitoring system** to measure nursing sensitive indicators provide monitoring of BPG adherence⁂	
Practice Setting *(Defined as inner context)*	Workload /staffing patterns			✓			
	Education & training processes				**Pain Council established—Interdisciplinary taskforce** leads initial policy development, education strategies and future policy revision⁂	**NPP reps develop formal and informal education** initiatives at dept and unit level in 2014 initially performed by the Pain Council.⁂	**Ongoing Education** to support Pain P/P use by NPP and Educators: -education days,: -mandatory online modules: -updates, refreshers, seminars⁂
					Educating Champions –to be clinical experts on units, with APNs:⁂	**Trains 170 Unit level expertise** to support use of Pain P/P s = Champions, educators, APNs, work across units as clinical resource⁂	**Ongoing Training** to support Pain P/P use by NPP and Educators: -general hospital orientation,: -—1 on 1 training, in-services, solve recurrent problems⁂
						Ongoing pain care education support at dept and unit levels becomes tailored over time ie 1 on 1, case studies	
						Mandatory **eLearn training** system	
						Unit specific training of staff provided **based on audit remedial action plans** to improve on related BPG survey indicators	

(*continued*)

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TABLE 2 Continued

DSF Themes/ Constructs (19)	Integrated Determinants *N* = 32	*N* = 32 Unique Determinants			*N* = 29 Unique Knowledge Translation Interventions (KTIs0		
		Department RNs Implementation Determinants (0–2 years.) *n* = 3	Department RNs Sustainability Determinants (>2–10 years) *n* = 12	Unit RNs Sustainability Determinants (at 10 years) *n* = 31	Department RNs Implementation Phase (0–2 years.) KTIs (*n* = 12)	Department RNs Sustained Phase (>2–10 years.) KTIs (*n* = 22)	Unit RNs Sustained Phase (at 10 years.) KTIs (*n* = 11)
		3 ongoing Determinants			8 ongoing KTIs		
			2 + 8 Unique Determinants	2 + 19 Unique Determinants	+ 4 unique Imp KTIs	+ 14 unique Sust KTIs	+ 3 unique Sust KTIs
						Develop unit specific **additional resources/tools** over time	
Practice Setting *(Defined as inner context)*	Processual—Planning, method, & timing of embedding innovation			✓	Use **multi-modal approach to disseminate**		
	Processual- project structure & system to monitor/manage innovation					**Spread EBP** to additional areas	
					Established Pain BPG taskforce/ workgroup in NPP dept—enduring central reporting and monitoring structure for ongoing implementation and evaluation⁂	**NPP and Unit Leaders facilitate/ lead remedial action plan for under performing units**⁂	**Monitoring and evaluation:** Dept level—ongoing training to do survey Unit level—audit and feedback provided (timely sharing of audit data, focuses biannual audit questions on target behaviors) Unit level—Patient satisfaction survey results shared reviews incidents and develop strategies to prevent them in staff mtgs⁂
	Organization—communication capacity for monitoring (reporting & feedback)			✓		Ongoing biannual **training** of staff **to conduct prevalence survey**	
						NPP Establishes regular performance monitoring: includes results from biannual prevalence audit and internal incident reporting	
						Timely reporting of prevalence survey results led to **course correcting changes**	
	Formal communicating/reporting systems for client info between practitioners (documented)			✓			Establishing effective communications between providers, reporting practices —bedside exchange, whiteboards, clipboards
Broader system (*Defined as: external condition, context, system, or environment*)	External conditions, compatibility for innovation (consumer demand)		✓				
	External pressure/demand (e.g., professional/regulatory bodies, Ministry, funding bodies)✱	✓✱	✓✱	✓✱		**New evidence released—** Integrating into BPG and ongoing education	

(*continued*)

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TABLE 2 Continued

DSF Themes/ Constructs (19)	Integrated Determinants $N = 32$	$N = 32$ Unique Determinants			$N = 29$ Unique Knowledge Translation Interventions (KTIs0		
		Department RNs Implementation Determinants (0–2 years.) $n = 3$	Department RNs Sustainability Determinants (>2–10 years) $n = 12$	Unit RNs Sustainability Determinants (at 10 years) $n = 31$	Department RNs Implementation Phase (0–2 years.) KTIs ($n = 12$)	Department RNs Sustained Phase (>2–10 years.) KTIs ($n = 22$)	Unit RNs Sustained Phase (at 10 years.) KTIs ($n = 11$)
		3 ongoing Determinants			8 ongoing KTIs		
			2 + 8 Unique Determinants	2 + 19 Unique Determinants	+ 4 unique Imp KTIs	+ 14 unique Sust KTIs	+ 3 unique Sust KTIs
Broader system (*Defined as: external condition, context, system, or environment*)	Connection to broader external context (regional, national, international links)		✓			**## Staff participation on a regional network**—provide access to new research and related outcomes for pain management	
	External Support for innovation from Stakeholders (recognition)		✓			**Benchmarking** to external sources best practices	
	Goal Alignment with external agencies (e.g., Education institutes)		✓				

✷Determinants common over three timeframes—Implementation phases (0–2 years), Sustained use phases (2–10 years, and at 10 years).
⁂KTIs common over three timeframes– Implementation phases (0–2 years), Sustained use phases (2–10 years, and at 10 years).

survey indicators; (vii) developing additional unit specific BPG resources/tools: (viii) spreading the Pain BPG to outpatient units; (ix) offering ongoing biannual training of staff to conduct prevalence surveys; (x) requiring leaders to formally report unit performance monitoring related to BPGs; (xi) developing remedial action plans in response to timely prevalence reports; (xii) integrating new evidence into BPG and ongoing education initiatives; (xiii) encouraging staff participation on regional networks; and (xiv) benchmarking performance to external sources and best practices.

Unit level nurses further identified three KTIs unique to the ten-year timeframe (see **Table 2**). Specifically, unit nurses indicated (i) digitalizing or embedding recommendations from the Pain Policy/protocol into the eHealth record; (ii) mentorship by senior nurses; and (iii) effective communication and reporting practices between providers influenced their sustained use of the Pain BPG. Notably, unit level audit findings reportedly demonstrated 'Innovation' and 'Practice Setting' KTIs designed to standardize and monitor nursing documentation practices over time effectively promoted ongoing EBP use over time (15).

Analysis

Qualitative content analysis (20) was conducted to identify the total number of unique constructs, determinants and KTIs among the key data sources. Initially, we deductively mapped the three constructs, determinants and related KTIs identified in the empirical case study (15) to the seven constructs synthesized from theoretical conceptualizations of the eight sustainability frameworks included in the systematic review (7). We then inductively triangulated the determinants and related KTIs from the case study with the determinants identified within the systematic review, removing duplicates, and maintaining alignment or grouping within the seven constructs. Determinants identified in the case study, not previously identified within the synthesis of the eight F/M/Ts, were then examined by comparing them with those identified in two recent reviews related to sustainability (1, 21). Finally, all 29 KTIs derived from the case study (15) were compared with the current literature (16) to examine similarities and differences. Lastly, we present main observations related to the resultant synthesis of constructs, determinants and KTIs, which formed the '*Sustaining Innovations in Tertiary Settings*' (SITS) framework.

Results

Combined results for tertiary settings

Qualitative content analysis and triangulation of the constructs or concepts, determinants and related KTIs from the case study (15) and the systematic review (7) revealed a comprehensive meta-synthesis of 7 unique constructs, 49 unique sustainability determinants, and 29 related KTIs (see **Table 3**). We present our

TABLE 3 Combined findings for sustaining innovations in tertiary settings.

Dynamic Sustainability Framework (DSF) Constructs (19)	7 Themes/Constructs (7)	Determinants (*N* = 49)	Unspecified setting Fwks					Acute care Fwks			Imp Factors (0–2 years.) *n* = 3	Sust Factors (>2–10 years) *n* = 12	Sust Factors (at 10 years) *n* = 31	Department RNs Implementation (0–2 years.) 8 + 4 KTIs (*n* = 12)	Department RNs Sustainability (>2–10 years.) 8 + 14 KTIs (*n* = 22)	Unit RNs Sustainability (at 10 years.) 8 + 3 KTIs (*n* = 11)
			1	2	3	5	6	4	7	8						
Innovation *(Defined as: new process/change/ product/practice or program, innovation, intervention*	**Innovation** *(defined as: new process/change/ product/practice or program, innovation, intervention)*	Relevance/consistent with competitive strategy (to addresses need/problem*	✓	✓			✓		✓		✓✸	✓✸				
		Characteristics (scale, shape & form, age, nature, type, integrity)*	✓	✓		✓			✓							
		Perceived centrality to organizational performance /platform /services*	✓	✓		✓			✓							
		Fit with org's vision/mission, procedures/ strategies	✓		✓				✓							
		Adaptability of innovation			✓		✓		✓					**Embedding of Pain P/P** into existing unit processes⁂	**Embed ongoing refinements** into existing routine practices/ processes & Pain P/P⁂	**Routinize recommendations into nursing forms and practices/ processes: e**mbed prompts⁂
																Digitalized Pain P/P and forms into new eHealth record
														Pain P/P established Interdisciplinary for all disciplines		
		Benefits to patient, staff, organization (cost effective, efficiency & quality of care)*		✓	✓	✓	✓		✓				✓			
		Barrier Identification					✓							**Use frameworks** to guide implementation and Id barriers		
Practice Setting *(Defined as inner context)*	**Adopters** *(defined as: staff, stakeholder, user, adopter, actor, and or individual)*	Human resources—recruitment, processes, succession and leave planning (staffing/compliment)				✓	✓					✓		**Secure internal financial** commitment—time and Human resources to participate on cttees and to implement KTIs		
		Student turnover (medical)**										✓				
		Individual commitment to innovation*	✓	✓			✓		✓				✓			
		Individual competency (skill knowledge, absorptive capacity) to perform innovation and time management to use innovation*	✓	✓		✓			✓	✓			✓✓			
		expert consultants /resources**											✓			
		Internal cohesion btwn individual & commitment within the organization /stakeholder engagement leads to increased performance (senior nurse mentors /influencers)		✓					✓	✓			✓			**Mentorship used by senior nurses to** support Pain P/P use:

(*continued*)

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TABLE 3 Continued

Dynamic Sustainability Framework (DSF) Constructs (10)	7 Themes/Constructs (9)	Determinants (*N* = 49)	Unspecified setting Fwks					Acute care Fwks			Imp Factors (0–2 years.) *n* = 3	Sust Factors (>2–10 years) *n* = 12	Sust Factors (at 10 years) *n* = 31	Department RNs Implementation (0–2 years.) 8 + 4 KTIs (*n* = 12)	Department RNs Sustainability (>2–10 years.) 8 + 14 KTIs (*n* = 22)	Unit RNs Sustainability (at 10 years.) 8 + 3 KTIs (*n* = 11)
			1	2	3	5	6	4	7	8						
		Stakeholder Commitment to innovation			✓			✓		✓			✓✓✓✓	**Joint collaboration** of human resources **from all levels of nursing** plus other disciplines to develop departmental implementation plan⁂		**Engages IP stakeholder involvement:** all professions to follow policy participate on cttees⁂
		Stakeholder beliefs, attitude, perceptions, emotions, expectations towards innovation and user motivation/resistance	✓		✓		✓					✓	✓✓			
		Population characteristic/ needs/acuity level**											✓			
		Users awareness / familiarity with innovation**											✓			
		Champion presence & involvement					✓		✓							
Practice Setting *(Defined as inner context)*	**Leadership & Management** *(defined as: style, approach, behaviors, engagement support, or feedback)*	**leadership commitment (dept level)****									✓✷	✓✷		**Formalize BPG Coordinator role**⁂	**Dept Leaders Comparing survey results** among units created a sense of competition among leaders and users to improve⁂	**Leadership strategies**⁂ -Clinical Coordinator- dept level: (support for big issues during shifts) -Clinical Care Leaders—unit level (get involved in unit level issues to support ongoing improvements) -Unit Managers—unit level (get involved in unit wide issues, help with remedial action plans to reinforce target behaviors, review incidents, encourages education training)
		Management approach & engagement (commitment unit level)*	✓	✓	✓	✓			✓	✓		✓✷	✓✓✓✷			
		Senior Leadership involvement & actions*	✓	✓	✓				✓			✓				
	Inner Context *(defined as: context, practice setting or organization)*	Infrastructure support- Policies & Procedures based on Innovation*	✓		✓				✓	✓			✓			
		Infrastructure support for innovation in job description with mechanism for recognizing achievement	✓		✓			✓							**Performance Evaluation indicators** for monitoring rt innovation = leaders, managers, and staff	
		Infrastructure support- equipment & supplies for innovation (and resources = pamphlets)*			✓			✓	✓	✓			✓			
		Organization—Absorptive capacity for innovation							✓	✓						

(*continued*)

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TABLE 3 Continued

Dynamic Sustainability Framework (DSF) Constructs (19)	7 Themes/Constructs (9)	Determinants (*N* = 49)	Unspecified setting Fwks					Acute care Fwks			Imp Factors (0–2 years.) *n* = 3	Sust Factors (>2–10 years) *n* = 12	Sust Factors (at 10 years) *n* = 31	Department RNs Implementation (0–2 years.) 8 + 4 KTIs (*n* = 12)	Department RNs Sustainability (>2–10 years.) 8 + 14 KTIs (*n* = 22)	Unit RNs Sustainability (at 10 years.) 8 + 3 KTIs (*n* = 11)
			1	2	3	5	6	4	7	8						
		Physical layout/structure of wards**											✓			
		Competing corporate priorities**										✓				
		Cultural—Beliefs, values & perceptions to innov	✓						✓				✓			
		Cultural—Climate*	✓	✓		✓			✓				✓			
		Cultural—innovation integrated into Norms (documents, protocols, manuals)	✓					✓					✓		**Unit leaders lead dept and unit level patient centered initiatives for pain care based on unit routine practices** -with adoption of EBP care	
		Team culture embraces innovation**											✓	**Obtaining buy-in and Formalize nurse leaders' involvement** on Steering Cttee⁂	**Corporate level Internal cttees' support ongoing review of clinical tactics** support sustained use ie Patient Experience Steering cttee and Accreditation workgroup⁂	**Fostering an IP and EBP culture** among IP team to support Pain P/P use:⁂
		Political internal stakeholder coalition, power, influence	✓				✓		✓						**Dept determine EBP priorities**	
		Financial performance budgeting & measurement	✓				✓							**Secure external funds**⁂ a)RNAO PBSO—secure operating funds for initial training and resource s to build capacity b)secure capital external financial support—for point of care surveying system	**Development of an electronic monitoring system** to measure nursing sensitive indicators provide monitoring of BPG adherence⁂	
		Financial-internal funds & other non-financial resources of innovation					✓		✓							
Practice Setting *(Defined as inner context)*	**Inner Processes** *(defined as processes, methods, systems, in the inner environment)*	**workload /staffing patterns****											✓			
		Education & training processes*			✓	✓	✓	✓	✓					**Pain Council established—Interdisciplinary taskforce** leads initial policy development, education strategies and future policy revision⁂	**NPP reps develop formal and informal education** initiatives at dept and unit level in 2014 initially performed by the Pain Council.⁂	**Ongoing Education** to support Pain P/P use by NPP and Educators:⁂ -education days, -mandatory online modules -updates, refreshers, seminars
														Training/Educating Champions –to be clinical experts on units, with APNs	**Trains 170 Unit level expertise** to support use of Pain P/P s = Champions, educators, APNs, work across units as clinical resource	**Ongoing Training** to support Pain P/P use by NPP and Educators: -general hospital orientation, -1 on 1 training, in-services, solve recurrent problems

(*continued*)

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TABLE 3 Continued

Dynamic Sustainability Framework (DSF) Constructs (10)	7 Themes/Constructs (9)	Determinants (*N* = 49)	Unspecified setting Fwks					Acute care Fwks			Imp Factors (0–2 years.) *n* = 3	Sust Factors (>2–10 years) *n* = 12	Sust Factors (at 10 years) *n* = 31	Department RNs Implementation (0–2 years.) 8 + 4 KTIs (*n* = 12)	Department RNs Sustainability (>2–10 years.) 8 + 14 KTIs (*n* = 22)	Unit RNs Sustainability (at 10 years.) 8 + 3 KTIs (*n* = 11)
			1	2	3	5	6	4	7	8						
															Ongoing pain care education support at dept and unit levels becomes tailored overtime ie 1 on 1, case studies	
															Mandatory **eLearn training** system	
															Unit specific training of staff provided **based on audit remedial action plans** to improve on related BPG survey indicators	
															Develop unit specific **additional resources/tools** overtime	
		Processual—Planning, method, & timing of embedding innovation	✓					✓	✓				✓	Use **multi-modal approach to disseminate**		
		Processual- project structure & system to monitor/manage innovation*	✓		✓	✓		✓	✓						**Spread EBP** to additional areas	
														Established Pain BPG taskforce/workgroup in NPP dept—enduring central reporting and monitoring structure for ongoing implementation and evaluation⁂	**NPP and Unit Leaders facilitate/lead remedial action plan for under performing units**⁂	**Monitoring and evaluation:**⁂ Dept level—ongoing training to do survey Unit level—audit and feedback provided (timely sharing of audit data, focuses biannual audit questions on target behaviors) Unit level—Patient satisfaction survey results shared reviews incidents and develop strategies to prevent them in staff mtgs
		Organization—communication capacity for monitoring (reporting & feedback)*	✓	✓	✓	✓	✓	✓	✓				✓		Ongoing biannual **training** of staff **to conduct prevalence survey**	
															NPP Establishes regular performance monitoring: includes results from biannual prevalence audit and internal incident reporting	
															Timely reporting of prevalence survey results led to **course correcting changes**	
		Formal communicating/ reporting systems for client info btwn practitioners (documented)**											✓✓			Establishing effective communications between providers, reporting practices—bedside exchange, whiteboards, clipboards
		Behavioural change strategies								✓						

(*continued*)

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TABLE 3 Continued

Dynamic Sustainability Framework (DSF) Constructs (10)	7 Themes/Constructs (7)	Determinants ($N = 49$)	Unspecified setting Fwks					Acute care Fwks			Imp Factors (0–2 years.) $n = 3$	Sust Factors (>2–10 years) $n = 12$	Sust Factors (at 10 years) $n = 31$	Department RNs Implementation (0–2 years.) 8 + 4 KTIs ($n = 12$)	Department RNs Sustainability (>2–10 years.) 8 + 14 KTIs ($n = 22$)	Unit RNs Sustainability (at 10 years.) 8 + 3 KTIs ($n = 11$)
			1	2	3	5	6	4	7	8						
Broader system (*Defined as: external condition, context, system, or environment)*	**Outer Context** (defined as: external condition, context, system, or environment)	Soci-economic political threats, stability	✓			✓			✓							
		External conditions, compatibility for innovation (consumer demand)*	✓	✓		✓			✓			✓				
		External pressure/demand (e.g., professional/regulatory bodies, Ministry, funding bodies)**									✓✷	✓✷	✓		**New evidence released—** Integrating into BPG and ongoing education	
		Connection to broader external context (regional, national, international links)		✓			✓		✓			✓			**## Staff participation on a regional network—**provide access to new research and related outcomes for pain management	
		External Support for innovation from Stakeholders (recognition)	✓	✓					✓			✓			**Benchmarking** to external sources best practices	
		Goal Alignment with external agencies (e.g., Education institutes)**										✓				
		Political-Policy, legislation & Interests*		✓		✓	✓		✓							
		Financial-**external** funds & other non-financial resources of innovation							✓							
Outcomes (*Defined as the continuation of intended benefits*)	**Outcomes** (defined as: outcomes, teamwork behaviors, consequences, or continuation of benefits)	No factors explicitly defined in frameworks for this concept	✓				✓		✓	✓						

1 = Buchanan SOCF, 2 = Racine MSI, 3 = Maher NHS-SM, 4 = Slaghuis FMIS-WP, 5 = Chambers DSF, 6 = Fox SITF, 7 = Fleiszer SIHF, 8 = Frykmann DCOMF.

*Common Determinants—occurs in 4 or more F/M/Ts from systematic review (7).

**12 Sustainability determinants—additions from case study (15).

✷3 Common Determinants over three timeframes—Implementation phases (0–2 years), Sustained use phases (2–10 years, and at 10 years).

⁂8 Common KTIs over three timeframes—Implementation phases (0–2 years), Sustained use phases (2–10 years, and at 10 years).

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comparison of these integrated findings to the evolving literature to confirm inclusion within the new framework, entitled '*Sustaining Innovations in Tertiary Settings*' (SITS) (see **Figure 1**, and **Table 4** for details).

Determinants influencing sustainability in tertiary settings

Examination of the 49 determinants revealed 20 common sustainability determinants between the systematic review (7) and case study results (15), 17 determinants unique to the systematic review, and 12 determinants unique to the case study. All 49 sustainability determinants aligned with 6 (of the 7) constructs identified in the systematic review (7) (see **Figure 2**). Notably, no determinants were reported for the 'Outcome' construct in the case study (15). This is not unexpected given 'Outcomes' is not identified as a construct within the DSF (19), but instead defined as "the continuation of intended benefits" (19), a finding previously noted (7, 22).

The 17 sustainability determinants previously identified in the systematic review (7) did not align with those in the case study (15). This finding is not surprising, given the case study only used one of the frameworks; namely the DSF (19), included in the systematic review to guide data collection and analysis (15). As such, the DSF did provide the same comprehensive list of determinants provided in the results of the systematic review (7). Furthermore, our review of the case study data collection tools indicated no specific questions were used related to the 17 determinants. Thus, we cannot say with any definitiveness whether the 17 determinants were present (or not) in the case study (15). However, this does demonstrate not all determinants apply every time in all real-world settings.

The remaining 12 sustainability determinants, uniquely identified in the case study (15), lie within the five 'context constructs' identified in the systematic review (e.g., *Adopters, Leadership & Management, Inner Context, Inner Processes, Outer Context*) (7), and those previously reported in the evolving literature related to sustainability of EBPs in healthcare settings (1, 21). Specifically, the 12 determinants align with the 'domains, attributes and related features of context' influencing the use of EBPs in research and clinical practice identified in a recent review and concept analysis of context by Squires et al. (21) and the 'emerging contextual influences' impacting sustainability identified in another review by Shelton et al. (1).

Construct/theme similarities in the literature categorizing the twelve determinants

We present similarities between the 12 context determinants and two reviews in the evolving literature (1, 21) influencing our decision to include all 12 determinants in the *SITS framework* (see **Table 5**). First, by comparison, two current reviews in the literature use similar definitions and or categorization for the 12 context determinants as those previously identified in the synthesis of eight F/M/Ts in the systematic review (hereafter referenced Nadalin Penno et al.) (7). Specifically, Squires et al. (21) uses the term 'Domains' and Shelton et al. (1) uses the term 'Factors (themes)', identifying similar determinants within the same categories/groupings, having similar definitions. This confirms the addition of the 12 determinants to similar constructs identified in the Nadalin Penno et al. (7) review incorporated into the *SITS framework*.

Specifically, the '*Adopters*' construct identified by Nadalin Penno et al. (7) continues to be uniquely categorized and defined as 'users of the innovation', which includes both providers and the consumers in the context in both published reviews (1, 21). For example, *Adopter* constructs comparisons in these two published reviews include: the "Domain: Providers or Users within the Context" (21), and the "Implementors and Population Characteristics Factors" (1). Second, '*Leadership*' commitment or support for the innovation is also grouped separately by both reviews in the literature, either as an attribute within the "Inner Context" (1) or within the "Domain: Internal Arrangement of Context" (21). This finding further corroborates the previous distinction of *Leadership* as a separate context construct noted in the Nadalin Penno et al. (7) review, not evident in a previous concept analysis on healthcare innovation sustainability (23). Third, in the Nadalin Penno et al. (7) review the '*Inner Context*' construct includes internal structural determinants, separate from a '*Inner Processes*' construct which includes established system or network determinants that exist to support the innovation. Similar determinant groupings for these two constructs are evident in both published reviews (1, 21). Lastly, a similar '*Outer Context*' construct is evident across all three reviews (1, 7, 21). Alignment of these 12 context determinants with previous identified determinants (i.e., factors), definitions, and their categorizations in the current literature reviews (1, 21) reinforces their importance for sustainability. It further supports their addition to the 37 determinants identified in the Nadalin Penno et al. (7) review, resulting in a total of 49 (37 + 12) unique sustainability determinants presented in the *SITS* framework (see **Table 4**, and **Figure 1**).

KTIs influencing sustainability in tertiary settings

Comparing 29 unique KTIs with the literature

Comparing the 29 KTIs to the 'themes and approaches' (constructs) identified in a review on the sustainability of approaches in healthcare by Lennox et al. (16) confirmed their inclusion in the *SITS framework*. The aim of the Lennox review was to identify studies that described approaches or strategies used related to sustainability in healthcare, and to describe the different perspective, applications and constructs within the approaches to guide future use by healthcare teams and researchers. The Lennox review included a total sixty-two publications each identifying a sustainability approach (e.g., 32 frameworks, 16 models, 8 tools, 4 strategies, 1 checklist, 1 process). The search included publications between 1989 and Sept 2017, having similar end dates in the systematic review (e.g., July 2018) (7). The majority of approaches (i.e., 37% or 23/62)

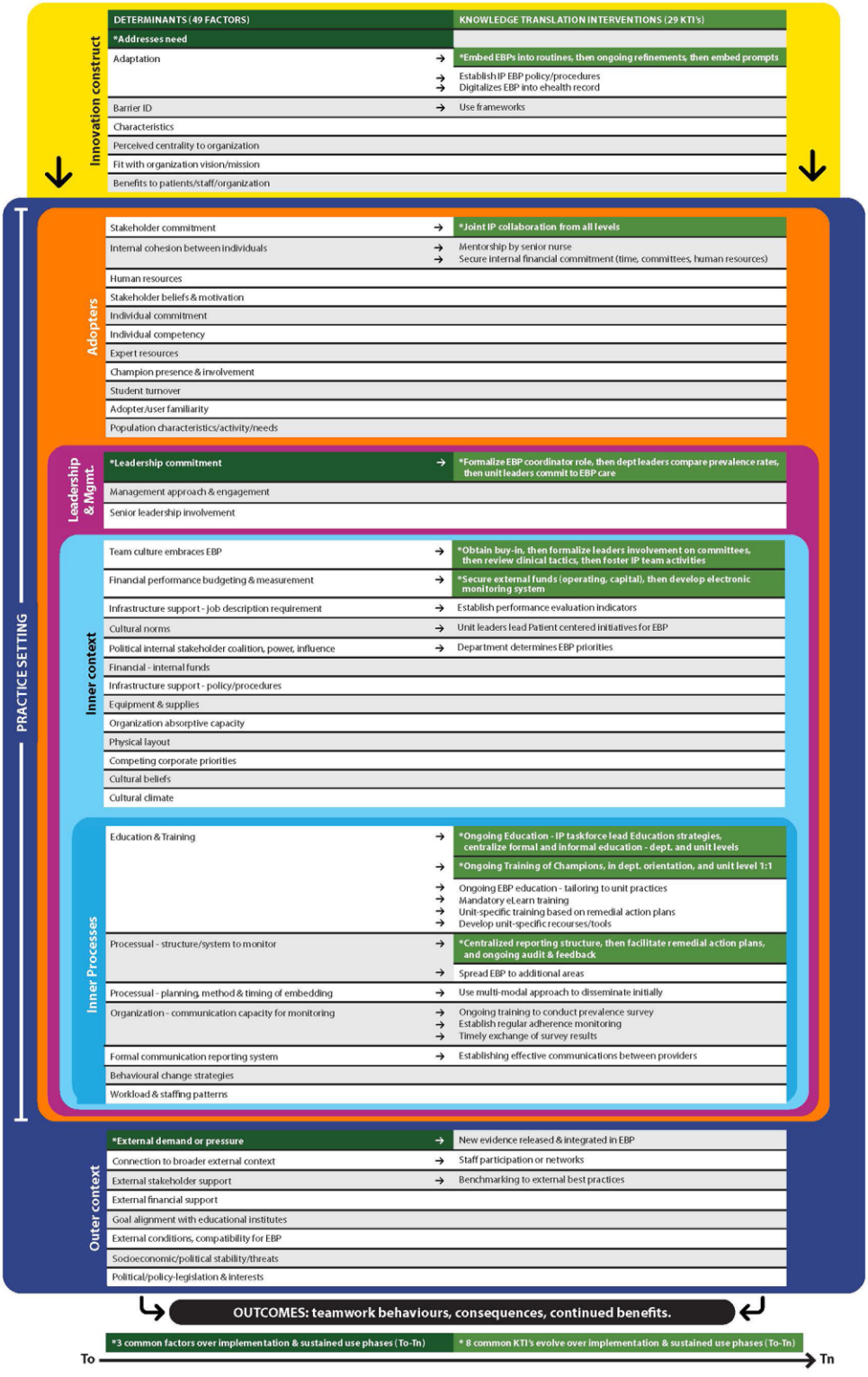

FIGURE 1
Sustaining innovations in tertiary settings (SITS) framework.

were designed for use in general healthcare and did not specify a specific healthcare setting for use. Additionally, 31% (or 19/62) of the approaches were designed for use in public health settings, followed by 26% (or 16/62) of approaches designed for use in community settings. Only 3% (2/62) of the approaches were designed for use in acute care. Constructs across approaches were compared and 40 unique constructs for sustainability were identified. Comparisons across approaches (62) revealed 6

TABLE 4 The sustaining innovations in tertiary settings (SITS) framework.

7 Constructs	49 Unique Sustainability Determinants	29 Unique Sustainability-orientated Knowledge Translation Interventions (KTIs)		
(*N* = 7)	(*N* = 49)	Department Level Implementation Phase KTIs (0–2 years.) (*N* = 8 + 4)	Department Level Sustainability Phase KTIs (>2–10 years.) (*N* = 8 + 14)	Unit Level Sustainability Phase KTIs (at 10 years.) (*N* = 8 + 3)
Innovation *(defined as: new process/change/ product/practice or program, innovation, intervention)*	Relevance/consistent with competitive strategy (addresses **NEED or** problem)✷			
	Adaptability of innovation	⁂Embedding of EBP into existing unit processes	⁂Embed ongoing refinements into existing routine practices/ processes	⁂Routinize recommendations into nursing forms and practices/ processes: embed prompts
				Digitalized EBP and forms into new eHealth record
		Established Interdisciplinary EBP policy/procedure for all disciplines		
	Barrier Identification	**Use frameworks** to guide implementation and identify barriers		
	Characteristics (scale, shape & form, age, nature, type, integrity)			
	Perceived centrality to organizational performance /platform /services			
	Fit with org's vision/mission, procedures/ strategies			
	Benefits to patient, staff, organization (cost effective, efficiency & quality of care)			
Adopters *(defined as: staff, stakeholder, user, adopter, actor, and or individual)*	Stakeholder Commitment to innovation	⁂Joint collaboration of human resources **from all levels of nursing** plus other disciplines to develop departmental implementation plan		⁂Engages IP stakeholder involvement: all professions to follow policy participate on cttees
	Internal cohesion between individual & commitment within the organization /stakeholder engagement leads to increased performance (senior nurse mentors /influencers)			**Mentorship used by senior nurses** to support EBP use:
	Human resources—recruitment, processes, succession and leave planning (staffing/compliment)	**Secure internal financial** commitment—time and Human resources to participate on cttees and to implement KTIs		
	Stakeholder beliefs, attitude, perceptions, emotions, expectations towards innovation and user motivation/resistance			
	Individual commitment to innovation			
	Individual competency (skill knowledge, absorptive capacity) to perform innovation and time management to use innovation			
	expert consultants /resources**			
	Champion presence & involvement			
	Student turnover (medical)**			
	Users awareness / familiarity with innovation**			
	Population characteristic/needs/ acuity level**			
Leadership & Management *(defined as: style, approach,*	**Leadership commitment (dept level)**✷,****	⁂Formalize EBP Coordinator role	⁂ Dept Leaders Comparing survey results among units created a sense of competition among leaders and users to improve	⁂Leadership strategies -Clinical Coordinator- dept level: (support for big issues during shifts)

(*continued*)

TABLE 4 Continued

7 Constructs	49 Unique Sustainability Determinants	29 Unique Sustainability-orientated Knowledge Translation Interventions (KTIs)		
(*N* = 7)	(*N* = 49)	Department Level Implementation Phase KTIs (0–2 years.) (*N* = 8 + 4)	Department Level Sustainability Phase KTIs (>2–10 years.) (*N* = 8 + 14)	Unit Level Sustainability Phase KTIs (at 10 years.) (*N* = 8 + 3)
behaviors, engagement support, or feedback)	Management approach & engagement (commitment unit level)			-Clinical Care Leaders—unit level (get involved in unit level issues to support ongoing improvements) -Unit Managers—unit level (get involved in unit wide issues, help with remedial action plans to reinforce target behaviors, review incidents, encourages education training)
	Senior Leadership involvement & actions			
Inner Context *(defined as: context, practice setting or organization)*	**Team culture embraces innovation****	⁂Obtaining buy-in and Formalize nurse leaders' involvement on Steering Cttee	⁂Corporate level Internal cttees' support ongoing review of clinical tactics support sustained use ie Patient Experience Steering cttee and Accreditation workgroup	⁂Fostering an IP and EBP culture among IP team to support EBP use:
	Financial performance budgeting & measurement	⁂ Secure external funds a)RNAO PBSO—secure operating funds for initial training and resource s to build capacity b)secure capital external financial support—for point of care surveying system	⁂Development of an electronic monitoring system to measure nursing sensitive indicators provide monitoring of EBP adherence	
	Infrastructure support for innovation in job description with mechanism for recognizing achievement—requirement		**Performance Evaluation indicators** for monitoring rt innovation = leaders, managers, and staff	
	Cultural—innovation integrated into Norms (documents, protocols, manuals)		**Unit leaders lead dept and unit level patient centered initiatives for EBP based on unit routine practices**	
	Political internal stakeholder coalition, power, influence		**Depts determine EBP priorities**	
	Financial-internal funds & other non-financial resources of innovation			
	Infrastructure support- Policies & Procedures based on Innovation			
	Infrastructure support-equipment & supplies for innovation (and resources = pamphlets)			
	Organization—Absorptive capacity for innovation			
	physical layout/structure of wards**			
	competing corporate priorities**			
	Cultural—Beliefs, values & perceptions to innovation			
	Cultural—Climate			
Inner Processes *(defined as processes, methods, systems in the inner environment)*	Education & training processes	⁂Pain Council established—Interdisciplinary taskforce leads initial policy development, education strategies and future policy revision	⁂NPP reps develop formal and informal education initiatives at dept and unit level in 2014 initially performed by the Pain Council.	⁂Ongoing Education to support EBP use by NPP and Educators: -education days, -mandatory online modules -updates, refreshers, seminars
		⁂Training/Educating Champions – to be clinical experts on units, with APNs	⁂Trains 170 Unit level expertise to support use of EBP s = Champions, educators, APNs, work across units as clinical resource	⁂Ongoing Training to support EBP use by NPP and Educators: -general hospital orientation, -1 on 1 training, in-services, solve recurrent problems

(*continued*)

TABLE 4 Continued

7 Constructs	49 Unique Sustainability Determinants	29 Unique Sustainability-orientated Knowledge Translation Interventions (KTIs)		
(*N* = 7)	(*N* = 49)	Department Level Implementation Phase KTIs (0–2 years.) (*N* = 8 + 4)	Department Level Sustainability Phase KTIs (>2–10 years.) (*N* = 8 + 14)	Unit Level Sustainability Phase KTIs (at 10 years.) (*N* = 8 + 3)
			Ongoing EBP education support at dept and unit levels becomes tailored overtime i.e., 1 on 1, case studies	
			Mandatory **eLearn training** system	
			Unit specific training of staff provided **based on audit remedial action plans** to improve on related EBP survey indicators	
			Develop unit specific **additional resources/tools** overtime	
	Processual- project structure & system to monitor/manage innovation	⁂Established EBP taskforce/ workgroup in NPP dept—enduring central reporting and monitoring structure for ongoing implementation and evaluation	⁂NPP and Unit Leaders facilitate/lead remedial action plan for under performing units	⁂Monitoring and evaluation: Dept level—ongoing training to do survey Unit level—audit and feedback provided (timely sharing of audit data, focuses biannual audit questions on target behaviors) Unit level—Patient satisfaction survey results shared reviews incidents and develop strategies to prevent them in staff mtgs
			Spread EBP to additional areas	
	Processual—Planning, method, & timing of embedding innovation	Use **multi-modal approach to disseminate**		
	Organization—communication capacity for monitoring (reporting & feedback)		Ongoing biannual **training** of staff **to conduct prevalence survey**	
			NPP Establishes regular performance monitoring: includes results from biannual prevalence audit and internal incident reporting	
			Timely reporting of prevalence survey results led to **course correcting changes**	
	Formal communicating/ reporting systems for client info between practitioners (documented)**			Establishing effective communications between providers, reporting practices—bedside exchange, whiteboards, clipboards
	Behavioural change strategies			
	workload /staffing patterns**			
Outer Context (defined as: external condition, context, system, or environment)	**External pressure/demand (e.g., professional/regulatory bodies, Ministry, funding bodies)✱****		**New evidence released—** Integrating into EBP and ongoing education	
	Connection to broader external context (regional, national, international links)		**## Staff participation on a regional network—**provide access to new research and related outcomes for pain management	
	External Support for innovation from Stakeholders (recognition)		**Benchmarking** to external sources best practices	
	Financial-**external** funds & other non-financial resources of innovation			
	Goal Alignment with external agencies (e.g., Education institutes)**			

(*continued*)

TABLE 4 Continued

7 Constructs	49 Unique Sustainability Determinants	29 Unique Sustainability-orientated Knowledge Translation Interventions (KTIs)		
(*N* = 7)	(*N* = 49)	Department Level Implementation Phase KTIs (0–2 years.) (*N* = 8 + 4)	Department Level Sustainability Phase KTIs (>2–10 years.) (*N* = 8 + 14)	Unit Level Sustainability Phase KTIs (at 10 years.) (*N* = 8 + 3)
	External conditions, compatibility for innovation (consumer demand)			
	Soci-economic political threats, stability			
	Political-Policy, legislation & Interests			
Outcomes (defined as: outcomes, teamwork behaviors, consequences, or continuation of benefits)	No factors explicitly defined in frameworks for this concept			

**12 Sustainability Determinants- additions from the case study (15).
✷3 Common Determinants over three timeframes—Implementation phase (0–2 years), Sustained use phase (2–10 years, and at 10 years).
⁂8 Common KTI over three timeframes—Implementation phase (0–2 years), Sustained use phase (2–10 years, and at 10 years).

constructs that were included in over 75% (47/62) of the approaches regardless of the proposed interventions, setting or level of application. From their findings, Lennox et al. (16) developed a framework entitled, the "Consolidated Framework for Sustainability Constructs in Healthcare" (hereafter Lennox CF), which includes 6 themes and 40 constructs for sustainability. Thus, we compared the KTIs identified in the case study (15) to the 6 themes and 40 constructs identified in the Lennox et al. (16) review. Given the Lennox review (16) is the first review reported in the current literature identifying approaches for the sustainability of innovations in healthcare, we conducted a critical appraisal using the AMSTAR 2 rating tool (24). We determined a moderate to high confidence rating for the results (see **Supplementary Material file S1**).

We present four key considerations influencing the decision to include all 29 KTIs in the *SITS framework*. Details of the comparison of the 29 KTIs with the forty constructs reported in the Lennox CF (16) are presented on **Table 6**. First, the six themes identified in the Lennox CF (16) aligned with six constructs identified in the Nadalin Penno et al. (7) review, with minimal regrouping of the Lennox CF themes. This alignment confirms the applicability and relevance of the six constructs identified in the Nadalin Penno et al. (7) review to map these 29 KTIs to. Second, all 29 KTIs mapped to 17 (out of 40 constructs) constructs identified in the Lennox CF, that were evident in no less than 52%(32 out of 62) and as high as 90% (56 out of 62) approaches included in the Lennox et al. (16) review. Given the studies included in the Lennox review involved a range of settings, a variety of EBPs, and different levels of application, this alignment suggests potential relevance for the 29 KTIs beyond tertiary settings in other contexts, with other innovations, and level of application. Third, the 29 KTIs designed for use by acute care nurses in the case study (15) were not exact matches but rather considered similar in nature and several were grouped under the same construct. For example, 7 (of the 29) KTIs that included some form of ongoing training (e.g., eLearn modules, 1 on 1 training etc.) aligned with the Lennox CF construct entitled 'Training and Capacity Building'. Fourth, only 2 out 62 studies (3%) included in the Lennox et al. (16) review were designed for acute care. Thus, the 29 KTIs identified in the *SITS framework* provide further specificity of KTIs designed for use in tertiary contexts, not evident in the Lennox et al. (16) review. This finding also highlights the need and importance of empirical research to further explicate the specific KTIs for sustainability in tertiary settings for acute clinical practice. Overall, the 29 KTIs included in the *SITS framework* provide further evidence to guide or inform future sustainability approaches and research for acute care.

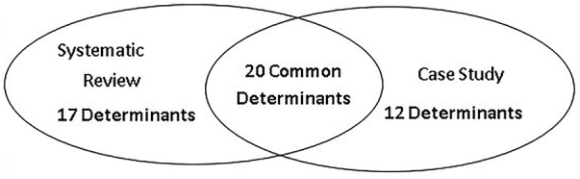

FIGURE 2
Diagram of the 49 unique sustainability determinants for tertiary settings.

Discussion

It is apparent from this research that determinants and KTIs both influence the way in which healthcare innovations are sustained over time in tertiary settings. What really matters is how and what individuals within the departments and units do

TABLE 5 Twelve sustainability determinants mapped to current reviews (1, 21).

12 Sustainability Determinants (Case Study Determinants mapped to Systematic Review Constructs identified in Nadalin Penno et al. (7)	Concept Analysis of "Context" (Squires, Graham et al. 2019) (21)	Emerging Sustainability Factors (themes) (Shelton et al. 2018) (1)
Adopter Construct Determinants: • student turnover (medical) • expert consultants • individual awareness/familiarity with innovation·population characteristics/needs/acuity level	**Domain = Providers within the Context** **Attribute** = People, **Feature** = Staffing composition **Attribute** = People **Feature** = Staffing qualifications & expertise **Attribute** = People **Feature** = Staffing qualifications & expertise **Domain = User of Context** **Attribute** = Patient Population, **Feature** = Patient/client demographics	**Implementor & Population Characteristics Factors** - Provider/implementor characteristics - Implementation expertise - Implementer characteristics - Population characteristics
Leadership & Management Construct Determinants: • leadership commitment (dept level);	**Domain = Internal Arrangement of Context** **Attribute** = Leadership, **Feature** = Active and Formal leadership	**Inner Context Factors** - Leadership/support
Inner Context Construct Determinants: • physical layout • competing internal priorities • team culture embraces innovation	**Domain = Internal Infrastructures/Networks** **Attribute** = Physical Infrastructure, **Feature** = physical structure **Attribute** = Social Infrastructure, **Feature** = formal organizational priorities **Attribute** = Communications & Relationships, **Feature** = Social influence	**Inner Context Factors** - Structural Characteristic - Climate/culture - Climate/culture
Inner Processes Construct Determinants: • workload/staffing patterns • documented communication/ reporting systems;	**Domain = Internal Infrastructure/Networks** **Attribute** = Social Infrastructure, **Feature** = organization of care processes **Attribute** = Communications & Relationships, **Feature** = formal communication	**Processes Factors** - Team Functioning - Communication
Outer Context Construct Determinants: • external pressure/demand from professional/regulatory bodies • goal alignment with external agencies.	**Domain = Broader System related to Context** **Attribute** = Market, **Feature** = competitive pressure **Attribute** = Collaborative Relationship, **Feature** = collaborative practice	**Outer Factors** - Policy and legislation - Values, priorities, needs

that impacts sustainability. It is important to understand the influences underlying the determinants in real world settings and how the focus of the KTIs must adapt and or evolve with the integration of an innovation at different levels of application (e.g., departmental verses unit level use), and over time. With this in mind, the *SITS framework* uniquely pairs or maps sustainability determinants with sustainability-orientated KTIs demonstrating how the focus varies with level of application (e.g., departmental use—across several units at one time, to unit specific level use) and over time (i.e., during implementation and sustained use phases) (see **Table 4** and **Figure 1**). To our knowledge, the *SITS framework* provides the first theory and evidence informed comprehensive list pairing together sustainability determinants and related sustainability-orientated KTIs to guide practitioners and researchers sustain the use of EBPs in tertiary settings over time.

Main observations related to 49 unique sustainability determinants

Seven main observations related to the 49 sustainability determinants influencing sustainability of EBPs in tertiary settings over time within the *SITS framework* include:

(i) Impact of context determinants on sustainment
(ii) Influence of three determinants and constructs over time;
(iii) Similarities among theoretical and empirically derived determinants
(iv) Sustainability and level of application (e.g., department and unit levels)
(v) Potential utility of the twelve determinants beyond tertiary settings
(vi) The influence of academic institutes on sustainability of EBPs
(vii) Collaboration with experts affects sustainability of EBPs

Impact of context determinants on sustainment

Adding the twelve determinants identified in the case study (15) to the 37 in the Nadalin-Penno et al. (7) review, previously derived from eight F/M/Ts related to sustainability of EBPs within acute care contexts, provides further conceptual clarity to the concept and the determinants influencing sustainability, suggested by researchers (1, 14). It also illuminates the importance of considering aspects of 'local context' that promote or inhibit the sustainability of EBPs in healthcare contexts to achieve desired program goals and population outcomes over time, recently purported by researchers (1, 14, 25). For example, the *SITS framework* demonstrates 78% (25 out of 32) of determinants influencing sustainability in tertiary settings lie within four 'context' constructs; namely *Adopters, Leadership &Management, Inner Context, and Inner Processes*. Determinants within these constructs varied among case study participants (15) providing insight into 'why' the sustained use of EBPs varied among department and unit nurses (subcases) within the same organization. Similarly, in a recent study by Shrubsole et al. (26), local internal context and individual (or adopter) determinants were identified as key factors influencing sustained use of an EBP among clinicians working within four

TABLE 6 Integrated KTIs (*N* = 29) compared to Lennox et al, 2018 (16).

Systematic Review 7 constructs	Implementation Phase (0–2 years.) Department Level KTIs: Department RNs	Sustainability Phase (>2–10 years.) Department level KTIs: Department RNs	Sustainability Phase (at 10 years.) Unit level KTIs: Unit RNs	Lennox et al. 2018 Approaches for Sustainability (% = no. of studies using approach/total studies in review)	Lennox et al. 2018 6 Themes
	8 Imp/Sust KTIs + 4 Imp KTIs unique to Department RNs (*n* = 12)	8 Imp/Sust KTIs + 14 Sust KTIs unique to Department RNs (*n* = 22)	8 Imp/Sust KTIs + 3 Sust KTIs unique to Unit RNs (*n* = 11)		
Innovation	**Embedding of Pain P/P****	**Embed ongoing refinements****	embed prompts**	• **Intervention adaptation and receptivity 73% (45/62)**	Initiative Design
			Digitalized Pain P/P and forms	**Integration with existing programs and policies 79% (49/62)**	
	Interdisciplinary Pain P/P established			Integration with existing programs and policies 79% (49/62)	
	Use frameworks to ID barriers to integrate into routine practices			Integration with existing programs and policies 79% (49/62)	
Adopters	**Secure internal financial** commitment—time and Human resources to			**Staff involvement 42%** **Resource Staff 26%** **Resource Time 6%** **74%(46/62)**	The People Involved
			Mentorship by senior nurses	• **Relationships and collaboration and networks 65% (40/62)**	
	Joint collaboration from all levels of nursing plus other disciplines to develop departmental implementation plan**		**Engages IP stakeholder involvement** on cttees**	• **Stakeholder participation 79% (49/62)**	
Leadership & Management	**Formalize BPG Coordinator role** to**	NPP dept leaders **comparing survey results among units** created a sense of competition among unit leaders and users to improve unit**	**Leadership strategies** -Clinical Coordinator—dept level: -Clinical Care Leaders—unit level -Unit Managers—unit level**	• **Leadership and champions 73% (45/62)**	
Inner Context		**Performance Evaluation indicators** for monitoring		• **Accountability of roles and responsibilities 56% (35/62)**	The Organizational Setting
		Unit leaders lead dept and unit level **patient centered initiatives for pain care**		• Defining aims and shared vision 53% (33/62)	
	Obtaining buy-in and Formalize nurse leaders' involvement on Steering Cttee**	**Corporate level Internal cttees' support ongoing review of clinical tactics** support sustained use**	**Fostering an IP and EBP culture** among IP team to support Pain P/P**	• **Organizational values and culture 71% (44/62)**	
		Dept determine EBP priorities		• **Defining aims and shared vision 53% (33/62)**	
	Secure external funds** a)RNAO PBSO—secure operating funds for initial training and resource s to build capacity b)secure capital external financial support—for point of care surveying system	**Development of an electronic monitoring system** to measure nursing sensitive indicators provide monitoring of BPG adherence**		• **Funding 68% (42/62)** • **General resources 90% (56/62)**	The Resources
Inner Processes	**Pain Council established—Interdisciplinary taskforce****	**NPP reps develop formal and informal education** initiatives at dept & unit level in 2014 performed by Pain Council.**	**Ongoing Education** to support Pain P/P use by NPP and Educators:**	• **Training and capacity building 76% (47/62)**	Negotiating Initiative processes and Initiative Delivery
	Training Champions**	**Trains 170 Unit level expertise** = Champions, educators, APNs, work across units**	**Ongoing Training** to support Pain P/P use by NPP and Educators:**	• Training and capacity building 76% (47/62)	
		***Ongoing pain care education** support at dept and unit levels becomes tailored overtime i.e. 1 on 1, case studies		• Training and capacity building 76% (47/62)	

(*continued*)

TABLE 6 Continued

Systematic Review 7 constructs	Implementation Phase (0–2 years.) Department Level KTIs: Department RNs	Sustainability Phase (>2–10 years.) Department level KTIs: Department RNs	Sustainability Phase (at 10 years.) Unit level KTIs: Unit RNs	Lennox et al. 2018 Approaches for Sustainability (% = no. of studies using approach/total studies in review)	Lennox et al. 2018 6 Themes
	8 Imp/Sust KTIs + 4 Imp KTIs unique to Department RNs ($n = 12$)	8 Imp/Sust KTIs + 14 Sust KTIs unique to Department RNs ($n = 22$)	8 Imp/Sust KTIs + 3 Sust KTIs unique to Unit RNs ($n = 11$)		
		*Mandatory **eLearn training** system		• Training and capacity building 76% (47/62)	
		***Unit specific training** of staff provided **based on audit remedial action plans** to improve			
		Develop unit specific **additional resources/tools** overtime		• General resources 90% (56/62)	
	Use **multi-modal approach to disseminate**			• Training and capacity building 76% (47/62)	
		Spread EBP to additional areas		• Training and capacity building 76% (47/62)	
	Established Pain BPG taskforce/workgroup in NPP dept –**	**NPP and Unit Leaders facilitate/lead remedial action plan for under performing units****	**Monitoring and evaluation:** Dept level - ongoing training to do survey Unit level - audit and feedback Unit level - Patient satisfaction survey results shared**	■ **Monitoring progress overtime 84% (52/62)**	
		Ongoing biannual staff **training to conduct prevalence survey**		■ Monitoring progress overtime 84% (52/62)	
		NPP Establishes regular performance monitoring:		■ Monitoring progress overtime 84% (52/62)	
		Timely reporting of prevalence survey results led to **course correcting changes**		■ Monitoring progress overtime 84% (52/62)	
			Establishing effective communications between providers,	• Relationships and collaboration and networks 65% (40/62)	
Outer Context		**New evidence released—** integrate into BPG		• **Evidence base for the initiative 52% (32/62)**	The External Environment
		Staff participation on a regional network		• **Community participation 56% (35/62)**	
		Benchmarking to external sources best practices		• Evidence base for the initiative 52% (32/62)	
Outcomes					

**8 Common KTIs across Implementation (Imp) (0–2 years.) and Sustained use phases (Sust) (>2–10 years. and at 10 years.)

different hospitals. These findings highlight the need to focus on the specific unit-level 'context' determinants influencing practice use (or not) before developing or choosing KTIs meant to integrate the EBP recommendations into routine practice, suggested by Lennox (16). Overall, the *SITS framework* further clarifies for practitioners and researchers what internal and external contextual determinants potentially influence the sustainability of healthcare EBPs in real-world tertiary settings, such as hospitals. In summary, understanding context does matter for sustainability of EBPs in acute clinical practice within tertiary settings!

Influence of three determinants and constructs over time

Three determinants identified in the case study (15) during the implementation use phase (0–2 years.) were identified as having an influence during the sustained use phases (i.e., >2–10 years., at 10 years.). They include: *need* for the innovation; *leadership commitment*; and *external demand or pressure* for the innovation. These three determinants are also evident in the Nadalin Penno et al. (7) review. This finding demonstrates the potential impact of these determinants during both the implementation and sustained use phases of an innovation in tertiary settings,

suggested in the literature (7, 10, 27). Furthermore, the three determinants span three different constructs: the *Innovation*, *Leadership & Management*, and *Outer Context* respectively. Case study (15) findings revealed how KTIs efforts were adapted over time to improve adherence to the innovation (e.g., Pain BPG recommendations) with their level of application (e.g., department verses unit) triggered by the focus of the adopters/users. Thus, researchers and practitioners should be mindful of how the underlying constructs change or evolve over time and the impact on these three determinants for two reasons: (1) to gain a better understanding of determinants that may potentially influence healthcare innovation sustainability during both the implementation and sustained use phases, and (2) to inform how to best tailor KTI efforts for sustainability previously suggested in the literature (2, 17).

Similarities among theoretical and empirically derived determinants

Comparing determinants between the data sources revealed 68% (11 out of 16) alignment between those determinants identified as 'common'; occurring in more than 4 F/M/Ts in the Nadalin Penno et al. (7) review, and those identified in the case study (15). This finding demonstrates that not all theoretically nor empirically derived determinants occur in similar settings. There is a need for further empirical investigation of the barriers and facilitators influencing sustainability within tertiary settings to refine the *SITS framework*. This finding demonstrates the importance of empirical research to build comprehensive theorical frameworks to guide practitioners and researchers in clinical practice, suggested by other researchers (4, 5, 10) and sustainability framework authors (7).

Sustainability determinants and level of application

The *SITS framework* contains sustainability determinants derived from both departmental and unit level nurses (i.e., level of application), a perspective not made explicit among known theoretical conceptualizations for sustainability.

Similarities

Two determinants reported among case study department and unit level nurses highlight the importance of 'building capacity for an innovation through (i) *stakeholder motivation and commitment* to the innovation', and (ii) '*leadership engagement at all levels*' within the organization to promote sustainability over time (15). These empirical findings align with those identified in the systematic review (7), wherein the majority of F/M/Ts (5 or more) identified adopters (or individuals, stakeholders) *belief in* and *commitment towards* the innovation, and *leadership and management commitment at all levels* (e.g., Board, department, and unit level) as key determinants influencing sustainability. Furthermore, facilitating determinants, such as the positional influence of leaders who impart the value of the change to decision makers, and the network of support and or commitment provided by a range of stakeholders, reportedly influenced whether an innovation was sustained in practice in previous studies (28, 29). Case study findings also reinforced the shared commitment of all stakeholders, including leaders', across the organization to prioritize the innovation (e.g., EB care) contributed to a sustainability-promoting culture of shared accountability, also evident in previous studies (19, 29–34).

Differences

Differences identified by case study participants (15) reflected a viewpoint based on their respective roles and responsibilities related to the innovation. For example, determinants identified by department level nurses focused mainly on organizational-wide (*Inner Context*) and *Outer Context* influences, while determinants identified by unit nurses revealed their focus on the use of the *Innovation* at the clinical practice level with *Adopters*, within the *Inner Context*, and related *Inner Process* influences.

Specifically, department level or organizational-wide influences impacting sustainability of EPBs over time included: (i) *internal competing priorities* such as infection control rates, (ii) higher-level human resource concerns related to the *complement of nursing staff on units*, and (iii) the *frequent turnover of medical students* (e.g., clinical placement rotation changes). The following 'Outer Context' determinants affected sustainability over time: (iv) *goal alignment* for the innovation with education partners, (v) maintaining *connections with related networks*, (vi) *external pressure or demand* from accrediting, government and regulatory bodies, (vii) *external support or recognition* for their efforts from external stakeholders (e.g., Registered Nurses of Ontario)(RNAO) (15), and (viii) *compatibility of the innovation to meet consumer demand*. These departmental determinants reveal an 'outward focus' and insight into organizational-wide roles and responsibilities that positions department level nurse leaders "to act as conduits, linking outer and inner contextual influences" to ensure sustainability of the innovation over time in an ever-changing acute healthcare environment. Notably, leadership is identified in a previous study wherein the mid-level management role is described as being critical to enacting a tie between the unit level leaders and point of care (29). This finding highlights the importance of a separate construct for '*Leadership and Management*' in the *SITS framework* for sustainment within tertiary contexts.

The nineteen sustainability determinants identified by unit nurses in the case study (15) instead, reflected an individual and internal perspective, focused mainly on the 'innovation' and nurses' use of it within their unit. In essence, these determinants illuminate nurses' daily clinical practice' viewpoint. These nineteen determinants aligned with the *Innovation, Adopter, Inner Context, Inner Process* constructs in the *SITS framework* (see **Table 4** and **Figure 1**).

Innovation Determinants: First and foremost, case study unit level nurses reported *perceived innovation benefit* to patients/family and or staff was important for sustainability of the EBP (15). This '*Innovation*' determinant was identified in 5 F/M/Ts in the systematic review (7), and aligns with a recent study where hospital unit level hospital-based nurses previously reported continued benefits as an essential innovation characteristic for sustainability of BPGs (35).

Adopter Determinants. Four out of the seven '*Adopter*' determinants identified by unit nurses, aligned with sustainability determinants identified in the systematic review (7). They include (i) *stakeholder commitment* towards the innovation, (ii) *individual commitment* to the innovation, *(iii) individual competency* to perform the innovation, and (iv) the *internal cohesion* between individuals leads to increased performance. The following three out of the seven '*Adopter*' determinants added to those previously identified in the systematic review (7): (v) *population characteristics* related to the use of the innovation, (vi) *user awareness and or familiarity* with the innovation, and (vii) the presence of *expert consultants*. Unit nurses reported *patient* (population) *characteristics*, such as their preferences or acuity level, influenced their use of the EBP (15). Patient involvement was identified in the recent review by Lennox et al. (16) in 16% (10 out of 62) of studies to influence sustained use of EBPs in clinical practice. A recent concept analysis on context related to research utilization in practice identified *expertise of providers* within the context as a key feature (21). In a recent review by Cowie et al. (14) that identified barriers and facilitators influencing sustainability of hospital based interventions, having the appropriate expertise and knowledge in order to deliver the innovation was identified in 44% (14 out of 32) of studies, and engaging all persons with innovation expertise was identified as a major facilitating factor underpinning sustainability in 47% (15 out of 32) of studies. Unit nurses also reported that education initiatives (e.g., mandatory eLearn modules, general hospital orientation, annual pain education days) offered to them supported the training of new nurses and updated *nurses' awareness* of policy refinements. These findings substantiate the importance of having an infrastructure that supports *user awareness and or familiarity* to perform the innovation suggested in the literature (2, 14, 36).

Additionally, in the case study unit nurses either reported the *internal cohesion between individuals* [e.g., senior nurse mentors, interprofessional team (IP) members], or *stakeholders' commitment* (e.g., formal clinical leader) facilitated their daily use of the Pain BPG recommendations (15). This finding reflects the unique difference observed regarding leadership support between the units. However, whether there is formal (managers) or informal (mentors and interprofessional team members) leadership support at the unit level, it is important to recognize the linkages and interactions between and attributes of these key individuals (e.g., managers, mentors) are important for sustainability among unit level nurses in tertiary settings. This highlights that EBP sustainability in nursing practice is often dependent on linkages between the persons (*Adopters*) and clinical processes and practices within the network of care it is situated in which has been identified in a previous study (35).

Inner Context Determinants. Unit nurses indicated seven '*Inner Context*' determinants influenced their use of the EBP. Five out of seven align with determinants identified in the systematic review (7). They included: having infrastructure supports for the innovations such as (i) *policies,* (ii) *equipment and supplies* (e.g., pumps), (iii) *shared cultural beliefs and or perceptions* towards the innovation (e.g., EB care), (iv) a *climate* that facilitated the EB care, and (v) a *culture that integrates the innovation into context norms* (documents, protocols, manuals). The remaining two '*Inner Context*' determinants add to those identified in the systematic review (7): (vi) *the physical layout* of unit - between two floors, and (vii) having *a team culture* that embraced the innovation. These '*Inner Context*' determinants further demonstrate that infrastructure supports and promoting a culture that embraces the innovation are needed to for successful sustainability of EBPs in clinical practice, reported by Lennox et al. (16), Shelton et al. (1), and Squires et al. (21).

Inner Process Determinants. Unit nurses indicated four '*Inner Process*' determinants influenced their sustained use of the EBP (15). Two that align with determinants in the systematic review (7) include: (i) having a *plan, method and schedule* to integrate the innovation and any updates or revisions into routine practices, and (ii) having *established communication system* to provide audit and feedback on adherence rates to EBP recommendations, and reporting processes for remedial plans. The remaining two '*Inner Process*' determinants added to those in the systematic review (7): (iii) establishing *formal communication or reporting systems* to share innovation related patient information between practitioners (e.g., verbal shift reports) and between patients (e.g., in room care boards), and *(iv) workload or staffing patterns. 'Inner Process'* determinants consisted of both formal (e.g., prevalence survey) and informal (e.g., verbal reports, care boards) systems. Establishing a means to monitor the long-term progress of the hospital-based innovations was identified in 59%(19 out of 32) of studies as one of the most frequently reported facilitating determinant for the sustainability of hospital-based innovations over time (14). Similar consistent reinforcement and feedback on maintaining EBPs provided to unit nurses by clinical leaders contributed to a sustainability-promoting culture of hospital-based innovations in other studies (29, 35).

Potential utility of the twelve determinants beyond tertiary settings

In the Squires et al. (21) review and concept analysis of context, they set out to examine the domains, attributes and features of context influencing research use (i.e., EBPs) among healthcare professionals. Seventy publications were included in the review and sources included several theories, models, tools, and studies from a variety of healthcare settings and countries, including a variety of EBPs, and different levels of application. A "Framework for Context" was developed comprised of 6 domains, 21 attributes and 89 unique features of the attributes, irrespective of setting, type of clinical EBPs, or professional roles (e.g., nurse, other healthcare team members) supporting a broader utility (21). Similarly, factors identified in the Shelton et al. (1) review included those from multiple settings and contexts, informed by the current evidence base (1). The twelve determinants reported by nurses in the case study (15) are similar to those identified in the two current reviews, potentially extending the utility of the twelve sustainability determinants in the *SITS framework* to other settings (1, 21), healthcare team members and EBPs (21).

Influence of academic institutions on innovation sustained use

The following observation is based on two (out of the twelve) determinants reported by nurses in the case study that influenced their use of the EBP in clinical practice: (i) *medical student turnover,* and (ii) *shared vision or goal alignment* (15). Partnerships are often established between healthcare agencies and educational institutions based on shared goals (e.g., provide EB care) and to facilitate medical student clinical placements, internships or residencies. It is not uncommon to expect medical trainees to implement EBPs. Case study nurses also reported frequent *medical resident team rotation changes* inhibited the sustained use of the EBPs on their units (15). As a result, EBP training offered during general hospital orientation and to students (all types) was required. This included completing mandatory eLearn modules to ensure congruence with the established Pain protocol or policy. These two context determinants are also identified in a current review (21) to influence the use of EBPs in clinical practice, reinforcing their importance for sustainment in complex ever-changing in acute care environments.

Collaboration with experts affects sustainability

Case study nurses reported having access to available '*expert consultants*' on their unit supported their ongoing use of EBPs ten years post-implementation (15). With increasing complexity and acuity of acute inpatients care, management of patient outcomes often requires collaboration and interdependence of various disciplines, such as nurse champions, physicians, and specialty services such as acute pain service (APS) team. Over ten years, case study findings revealed 170 BPG nurse champions were educated and trained to provide unit level expertise on guideline use to unit team members (15). They also formalized two advanced pain management teams: acute and palliative care services, which physicians and nurses could access when needed, to support advanced pain management needs (15). Expert consultants is identified as an attribute in the two recent reviews either as "staff expertise" (21) or "implementor expertise" (1) and is evident in previous studies (9, 35, 37, 38). Others have also observed that engaging *supportive multiple stakeholders* in clinical processes with 'identified roles' such as *experts*, promotes ongoing use of healthcare innovations in clinical practice (16). Having expert consultants at the unit level reinforces the conclusion noted in previous studies, that nurses work is part of a larger network of interprofessional collaborative care, including experts, that ultimately can affect sustainability of EBPs (35, 39). Thus, this determinant provides further evidence collaboration among experts and other practitioners is often necessary to promote sustainabiltiy of EBPs in tertiary settings.

Main observations related to 29 sustainability-orientated KTIs

We present seven main observations related to the 29 KTIs included in the *SITS framework* that effectively fostered change behaviors and facilitated sustainability of an EBP in tertiary setting over time. They include:

(i) Eight KTIs had continuous impact on sustainability;
(ii) Providing timely reporting and feedback promoted sustained use;
(iii) Using an incremental approach to address adherence
(iv) Using a user participatory approach influenced adherence;
(v) Monitoring adherence promoted accountability and built capacity for EB care;
(vi) Creating leadership accountability for EBP outcomes;
(vii) Unit informal practices or processes may unknowingly influence adherence measurement.

Eight KTIs had continuous impact on sustainability

In the case study, eight (out of 29) KTIs had a continuous impact during the implementation use phase (0–2 years) and sustained use phases (e.g., >2–10 years., at 10 years post implementation (15).These eight KTIs provide insight into how the focus of the KTIs evolved over time with the change in level of application (e.g., department-across units verses unit specific use) to fit within the context. This novel finding is important to consider when designing KTIs to be used in an ever-changing healthcare setting such as a hospital. To this end, the linking or tailoring of KTIs to promote, address, or overcome the identified determinants aimed at sustaining EBPs, such as BPGs, during the dynamic ongoing sustainability phase is a necessary step. The added value or effectiveness of tailoring KTIs over time to support the integration of the innovation into routine practices or processes (local context), previously identified as an implementation strategy to overcome barriers to change (40, 41), now adds to sustainability knowledge. Notably, the eight multi-layered KTIs used by departmental and unit level participants in the case study (15) to integrate the EBP into routine practices and over time facilitated sustainability. This finding exemplifies how the agents/actors, strategies, and changing contexts are interrelated suggested by Mielke et al. (25) in a recent study examining the successful and sustainable implementation of complex innovations or interventions in dynamic contexts. Findings also add credence to the conceptualization that sustainability of healthcare innovations in clinical practice is as an "*ongoing dynamic process*" suggested in the systematic review (7), evident in existing sustainability frameworks (19, 23, 33, 42, 43), and the literature (14, 25, 44).

Providing timely reporting and feedback

The *timely reporting and feedback* of performance data (e.g., prevalence survey, patient satisfaction results) to clinical leaders and unit nurses and comparing of results among units created 'a sense of competition' that spurred a chain of activities to improve (15). Specifically, ongoing changes in measurement activities became more focused and sophisticated to target selected EBP recommendation behaviours. Additionally, establishing a point of care *monitoring system* that provided *regular reports on adherence rates* to EBP recommendations produced the necessary data critical to determine remedial action

plans (a *feedback mechanism*) for the sustained use of the EBPs at the unit level (i.e., local context) (15). These KTIs are congruent with evidence in the literature pertaining to both phases. Specifically, studies have previously identified *audit and feedback strategies* (i.e., KTIs) effectively contribute to the uptake of EBPs during the implementation phase(Powell et al., 2015) and the sustained use phase (16) in clinical practice. Fleiszer et al. (35) also reports *regular feedback on BPG audit results* reinforced expectations and promoted sustained use of BPGs among nurses in a tertiary setting (hospital).

Using an incremental approach to address adherence

The *use of an incremental approach* to influence adherence to EBP recommendations shifted the focus and design of KTIs over time (15). For example, KTI efforts in the case study during implementation (0–2 years.) were focused on integrating recommendations into existing organizational-wide documentation and orientation processes and practices. However, during the sustained use phase, the linking of KTIs to targeted behaviors (i.e., focusing efforts on one recommendation at a time) at the department level over time (i.e., *an incremental approach*) while subsequently designing KTIs to address unit specific level low adherence rates (i.e., adapting KTIs to unit specific routines, practices, and processes) promoted sustainability (15). This change reflects the realization that it is impossible for an organization to obtain high adherence to all BPG recommendations, on all units, at the same time. The integration and adaptation of the innovation into existing organizational programs and policies (i.e., routine practices and processes) at the department and unit levels was identified as key KTIs or approaches in the Lennox et al. (16) review, in 79% and 73% of studies respectively, regardless of the innovation, or setting. The ongoing use of these eight KTI demonstrates how innovation integration and adaption is also necessary for sustainability of EBPs in tertiary settings, adding to the existing knowledge.

Use of a user participatory approach facilitates sustainability

The use of a *user participatory approach* to engage leaders and users in the development of KTIs to enhance adherence to EBPs facilitated sustainability in the case study (15). For example, at the department level, engaging users on EBP committees and or taskforces initially mandated to develop a multi-modal approach to disseminate EBPs, and later to monitor guideline adherence rates and related patient outcomes, reportedly promoted commitment to Pain BPG and its sustained use over time. At the unit level, the use of a participatory approach encouraged unit nurses and other team members to collectively develop and tailor KTIs (i.e., remedial plans) to address low adherence rates to selected target behaviors (15). Promoting a '*user participatory approach*' as a means to promote guideline use, also evident in the literature (45, 46), seems to be an effective means for EBP sustainability beyond the implementation phase. These findings confirm the notion that to produce real-world change over time there is a "need to consider staff and system domains as active components in the change process rather than imposing change" (45) for sustainability.

Monitoring adherence promoted accountability and built capacity for EB care

Case study participants reported the combined training of nurses to be surveyors to conduct the biannual audits (e.g., monitoring) served to increase their accountability towards sustaining EBPs in clinical practice while building their capacity for EBP use within their setting (15). Fleiszer et al. (35) also reports using nurses as auditors served to strengthen accountability. Training is identified as a key KTI in sustainability of healthcare innovations by several researchers (14, 16, 19, 47, 48). In the Lennox et al. (16) review, monitoring progress using a standardized mechanism, such as a prevalence survey, was identified in 84% (52 out of 62) of approaches as a key strategy for the sustainability of innovations in healthcare. In a recent review by Lynn et al. (18), measuring EBP recommendations at multiple time points is necessary to adjust for the adaptation of the EBPs, changes within the local context, and determining continued benefits on patient outcomes over time. Thus, the combination of KTIs (e.g., training and monitoring) should be an important consideration for sustained use of EBPs among unit level nurses in changing tertiary settings.

Creating leadership accountability for EBP outcomes

The inclusion of an EBP-related performance criterion into the performance evaluation system of leaders, had a trickled down impact on frontline staff performance expectations, critical to the process of change, creating an institutional system that held leadership and users accountable (i.e., responsibility for one's actions and to answer to someone with more authority) for the sustained use of EBPs (15) at both levels (organizational and unit). This KTI focused on obtaining shared accountability (e.g., getting buy-in) among stakeholders to deliver the innovation (e.g., Pain BPG) in support of the organization's vision for EB care. The use of an EBP criterion for individual performance evaluation is not explicitly identified as a KTI in a recent review of sustainability approaches, rather the literature suggests "incentives" and or "job requirements" are necessary for sustainability of EBPs (16). Thus, the EBP performance criterion exemplifies how to design a KTI for use in tertiary settings to promote use of EBPs in clinical practice. This KTI is congruent with other studies wherein point of care nursing leaders promoted shared accountability by reinforcing the expectation of EB care as the practice standard on their units using multiple strategies, one of which included evaluating performance (29, 35).

Unit informal practices or processes may unknowingly influence adherence measurement

The assumption case study nurses were not carrying out EBP recommendations could not be drawn solely based on the low adherence rates derived from the audited results (15). In fact, reported unit level practices and processes related to EBP

recommendations not recorded in the health record (e.g., use of clipboards, whiteboards, and verbal reports) provided insight into low adherence rates (15). The accuracy of nursing documentation among acute care nurses has been studied in similar acute care settings (49–51). Doran (51) and Paans (49, 50) have reported low rates or scores related to the accuracy of nursing intervention documentation. Doran et al. (51) further indicated that nurses' documented 'assessments of patient status' more frequently than the 'nursing interventions they were preforming'. Examination at point of care is needed to determine whether low adherence rates are due in part to a lack of accurate documentation. If so, effective KTIs to enhance or formalize documentation are required. More recently, the literature suggests it is important to routinely monitor KTIs such as these that facilitate or inhibit sustainability of EBP in acute care contexts (14). This is an important consideration for healthcare innovation sustainability given similar informal processes and or practices are likely common in many similar healthcare settings and not part of the formal documentation system.

Implications

Nursing leadership and practice implications

The implementation and sustainability of EBPs is a complex process. It requires the continued commitment and efforts of multiple supportive stakeholders across the organization from Board to unit level individuals. Establishing and supporting structural processes (e.g., systems to monitor the innovation) and infrastructure supports (e.g., policies, procedures, human resources) seems necessary to build capacity and a culture of shared accountability for the outcomes of sustaining the use of EBPs across the organization. Using a participatory approach to engage users of EBPs to participate on related committees and taskforces to support ongoing review of clinical tactics also facilitates buy-in promoting sustainability. Providing ongoing education and training at the organizational-wide (e.g., orientation sessions, education days) and unit level (e.g., one on one training, in-services) are needed to build capacity as well. Establishing an audit and feedback system that uses an incremental approach to guide ongoing efforts to address low adherence over time should also be considered. Finally, establishing an institutional system that reinforces leadership's commitment to sustaining EBPs, such as the use of a performance criterion or a requirement to report the impact of the use of the EBPs on patient outcomes as part of the organization's quality reporting system, promotes healthcare innovation sustainability.

Clinical practice level considerations for sustainment

Unit leader considerations

To achieve sustained use of EBPs at the point of care it is important to realize sustainability is dependant on the unit's team-wide efforts, not just an individual unit nurse's adherence to guidelines. Sustaining EBPs can be maximized if unit leaders maintain a unit-wide perspective on how recommendations are being integrated into daily routines, processes and practices. Unit level leaders (e.g., managers, champions, educators) should adopt strategies that promote use of EBP recommendations in regular and responsive ways to support ongoing use. For example, utilizing daily interprofessional patient rounds to discuss EBP related clinical management issues. Additionally, given conditions underlying sustainability determinants change over time, leaders also need to focus on establishing strategies that build capacity and accountability among Interprofessional (IP) team members to ensure sustained use. For example, establishing unit specific EBP priorities for monitoring, evaluation and collaborating with unit teams on developing remedial KTIs to address low adherence, and or to set benchmarks builds capacity. Encouraging unit nurses to participate in regular monitoring and evaluative processes (e.g., audits), on units not their own builds capacity and fosters accountability for EB care, promoting sustainability. Conclusively, unit leaders' efforts should focus on promoting a 'culture of shared accountability' for the ongoing use of EBPs among all team members to enhance sustainability at the practice level.

Unit nurse considerations

Unit nurses should be encouraged to participate in the establishment and ongoing revisions of EBP polices or protocols and determining the measurable indicators for each recommendation to be surveyed. Engaging unit nurses to identify established processes and practices related to EBP recommendations on their units and how to best to integrate *prompts* will promote sustained use. Attention to established informal practices and processes related to EBP recommendations that are not documented in the health record can provide insight into low adherence rates and provide a focus for how best to design KTIs that promote formal documentation of nurses' ongoing point of care related intervention efforts. Given increasing complexity, patient acuity levels, workloads, and time barriers in tertiary settings, it is imperative KTIs related to documenting recommendation efforts are flexible and motivational for nurses to carry out. Use of frameworks by unit nurses to identify barriers to guide sustainability efforts such as developing course correcting KTIs designed to incrementally address low adherence rates (e.g., tailoring of KTIs) facilitates sustained use. Encouraging unit nurses to participate in ongoing EBP education and training to become champions to provide expertise at the unit level is necessary to maintain awareness of refinements and new evidence at the unit level over time. Training unit nurses and IP team members to be surveyors to conduct the EBP prevalence audits promotes increased accountability towards sustaining EBPs in clinical practice while building their capacity for EB care within the setting.

Moreover, these ongoing internal efforts to improve patient outcomes that target collaboration among leaders, unit nurses, and IP team members for evidence-based care promotes sustained use of EBPs in acute clinical practice in tertiary settings. In short, sustainability depends on the linkages, shared

actions, and social influence of teams among unit leaders at the department and unit level, along with the nurses and IP team members at the point of care.

Strength and limitations

To our knowledge this is the first framework that pairs determinants, whether a facilitator or barrier to promote the sustained use of an EBP over time, to related KTIs for use in tertiary settings adding to the current knowledge. Sustainability determinants and related KTIs were derived from the synthesis and comprehensive analysis of healthcare sustainability F/M/Ts (7) and an in-depth, theory informed empirical study (15) which focused primarily on sustainability of an EBP in an acute care context. The resultant *SITS framework*, consists of seven sustainability constructs, forty-nine unique determinants, and twenty-nine unique KTIs primarily related to tertiary settings (see **Figure 1**). Novel insights are presented regarding the relationship between determinants, their level of application (i.e., organizational wide vs. unit level) and 'how' the focus of the related KTIs must evolve over time to resolve the fit between the EBP and the changing context during both phases. The eight KTIs identified that continuously impacted the sustainability of an EBP over time are important to consider when designing KTIs to be used in ever-changing healthcare settings. *The SITS framework* further confirms that healthcare innovation sustainability is an "ongoing phase" that occurs post the initial implementation use phase (beyond 0–2 years). Moreover, the *SITS framework* can be used as a practical guide or check list for those planning or currently implementing EBPs.

There are limitations to consider when using the *SITS framework*. First, the systematic review and theory analysis included sustainability F/M/Ts published by July 2018, and was restricted to four key databases, known to focus on healthcare and or implementation science. Thus, F/M/Ts from social science and management literature may have been missed. Second, the focus on one BPG, within one multi-site healthcare organization, from solely a nursing perspective is a limitation. However, unlike other BPGs, the Pain BPG was uniquely implemented across all inpatient units which we believe would have broad application to a variety of nursing environments, and results would serve to advance knowledge on the long-term sustainability of nursing BPGs. The applicability and refinement of the *SITS Framework* among other healthcare settings is recommended. Third, this research was not focused on differentiating the level of application related to findings, further clarification is needed. Instead, the design focused on having department and unit level nurses identify the unique sustainability constructs, determinants, and KTIs that effectively influenced sustained use of an EBP in their tertiary setting across all units over time and at the unit level at the ten year timeframe. Lastly, another limitation is the 'Outcome' construct remains underdeveloped in part due to the focus on a single practice guideline; the internal and external pressures unique to the Pain BPG; and the lack of evidence focused on this construct to date.

Future directions for sustainability research

Sustainability is an evolving field of research within implemenatation science. Understanding and measuring how sustainability research efforts can enhance progress towards improved patient outcomes is critical. To advance sustainability knowledge future inquiry should focus on the following the following five directions. First, further investigation in multiple tertiary settings is required to provide additional empirical evidence, to refine the *SITS framework* constructs and determinants, to inform the pairing of determinants and related sustainability KTIs or approaches, and to confirm generalization. Second, one of the eight KTIs identified as having an impact on sustained use of an EBP over time (e.g., use of prompts in formal documentation) should be selected to inform the design of an intervention study to explore applicability and further framework refinement. Third, future research is needed to further clarify and differentiate how a similar KTI is used by the different level actors and their role at the different level of application (organizational verses unit) to refine the *SITS framework*. Fourth, to understand the impact of implementation on sustainability of healthcare innovations, an examination of F/M/Ts containing both implementation and sustainability constructs and determinants for tertiary settings should be undertaken using a similar theory analysis approach (52). Results could then be compared to the *SITS framework* and interpretations made regarding potential overlap and or impact of implementation on sustainability, and further substantiate insights revealed in the *SITS framework*. Fifth, to inform the Outcome construct in the *SITS framework*, further examination is recommended to explicitly identify related sustainability indicators, previously supported in the literature by framework authors (19, 23, 34, 42) and researchers (1, 7). Focus should be on determining the level of influence or impact of an EBP on specified outcomes or type of outcomes (e.g., service or patient outcomes) post implementation (e.g., >2 years.), at any one of the four levels of change (e.g., individual, team or department, organization-wide, or system level) identified by Proctor et al. (27). Much remains to be learnt about this complex concept of sustainability. More focus is needed to understand the dynamic interactions between and among determinants across a variety of contexts and to evaluate planned KTIs to support the sustainability of healthcare innovations in real-world settings over time.

Conclusion

How *SITS framework* contributes to current knowledge

The *SITS framework* consists of seven sustainability constructs, forty-nine unique determinants, and twenty-nine unique related KTIs necessary to sustain EBPs in tertiary settings. It provides further conceptual clarity, and corroborates the recommendation

by researchers (7, 14) that sustainability is a dynamic process or phase to add to the current sustainability definition by Moore et al. (3). The *SITS framework*, as a novel resource, has practical implications for researchers, practitioners and administrators when designing, implementing and sustaining healthcare innovations, such as EBPs, for clinical practice in tertiary contexts. The majority of the forty-nine sustainability determinants identified are within the 5 'context' constructs, providing insight into "*why*" the sustained use of EBPs may vary among units and departments within the same or different setting. It also highlights the need to focus on the specific unit level contextual determinants influencing use (or not) before developing or choosing KTIs or approaches to effectively embed an EBP into routine practice if one expects to sustain its use over time. Additionally, the three key determinants identified as having a continuous influence during both the implementation and sustained use phases: a *need* for an innovation (e.g., EBP), *leadership commitment*, and *external demand or pressure* for the innovation, are important considerations for sustained use of EBPs in tertiary settings. Moreover, practitioners and researchers not only need to be mindful of the relationship between or among determinants, but the underlying conditions influencing determinants within the constructs over time for sustainability of healthcare innovations to prevail.

More importantly, the *SITS framework* highlights sustainability of EBPs in clinical practice does not rest solely on identifying the determinants influencing use, but "*how*" one manages the determinants over time matters. Specifically, determinant identification is only part of the equation for healthcare innovation sustainability, developing effective KTIs to improve nursing practice and related patient outcomes is the other critical part. Linking and tailoring of KTIs to promote, address, or overcome the identified determinants aimed at sustaining EBPs during the dynamic ongoing sustainability phase is a necessary step. Twenty-nine KTIs promoted sustained use of the EBP in tertiary settings, eight KTIs had a continuous impact during implementation phase (0–2 years), the sustained use phases (>2–10 years, at 10 years). The eight KTIs provided insight into "*how*" the focus of the KTIs evolved over time with the change in level of application (e.g., across units or departmental verses unit specific application) to fit within the local context. This is important to consider when designing KTIs to be used in an ever-changing acute healthcare context.

Together determinants and KTIs, undoubtingly do influence the way in which healthcare innovations are sustained. It is important to understand the influences underlying the determinants in real world settings and how the focus of the KTIs must evolve with the integration of an innovation at different levels of application and over time. Given healthcare innovation sustainability is a 'process' or 'ongoing stage', what really matters is "how" and "what" the organization does to sustain the innovation at all levels over time within ever-changing tertiary settings.

Data availability statement

The original contributions presented in the study are included in the article/**Supplementary Material**, further inquiries can be directed to the corresponding author.

Ethics statement

Ethical review and approval was not required for this study in accordance with the local legislation and institutional requirements.

Author contributions

LNP and thesis committee members (IG, BD, CB JS) conceived the study design. LNP was responsible for the data collection, and synthesis. LNP conducted the analysis of qualitative data. LNP produced all tables, figures and additional files. JS, IG, CB provided input into the analysis and interpretation. The initial draft of the manuscript was prepared by LNP as part of dissertation research, then circulated among all coauthors for comments and revision. All authors contributed to the article and approved the submitted version.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Publisher's note

Supplementary material

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Connecting the science and practice of implementation – applying the lens of context to inform study design in implementation research

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The saying "horses for courses" refers to the idea that different people and things possess different skills or qualities that are appropriate in different situations. In this paper, we apply the analogy of "horses for courses" to stimulate a debate about how and why we need to get better at selecting appropriate implementation research methods that take account of the context in which implementation occurs. To ensure that implementation research achieves its intended purpose of enhancing the uptake of research-informed evidence in policy and practice, we start from a position that implementation research should be explicitly connected to implementation practice. Building on our collective experience as implementation researchers, implementation practitioners (users of implementation research), implementation facilitators and implementation educators and subsequent deliberations with an international, inter-disciplinary group involved in practising and studying implementation, we present a discussion paper with practical suggestions that aim to inform more practice-relevant implementation research.

KEYWORDS

implementation research, implementation practice, context, adaptation, study design

Introduction

Implementation science has advanced significantly in the last two decades. When the journal Implementation Science launched in 2006, it defined implementation research as "*the scientific study of methods to promote the systematic uptake of research findings and other evidence-based practices into routine practice, and, hence, to improve the quality and effectiveness of health services*" (1, p.1) and subsequent work has advanced theoretical and empirical development in the field. Yet questions remain as to whether implementation science is achieving impact at the level of health systems and population health (2) and if

implementation science is in danger of re-creating the type of evidence-practice gap it was intended to address (2–5). In relation to this latter point – the apparent dis-connect between implementation science and implementation practice – critics have challenged the dominant paradigm of implementation research as it is currently conducted, notably a reliance on methodologies that emphasize experimental control and adherence to clearly specified protocols (3, 6). Why is this problematic and what should we be doing to address it? These are questions that we set out to explore with inter-disciplinary colleagues working in the field of implementation research and practice. In exploring these issues, we recognize that views will differ according to the ontological and epistemological positioning of the individuals and teams undertaking implementation research as this will guide the question/s they are seeking to address, and how. Our starting point is essentially a pragmatic one; we believe that implementation science should be useful to and used in practice. Indeed, some authors conceptualize implementation science more broadly than the study of implementation methods, positioning it as a "*connection between two equally important components, implementation research and implementation practice*" (7, p.2). As such, whilst "*implementation research seeks to understand and evaluate approaches used to translate evidence to the real world. Implementation practice seeks to apply and adapt these approaches in different contexts and settings to achieve positive outcomes*" (8, p.238).

This inter-connectedness between implementation research and implementation practice reflects our starting position and a belief that implementation research should generate transferable and applicable knowledge for implementation practice. In turn, this requires responsiveness and changes to modifiable contextual factors that influence implementation. For example, studies of the effectiveness of facilitation as an implementation strategy have shown mixed results (9, 10) and demonstrated that an important contextual factor is the level of support from clinical leaders in the implementation setting. Whilst this can be factored into the design of future research, leaders may change during the conduct of the study, potentially reducing the level of support for the facilitation intervention. This is a modifiable factor, which can either be reported on, or (the alternative option) acted upon, for example, by an additional strategy to engage the new leader and secure greater support. It is this type of more responsive approach to implementation research that the paper is advocating for.

Context and the complexity of implementation

Although initially conceptualized as a rational, linear process underpinned by traditional biomedical approaches to research translation (11), the complex, iterative and context-dependent nature of implementation is now well recognized (12, 13). This is apparent in the growing interest in applying complexity theory and complex adaptive systems thinking to implementation and implementation science, including attempts to combine different research paradigms to address the complex reality of health systems (13–15). Central to an understanding of complexity is the mediating role of context in presenting barriers and/or enablers of implementation (16–18). Many definitions of context exist in the literature. In this paper we adopt a broad interpretation of context as "*any feature of the circumstances in which an intervention is implemented that may interact with the intervention to produce variation in outcomes*" (19, p.24). As such, contextual factors exist at multiple levels of implementation from individuals and teams, through to organizations and health systems (17, 20). They do not work in isolation but interact in complex ways to impact implementation success. Contextual factors are represented to varying degrees in an array of implementation theories, frameworks, and models (21, 22), which can help to design theory-informed implementation interventions and predict and explain implementation processes and outcomes (23).

Advances in implementation science

Alongside the growth of implementation theories and frameworks, empirical studies have helped to establish an evidence base on the relative effectiveness of different implementation strategies, including, for example, audit and feedback, education and training, local opinion leaders and computerized reminders (24). Methodological developments are also apparent, particularly the introduction of hybrid trial designs that aim to simultaneously evaluate intervention and implementation effectiveness (25), increased use of pragmatic trial designs, and published guidance on improving the quality of randomized implementation trials (26). However, against this background of the developing science, the evidence-practice gap has remained largely static over the last 20 years. A key study in the US in 1998 indicated that 30%–50% of health care delivery was not in line with best available evidence (27); subsequent studies, published for example, in Europe (2001), Australia (2012 and 2018) and most recently in Canada (2022) reached similar conclusions (28–31) (**Table 1**). This suggests that a 30%–40% gap between the best available evidence and clinical practice persists, despite the investment that has gone into building the science of implementation. In turn, this could indicate that we are not putting into practice what we know from empirical and theoretical evidence on implementation and that the promise of implementation science is not being realized in terms of improving putative benefits on health systems and health outcomes. That is, we need to put more focus on the implementation of implementation science.

Approaches to studying implementation

Research to derive the evidence base for different implementation strategies has tended to emphasize questions of effectiveness, with a corresponding focus on experimental study

TABLE 1 Studies assessing appropriateness of care against evidence-based recommendations.

Country	Study	Authors	Year of publication	Appropriateness of care
United States of America	How good is the quality of health care in the United States?	Schuster, McGlynn & Brook (27)	1998	Preventive care – 50% Chronic conditions – 60% Acute care – 70%
Netherlands	Implementation of evidence-based guidelines for clinical practice in family medicine	Grol (28)	2001	67%
Australia	CareTrack: assessing the appropriateness of health care delivery in Australia	Runciman, Hunt, Hannaford, et al. (29)	2008	57%
Australia	CareTrack Kids: Quality of Health Care for Children in Australia, 2012–2013	Braithwaite, Hibbert, Jaffe, et al. (30)	2018	59.8%
Canada	Inappropriate use of clinical practices in Canada: a systematic review	Squires, Cho-Young, Aloisio, et al. (31)	2022	70%

designs that seek to control for, rather than respond to, contextual variation. This runs counter to the recognition that implementation is complex, non-linear, and heavily context-dependent, a fact borne out by large robust implementation trials that report null outcomes and demonstrate through embedded process evaluations the contextual variables that contributed to this result (Table 2). Typically, process evaluations are conducted and reported retrospectively to provide an explanatory account of the trial outcomes – *describing rather than responding and adapting* to contextual factors that influence the trajectory of implementation during the study. Furthermore, when considering implementation studies, there are likely to be broader questions of interest than simply the effectiveness of an implementation intervention, including recognized implementation outcomes such as acceptability, appropriateness, affordability, practicability, unintended consequences, equity and feasibility (40, 41). In this paper, we make the case for re-thinking the relationship between implementation research and implementation practice, highlighting the need to become better at working with context throughout the entire research process, from planning to conduct, analysis, interpretation, and dissemination of results, whilst maintaining relevance and rigour at all stages.

We engaged in a series of activities to explore these issues further and contribute to the debate on connecting the science and practice of implementation. Our intent is not to promote one research study design over another, but to stimulate debate about the range of research approaches needed to align the science and practice of implementation.

Connecting the science and practice of implementation: issues, challenges and opportunities

Our central aim was to produce a discussion paper and practical guidance to enable implementation teams to make better decisions about what study designs to apply and when. This started with a roundtable workshop and meetings amongst a small group of the authors (JRM, KS, PW, GH, IG), followed by wider engagement and consultation with an international group of implementation researchers and practitioners.

Our initial activity started with a two-day face-to-face meeting and subsequent virtual meetings to explore the relationship between context and implementation research methods, particularly how implementation research studies could be designed and conducted in a way that was more responsive to context in real-time. From our own experiences of conducting large implementation trials where contextual factors were highly influential (9, 10, 37, 42, 43), we wanted to explore how we could conduct robust research where context was more than a backdrop to the study. Our intent was to examine whether and how context could be addressed in a formative and flexible way throughout an implementation study, rather than the more typical way of considering it at the beginning (e.g., by assessing for likely contextual barriers and enablers) and/or at the end of the research (e.g., analyzing and reflecting on how well the implementation process went). In these initial deliberations, we considered several different issues including strengths and weaknesses of different research designs in terms of attending to and responding to context; the role of theory in connecting implementation science and practice; the role of process/implementation evaluation; and interpretations of fidelity in implementation research.

The output of these initial discussions was used to develop content for an interactive workshop at the 2019 meeting of the international Knowledge Utilization (KU) Colloquium (KU19). Prior to the COVID-19 pandemic this meeting had been held annually since its establishment in 2001 with participants representing implementation researchers, practitioners, and PhD students. Evaluation and research methods in implementation had been a discussion theme at a number of previous meetings of the colloquium. At the 2019 meeting in Montebello, Quebec, Canada, two of the authors (GH and JRM) ran a workshop session for approximately 80 colloquium participants, titled "Refreshing and advancing approaches to evaluation in implementation research". The objectives of the workshop were presented as an opportunity:

i. For participants to share their experiences of undertaking implementation research and the related challenges and successes.
ii. To engage the community in a discussion about whether and how to refresh our thinking and approaches to evaluation.
iii. To share and discuss ideas about factors that might be usefully considered in the evaluation of implementation interventions.

TABLE 2 Selected implementation trials with embedded process evaluations and null results.

Study	Year	Authors	Study design	Main outcome findings	Process evaluation findings to explain null trial result
TRACS – A structured training program for caregivers of inpatients after stroke	2014	Clarke, Godfrey, Hawkins, et al. (32)	Pragmatic, 2 arm cluster RCT; 36 UK stroke units	No clinical or statistical improvement at 6 months on primary or secondary outcomes	Contextual factors, including organisational history, team relationships, external policy and service development initiatives influenced the implementation of the caregiver training program in unintended ways
WISE – Implementation of a self-management support approach (WISE) across a health system	2014	Kennedy, Rogers, Chew-Graham, et al. (33)	Pragmatic, 2 arm cluster RCT; 44 UK general practices	No effect on 12-month primary (patient) outcomes	WISE not embedded because of a perceived lack of relevance and fit to the ethos and existing work and need for resources beyond the immediacy of the participating practices
OPERA – Older People's Exercise intervention in Residential and nursing Accommodation	2014	Ellard, Thorogood, Underwood, et al. (34)	Pragmatic, 2 arm cluster RCT; 78 care homes in England	No observed effect on primary or secondary outcomes	OPERA intervention failed to change the prevailing culture that prioritised protecting clients from harm over encouraging activity Overall low attendance at group exercise sessions and those residents most likely to benefit from the intervention were least likely to engage. Low levels of staff training and few home champions for the intervention
TICD – Tailored Implementation in Chronic Diseases (5 tailored programs for chronic conditions in primary care)	2016 2017	Jäger, Steinhäuser, Freund, et al. (35) Wensing (36)	Cluster RCTs of tailored implementation programs in 5 European countries: Netherlands – cardiovascular disease; 34 general practices England – obesity; 28 general practices Norway – depression; 80 municipalities Poland – COPD; 18 general practices Germany – polypharmacy/ multimorbidity; 21 general practices	Little overall observed impact on primary or secondary outcomes	Perceived relevance and credibility of practice recommendations Inability to adapt some of the contextual factors encountered, particularly at the outer context level "Determinants, interventions and contextual factors interacted in complex ways, which reduced their impact" (p.3)
FIRE – Facilitating Implementation of Research Evidence	2018	Rycroft-Malone, Seers, Eldh, et al. (37)	Pragmatic, 3 arm cluster RCT in in 4 European countries; 24 nursing homes	No significant differences in the primary outcome of documented compliance with guidance recommendations	Success of intervention implementation related to contextual factors, including fit and alignment, prioritisation and engagement, which determined a facilitator's opportunity to learn over time and enact the role
EPOCH – A multi-component quality improvement intervention to reduce mortality after emergency abdominal surgery	2018	Stephens, Peden, Pearse, et al. (38)	Stepped wedge cluster RCT; 93 UK hospitals	No improvement in primary outcomes, 90-day survival or hospital length of stay	Variable intervention fidelity at hospital level, difficult to engage clinical colleagues Quality improvement leads were attempting to deliver the intervention in challenging contexts with limited time and resources
T^3 – Triage, Treatment and Transfer of Stroke Patients	2020	McInnes, Dale, Craig, et al. (39)	Pragmatic, 2 arm cluster RCT; 26 emergency departments in Australia	No improvement in 90-day health outcomes of acute stroke patients	The implementation strategy was unable to overcome system and clinician level barriers. Some contextual factors were outside the control of a senior nurse, including low medical engagement, acceptance of supporting evidence and professional boundaries

A short introduction outlined some of the issues for consideration and discussion in relation to taking account of context, adaptation of implementation strategies, summative vs. formative process evaluation and issues of fidelity. Participants were then split into smaller roundtable groups to discuss the following question:

How could we design more impactful implementation intervention evaluation studies? Consider:

- *the whole research cycle from planning and design to implementation and evaluation*
- *designs and methods that enable attention to context, adaptability, engagement, and connecting implementation research and practice.*

After a period of discussion, each table nominated a spokesperson to take part in a facilitated feedback discussion, using a goldfish

bowl approach. JRM and GH facilitated the feedback process with other workshop participants observing the "goldfish" bowl. Discussion centred on three main themes: the appropriate use and operationalization of theory in implementation research; consideration of a broader range of study designs in implementation research; and building capacity and capability to undertake impactful implementation research. Notes of the discussion were captured and collated into an overall summary (Table 3). At the end of the session, participants were asked to self-nominate if they were interested in forming a working group to further develop the ideas put forward. Twenty-four responded in the affirmative to this invitation.

Following the KU19 event, the participants who had expressed an interest in continued involvement, were emailed a short template to complete. The template asked them to list up to 5 key issues they thought should be considered in relation to implementation research that was attentive to context and enabled adaptability, noting why the issue was important and when in the research cycle it was relevant to consider. This feedback was synthesized and fed back in a second round of consultation, giving participants the opportunity to add any further commentary or reflections and asking them to suggest exemplar study designs that could address the issues identified and any benefits and drawbacks of the approach.

TABLE 3 Summary of feedback from KU19 fishbowl discussion.

Theme	Discussion points
Theory	• Think about theory toolboxes, rather than rely on the use of single theories or frameworks • Inclusion of theory knowledgeable members on research teams • Operationalise theory with care
Approaches to implementation research	• Engage intended end-users of research throughout • (Better upfront) investment and planning, including greater attention to the ecosystem of implementation • Choose approaches that enable greater attention to incorporating context (e.g., critical and realist approaches, ethnography) • Select approaches that allow flexibility and adaptability (e.g., adaptive trial designs, stepped wedge designs, participatory and realist approaches) • Consider the need to balance flexibility with rigour • Build programs of research and conduct longitudinal studies • Think about how approaches enable scale up and sustainability of the intervention and/or the implementation strategy • View mechanisms more as a dimmer switch than binary
Capacity and capability	• Learn from other disciplines, e.g., team science • Build communities of practice around ways of implementing and methods of evaluation • Pay attention to building up implementation capacity and capability for implementation in study sites • Build the knowledge base and capacity for effective engagement between end-users and researchers throughout the research process

Connecting the science and practice of implementation – a way forward?

Ten participants responded to the first round of consultation (September 2019) and 9 to the second round (February 2020). A diversity of views was expressed in the feedback, however, there was clear support for working with more engaged, flexible, and context-responsive approaches that could bring implementation practice and research closer together. Suggestions of appropriate research designs were put forward, including theoretical and practical issues to be considered. Feedback was analyzed inductively and findings synthesized by the initial core group of authors (JRM, KS, PW, GH, IG) to identify key themes, presented below.

Engagement with intended users of implementation research

In line with approaches such as co-design, co-production and integrated knowledge translation (44, 45), participants highlighted the importance of engaging with intended users of implementation research, from community members and patients to clinicians, managers, and policy makers. Different groups can play different roles at different times in relation to implementation research. For example, patients, community members, clinicians and decision-makers can generate questions to be addressed by implementation research, clinicians (working with patients and the public) could be expected to apply the research findings in practice, and managers, educators, and policy makers could have a role in enabling, guiding, and supporting implementation. As such, involvement of intended users of the implementation research should be considered throughout the process of research, from identifying the significant priorities for implementation research to ensuring that implementation strategies are relevant, and findings are appropriately disseminated and actioned, thus increasing the likelihood of success and sustainment. The level of involvement can vary along a spectrum, ranging from passive information giving and consultation through to more active involvement and collaboration, with a corresponding shift in power-sharing amongst those involved (46). For the purposes of consistency throughout the paper, we use the term engagement to refer to the more active level of involvement, namely an equal partnership with intended users of implementation research, herewith referred to as implementation practitioners. We recognize that some roles such as clinical academics and embedded researchers may merge the implementation researcher and implementation practitioner roles (47).

Context responsiveness and flexibility

The need to embrace a wider range of methods to achieve greater engagement, flexibility and context responsiveness was emphasized, recognizing that different approaches have their own

strengths and weaknesses in terms of supporting adaptation to context. Several important challenges were highlighted in relation to adopting more flexible methods, such as understanding the complexity of balancing the requirements of fidelity with adaptation of implementation interventions, and the practicalities of operationalizing concepts in complexity theory, particularly when applying it prospectively. Issues of equity, diversity and inclusion were also viewed as important to consider when thinking about all types of implementation research methods and designs, for example, in terms of representative membership of the research team and the potential influence of contextual factors on accessibility and inclusiveness of the implementation strategy.

Alternative research approaches

Suggestions of alternative methodologies that could enable greater alignment with and consideration of context included participatory research, case study designs, realist evaluation, mixed methods approaches and trial designs such as stepped wedge and adaptive trials. A key point was raised related to the underlying ontological and epistemological position of implementation researchers. Adopting more context-responsive and adaptive approaches to implementation research was seen to align more closely with constructivist or realist ontology with related implications for interpretations of scientific rigour, fidelity, and the role and influence of the researcher. For example, views on whether and how tailoring and adapting interventions to context presents a threat to the rigour of a study varies according to the underlying philosophy adopted by the research team and the choice of research design. The feedback highlighted a need for this to be considered more clearly and explicitly described by implementation researchers.

Theoretical and practical considerations

The importance of program theory was highlighted, particularly in relation to theorizing the intended change prior to the start of a research study and focusing on theoretical rather than programmatic fidelity of implementation research (48, 49). Alongside methodological and theoretical positioning, a number of more practical considerations were raised, including clarity about thresholds for intervening to adapt the study design and/or implementation strategy and whether and how adaptation should be actively pursued to maintain equity, diversity and inclusion. Other practical issues identified related to how best to define and capture adaptations over time, how to resource detailed, prospective process evaluations that could fully inform and observe adaptations, and the timeframe for evaluation, which was often seen to be insufficient.

The synthesis of feedback from the consultation process informs the subsequent discussion and suggestions for moving the agenda forward.

Discussion

Much has been learned from studying and applying implementation methods over the last two decades. However, the persistent gap between research evidence and practice indicates a need to get better at connecting implementation research and implementation practice. From an implementation research perspective, this involves thinking differently about what methods are appropriate to use and when. Whilst perceptions of the implementation process have shifted from a rational-linear view to something that is multi-faceted and emergent, it could be argued that some implementation research has become stagnant and ignores or over-simplifies how context influences real-world implementation rather than working flexibly with the inherent complexity of implementation contexts. From our collective deliberation, we propose that implementation research needs to align more closely with the reality of implementation practice, so that it achieves the ultimate aim of improving the delivery of evidence-informed health care and accelerating the resulting impact on health, provider and health system outcomes.

To achieve this alignment requires several actions that embrace engagement between implementation researchers and implementation practitioners (4, 50). These actions also require an appreciation and acceptance of study designs that enable a higher degree of adaptability and responsiveness to context.

Engagement with intended users of implementation research

Engagement with implementation practitioners should underpin the research process, as exemplified by approaches such as co-design, co-production, and integrated knowledge translation (51, 52). This helps to ensure that the necessary relationships are in place to clearly understand the implementation problems to be addressed, the goals to be achieved, resource and support requirements, and what research methods and adaptations will be required to achieve identified goals. This includes clarity around the implementation outcomes of interest, for example, effectiveness of the implementation strategy; acceptability to key user groups, including patients, consumers and staff; feasibility; and costs of implementation. These are all factors that should be taken into account when selecting an appropriate evaluation study design. It is important to highlight that this approach to engagement is not simply a feature of research approaches such as participatory research but should be a principle underpinning all implementation research studies that aim to improve the uptake of research evidence in practice and policy. It requires particular attention to the relational aspects of implementation, such as fostering local ownership of the problem to be addressed and building capability and capacity amongst both researchers and end-users of research to engage in effective collaboration. Clinical academics and embedded researchers offer one way of bridging the implementation research-practice boundary, including

insights into specific contextual factors that could affect implementation processes and outcomes (53).

Appreciation and acceptance of study designs to enable responsiveness to context

Contextual influences are important at the planning (protocol development), execution and/or analysis phases of an implementation project. Some research designs lend themselves better to engaged approaches with intended end-users of the research to identify, manage and interpret contextual factors. Other than natural experiments, most designs have the potential to consider contextual factors at the protocol development phase, for example by assessing for potential barriers and enablers posed by contextual factors. However, not all study designs present an opportunity to act upon and modify the identified contextual factors in a responsive way. This is particularly the case for experimental studies that are purposefully designed to neutralise context throughout the research process, although more recent developments such as the adaptive trial design offer greater flexibility to account for contextual factors (54). Similarly, all designs present an opportunity to reflect upon contextual influences that affected the outcomes of implementation, particularly if there is a concurrent process evaluation of what is happening during implementation. However, whether this analysis is undertaken prospectively or retrospectively will determine the extent to which the data can inform real-time responsiveness to contextual factors. There is also variability during the execution of the study, as some designs are more amenable to adaptation of the implementation strategy, in response to (often unanticipated) contextual barriers and enablers. Typically, the more responsive or flexible approaches, such as participatory research and quality improvement, have inbuilt feedback loops which allow real-time monitoring, evaluation, and adaptation.

It is interesting to reflect on the effects that the COVID-19 pandemic had in terms of catalysing rapid change in a health system that is known to be slow to transform (55). Flexible approaches to implementation that were responsive to health system needs were critical for enabling rapid change (56). The pandemic response has highlighted the potential for adaptation to context in real-time and contributed to calls for rapid implementation approaches (57). However, rapid approaches to implementation must be considered alongside intentional engagement of end-users. Recent research, which aligns with our anecdotal experience, has shown a decrease in engagement among patients, the health system, and researchers during pandemic planning and response (58); some argue that there is no time to work in true partnership so researchers are falling back into more traditional directive modes of working. In part, this reflects the expectations of research commissioners and policy makers who, drawing on the COVID-19 experience, have a general expectation of more rapid approaches to translation and implementation. While we argue for research designs with higher degrees of adaptability and responsiveness to context, we caution those responsible for conducting and commissioning implementation research not to prioritize speed at the expense of effective collaboration.

Applying a lens of context to select appropriate research study designs

Building upon the feedback from our iterative discussions and consultation with implementation researchers and practitioners, we have developed a "horses for courses" table of study designs in terms of their potential to respond and adapt to contextual factors at different stages of the research process (**Table 4**). For each study design, we provide a brief description before indicating when and to what degree it can respond to contextual factors at the protocol development, study execution and/or analysis phase. For each of the three phases, we indicate the potential (high, medium or low) to respond to contextual factors, resulting in an overall high, medium, or low rating (colour coded accordingly in the table). This does not necessarily mean that some approaches are "better" than others, as each needs to be considered in terms of their strengths and weaknesses and the potential trade-offs when selecting one design or another. These considerations are addressed in the final column of the table.

Informed by our deliberative discussions, there are several pre-conditions to the study designs described in the table that help to optimise the impact of implementation research. These include a starting position that context is an important consideration in implementation research; the relationship between researchers and end-users of research; the need for process evaluation; and the role and contribution of theory.

As noted, we start from an assumed position that context mediates the effects of implementation and, as such, is something that we should work with, rather than seek to control, in implementation research. The ratings assigned to study design in **Table 4** are through a lens that "context matters". If this is a view shared by the implementation research team, then it is important to select a study design that will enable responsiveness and adaptation to context. We recognize that questions of fidelity arise when adapting implementation interventions to context. One way to address this is by specifying the core and adaptable components of the intervention to inform decisions about when tailoring to context is appropriate (117). Additionally, and as noted in the consultation feedback, it is important to consider fidelity alongside the program theory underpinning an implementation strategy. Theoretical fidelity is concerned with achieving the intended mechanisms of action of an intervention, as opposed to fidelity to component parts of the intervention (48, 49). A second condition relates to active engagement between the researcher/s and the intended users of the implementation research. This has important implications for the researchers' role as they can only optimise adaptation to context if they are working in an engaged way to monitor and respond to context in real-time. Thirdly, we highlight the importance of process evaluation in implementation research, in particular process evaluation that is embedded and prospective to capture changes in

TABLE 4 Summary of selective study designs with potential to respond to context during research phases of protocol development, execution of the study and analysis of findings.

Research design	Description	Responsiveness of study design to context			Considerations	Examples from literature
		Protocol development	Study execution	Analysis		
Participatory research	Defined by various terms, including participatory action research, community based participatory research, engaged scholarship, and integrated knowledge translation. It involves an approach that "partners the researcher and participants in a collaborative effort to address issues in specific systems" [(15) p.2] and to "to foster democratic processes in the co-creation of knowledge" [(59) p.7]	H	H	H	Engagement with intended end-users is a pre-requisite. Need to consider the time and resources required to build authentic and trusting relationships between research team members (61).	(60, 62)
Realist evaluation	Realist evaluation is a theory-driven approach driven by the question: what works, how, for whom, in what circumstances and to what extent? It involves developing and testing explanatory theory based on context, mechanism, and outcome configurations (CMOcs). These represent hypotheses about how a program works (O) because of the action of some underlying mechanism/s (M) that only function in particular contexts (C) (63, 64). Typically undertaken iteratively to test and refine theoretical propositions over time.	H	H	H	The theory-based approach of realist evaluation aligns with theory informed and informative implementation research and explicitly explores contextual influences on intervention outcomes (65). Development of CMOcs can be challenging (66). There are published examples of applying realist evaluation in implementation research, particularly to conduct process evaluations embedded within randomized controlled trials (37); however process evaluation needs to be conducted prospectively to enable optimal responsiveness to context and engagement with intended users of the research is important to articulate and refine program theory/ies. Whether a realist approach can be incorporated within randomised controlled trials is an area of debate (67, 68).	(37, 69)
Developmental evaluation	Described as an extension of utilization-focused evaluation (70) that is informed by complexity science and systems thinking. The focus is on users and real use of evaluation findings. This involves studying programs in context and understanding program activities as they operate in dynamic environments with complex interactions (71, 72).	H	H	H	Well suited to early stages of implementation and where a need for implementation strategy adaption is anticipated. Does not apply a conventional logic model, but applies systems thinking to map relationships, inter-connections, and assumptions about how change is expected to occur. Researchers need to be comfortable with uncertainty and be willing to change or abandon an intervention and/or implementation strategy mid-course if the data is suggesting another approach might be better. Detailed documentation throughout the study is important to capture decision points and feedback in a timely manner.	(71, 73)
Ethnography	With roots in anthropology, ethnography involves engagement with a small number of study settings to build relationships and undertake in-depth study. Data collection is typically iterative and involves qualitative methods of data collection such as observation, field notes and interviews. As such, if conducted in a participatory way, it is potentially well suited to incorporating end-user perspectives and examining complex implementation processes and contextual influences on implementation (74).	H	H	H	Evidence of increasing use in implementation research, although meanings of ethnography are contested which can make it difficult to evaluate the rigour of the research (74). As with other participatory approaches, reflexivity is an important skill and practice for researchers undertaking ethnographic study, as is awareness of positionality (75).	(76, 77)

(*Continued*)

TABLE 4 Continued

Research design	Description	Responsiveness of study design to context			Considerations	Examples from literature
		Protocol development	Study execution	Analysis		
Quality/rapid cycle improvement: Single site Multi-site collaborative	Quality improvement (QI) involves a systematic and coordinated approach to solving a problem using specific methods and tools with the aim of bringing about a measurable improvement [(78) p.3]. QI collaboratives involve groups of professionals coming together in real time, either from within an organisation or across multiple organisations, to learn from and motivate each other to improve the quality of health services. Collaboratives often use a structured approach, such as setting targets and undertaking rapid cycles of change (79).	H	H	H	Healthcare staff are likely to have existing knowledge and experience of quality improvement. There are recognized similarities between QI and implementation research and calls to align them more closely (80, 81). However, QI may lack a strong theory and evidence component compared to implementation science. Evidence on the impact of QI collaboratives is mixed, suggesting they "achieve positive – although limited and variable – improvements in processes of care and clinical outcomes" [(82) p.2] There is evidence to suggest that participation in QI collaborative activities may improve problem-solving skills, teamwork and shared leadership (83).	(82, 84)
Case study: Single site Multiple sites	Defined as "an empirical inquiry that investigates a contemporary phenomenon (the"case") in depth and within its real-world context" [(85) p.18] Typically, they are observational to understand phenomena and their causal mechanisms, including context. However, case study methods can vary from a more positivist to more constructionist focus, which could influence the extent to which they can respond to context (86).	H	M	M	When case study research is conducted using a prospective approach, then it is possible to identify and respond to contextual barriers and enablers during the study. Multi-site and longitudinal case studies (including studies of failure) are useful to capture the dynamics of implementation and build theory (87). However, in the field of implementation science to date, case studies have been described "as a form of *post hoc* process evaluation, to disseminate how the delivery of an intervention is achieved, the mechanisms by which implementation strategies produce change, or how context impacts implementation and related outcomes"[(88) p.2].	(87, 89)
Adaptive randomized controlled trial	Also described as sequential trial designs, adaptive designs allow for staged modifications to key components of the implementation interventions according to pre-specified decision rules. Unlike conventional experimental designs, where the learning typically occurs after the trial is completed, adaptive designs intend for continual learning as the data accumulate, hence the potential to respond to context (90). Examples include the Sequential Multiple Assignment Randomized Trial (SMART) design (54) and the Multiphase Optimization Strategy (MOST) design (91).	M	M	M	Adaptive designs have mostly been conducted in trials of clinical interventions and there are relatively few published examples of adaptive implementation trials. As there is a need for interim data analysis to inform decisions about modification, there is a need for access to rapidly available and measurable outcome data. Temporal trends are also important to consider and can add to the complexity of data analysis (92).	(93, 94)
Stepped wedge randomized controlled trial	Following a baseline period, the implementation intervention is sequentially rolled out to participants. The order of the roll-out sequence is randomized and by the end of the study all participants receive the intervention. "The design is particularly relevant where it is predicted that the intervention will do more good than harm … and/or where, for logistical, practical or financial reasons, it is impossible to deliver the intervention simultaneously to all participants" [(95), p.1]	M	L/M	M	The sequential nature of roll-out means that participants experience different length intervention periods, which can be problematic as those who come in later have a shorter time to implement. Temporal trends can influence the study results and make data analysis more complex (97). If a prospective process evaluation is embedded with the trial, then there could be potential to respond to identified contextual factors during the conduct of the study.	(96, 98)

(*Continued*)

TABLE 4 Continued

Research design	Description	Responsiveness of study design to context			Considerations	Examples from literature
		Protocol development	Study execution	Analysis		
Hybrid effectiveness-implementation trial	Originally proposed in 2012 as a type of experimental trial design that could combine questions about the effectiveness of an intervention with questions about how best to implement it (25). Three different types of hybrid design were proposed, ranging from a primary focus on testing intervention effectiveness whilst gathering some data about implementation (Type 1), to placing equal weight on testing both the intervention and implementation strategies (Type 2), or primarily testing an implementation strategy and implementation outcomes whilst collecting some information about the intervention (Type 3).	L/M	L	L/M	The hybrid design approach has been widely adopted in the field of implementation science and suggestions put forward for further development or expansion to address context (99). Initially the focus was on testing clinical interventions alongside implementation, although there are many examples of using the approach to evaluate implementation interventions. Ratings are likely to differ from Type 1 to Type 3; the greater the focus on implementation (Type 3), the greater the potential to respond to context if there is an embedded, prospective process evaluation. A recent reflection paper from the original developers of the hybrid design (100) suggests replacing the term 'design' with 'study' to acknowledge that the hybrid approach can be applied more broadly to non-trial research designs. This has the potential to change the level of responsiveness and adaptation to context.	(101, 102)
Pragmatic randomized controlled trial	In contrast to explanatory trials that aim to test the effectiveness of an intervention under optimal conditions, pragmatic trials are designed to evaluate effectiveness under real-world conditions such as the clinical practice setting (103). The PRECIS (The pragmatic explanatory continuum indicator summary tool) and updated PRECIS-2 tool was developed to help researchers design trials along the explanatory to pragmatic continuum taking account of factors such as eligibility criteria, recruitment, setting, flexibility of delivery and adherence (104).	L/M	L.	L	Frequently employed in implementation studies as they place an emphasis on external validity – asking not whether an implementation intervention can work but does it work in routine clinical or health policy contexts (26). This can involve assessment of contextual factors at the study design stage to inform the implementation strategy, although there would not be an active response to contextual factors that emerge during the study. The pragmatic nature of the research is expected to make findings more generalizable; however, what works in one context rarely works exactly the same in another context, raising questions about the degree of generalizability (103).	(105, 106)
Uncontrolled before and after study (pre-post study design)	Involves the measurement of specified outcomes before and after the delivery of the implementation intervention in the same study site or sites.	L/M	L	L	Relatively simple to conduct but cannot necessarily attribute observed changes to the intervention as other factors, including secular trends and unplanned changes, could be at play. Therefore, results have to interpreted with caution - there may be a tendency to over-estimate the effect size of the implementation intervention (107).	(108, 109)
Controlled before and after study	Similar to the pre-post design described above but a control population as similar as possible to the intervention site is identified and data are collected in both groups before and after implementation.	L/M	L	L	Can be difficult to identify a comparable control group and baseline starting points of the intervention and control groups may differ, meaning that some caution is required when interpreting results.	(110, 111)
Interrupted time series	Attempts to detect whether an intervention has an effect that is significantly greater than the underlying secular trends. This involves collecting data related to implementation outcomes at multiple time-points both pre- and post-intervention.	L	L	L	Need to collect sufficient data points, including pre-intervention, to undertake data analysis. This could have implications for the timescale of data collection and can be easier to do if there is access to routine data that can be used for analysis.	(112, 113)

(*Continued*)

TABLE 4 Continued

Research design	Description	Responsiveness of study design to context			Considerations	Examples from literature
		Protocol development	Study execution	Analysis		
Natural experiment	The research team do not plan or direct the implementation intervention but rather observe outcomes of interest and antecedents in their natural context (114).	L	L	L	Useful for studying implementation occurring a real-world context, but limited potential to respond to contextual factors during the research.	(115, 116)

context that could have implications for implementation success and to inform timely adaptations to the implementation strategy, as well as potential effects the implementation intervention may have on context over time. A final condition relates to the central role of theory and theorising in study design. In line with established guidance on the development and evaluation of complex interventions (23), our starting position is that implementation studies should be informed by theories that are relevant to implementation. Alongside applying theory to guide study design and evaluation, opportunities to move from theory-informed to theory-informative implementation research should be considered, for example, by theorising the dynamic relationships between implementation strategies, implementers and context during data analysis and interpretation (118). Careful documentation within process evaluations of what adaptations occurred, when, how and why can make important contributions to such theorising. The extent to which these conditions are met or not will influence the level of adaptability and responsiveness to context. All the study designs listed in the table have potential to be responsive to context or increase the level of responsiveness in the way they plan and conduct the study and data analysis. So, for example, study designs rated lower in the table could enhance their responsiveness to context by increasing engagement with intended end-users of their research and/or embedding a prospective process evaluation with iterative data analysis in their study.

How to use the table

As noted, **Table 4** is intended to be used when context is seen as an important consideration in implementation research. It is not intended to be prescriptive or a "rule-book" for study design selection as there is no definitive answer to the question "what is the right implementation research design"? Rather it aims to help implementation research teams (including implementation practitioners partnering with researchers) who believe context is important to implementation success to select study designs that will best enable them to identify and then respond to contextual factors during the development, conduct and analysis phases of research. Exactly which study design is appropriate will depend upon several factors including the stage and scale of the research and what trade-offs are acceptable to the research team in terms of strengths and weaknesses of different study designs. For example, if the study is concerned with early-stage development and field testing of an implementation strategy, questions of interest are likely to focus on feasibility, practicability, appropriateness and fit. Here, approaches classified as highly responsive are particularly beneficial to test and refine the implementation strategies in real-time and develop an in-depth understanding of the mechanisms of action and the relationships between mechanisms, context, and outcomes. At a later stage, questions of effectiveness and cost-effectiveness may become more important, in which case an adaptive trial design (coded as medium level) would be relevant as it can enable a continuing (although more limited) responsiveness to contextual factors.

BOX 1 Reflective questions to guide the selection of context-responsive study design in implementation research

- Who should be at the table to make decisions about the focus of the study, the questions of interest and the planning, conduct, dissemination and evaluation of the implementation research?
- Does our team reflect principles of equity, diversity and inclusion and accessibility?
- What are we aiming to achieve through the implementation research, for example, what are the research questions we are trying to answer?
- What outcomes are the most important to whom and when?
- Do we have a clear program theory or logic and theoretical framing of the study that team members have developed and agreed upon?
- What do we know about the context/s in which we will be implementing the intervention?
- How much contextual variability do we anticipate that could affect implementation outcomes?
- How flexible are we prepared to be in response to modifiable contextual barriers and enablers in order to optimize implementation outcomes?

The important point is that research teams should more critically reflect on who they involve as part of their research team and their choice of research design, according to the questions they are attempting to answer and the outcomes they are seeking to achieve (see Box 1). It is also important to note that the designs presented in **Table 4** are not exhaustive nor mutually exclusive. Indeed, there are many examples in the literature where different study designs are combined to bring together their relative strengths (15, 67), although this can raise questions about epistemological fit (68). Similarly, there are variations within some of the study designs listed, such as case studies (86) and hybrid studies (100), reflecting different worldviews and approaches within an overarching study design type.

Conclusions

To optimise the potential for implementation research to contribute to improving health and health system outcomes, this paper outlines a paradigm shift in how we conceptualise the relationship between implementation research and implementation practice. We argue that implementation research requires the use of study designs with higher degrees of adaptability and responsiveness to context to align more closely with the reality of implementation practice. Such approaches are critical to improve the delivery of evidence-informed health care and positively impact on patient experience, population health, provider experience, and health system outcomes, contributing to health equity and social justice (119). We recognise that the paper raises questions that require ongoing discussion and exploration, such as how best to balance rigour, fidelity and adaptation to context and how to truly address issues of equity, diversity, accessibility and inclusion. Important debates and developments are already underway in these areas [for example, (120–123)] as are ongoing methodological developments in study design that can help to inform future application and refinement of the ideas proposed in this paper.

Data availability statement

The original contributions presented in the study are included in the article, further inquiries can be directed to the corresponding author.

Ethics statement

Ethical review and approval was not required for this study in accordance with the local legislation and institutional requirements.

Author contributions

GH, JR-M, KS, PW and IDG: conceived the original ideas for the paper. GH and JR-M: facilitated a workshop at the Knowledge Utilisation 2019 meeting to explore the ideas further and establish a working group to write the paper. All authors contributed to the article and approved the submitted version.

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Conflict of interest

The remaining authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

The author JH declared that they were an editorial board member of Frontiers, at the time of submission. This had no impact on the peer review process and the final decision.

Publisher's note

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Increasing consumer engagement: tools to engage service users in quality improvement or implementation efforts

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Introduction: Engaging service users or consumers in quality improvement or implementing a new service is important across settings and may reduce health inequities. Implementation strategies leveraging consumer engagement are neither commonly used nor robustly operationalized in implementation science. Implementers (e.g., middle managers, facilitators) want to involve consumers in implementation activities, but do not always feel confident in how to proceed. We developed a compendium of tools called Consumer Voice to guide others how to engage consumers in design/delivery of implementation strategies. Although generalizable to other settings, we developed Consumer Voice within the context of implementing suicide prevention treatments in healthcare to reach rural U.S. military veterans, as there are suicide inequities for people in rural areas.

Methods: We developed Consumer Voice using a multistep process and human-centered design methods. In between steps, a design team met to generate insights from data, and decide which prototypes to create/refine. In preliminary work, we conducted a scan of examples in healthcare of patient engagement in implementation activities and interviewed two implementation experts about preferred learning styles. In Step 1, we interviewed 26 participants with experience in community engagement, implementation, or lived experience as a rural U.S. veteran with suicidal thoughts/behavior. In Step 2, 11 implementers beta tested prototypes then share feedback in focus groups. In Step 3, we reconvened participants from prior steps to review tools and, using nominal group technique, prioritized remaining recommendations.

Results: Consumer Voice is online, modular, and nonlinear for self-guided learning tailored to beginner, intermediate, or advanced experience with consumer engagement. Tools consist of slides, audiovisual content with written text, and templates. Findings indicated there is not one "right" way to engage consumers in implementation activities, rather that implementers wanted tools showcasing core principles for consumer engagement and practical ideas.

Discussion: Consumer Voice can be used by implementers to reflect and decide on how to apply consumer engagement implementation strategies to improve equitable dissemination and uptake of evidence-based practices. Most insights generated by user data were explicitly to build trust between consumers and professionals representing institutions, which may be one component to reducing healthcare inequities.

KEYWORDS

service users, consumer, patient engagement, patient and public involvement, community engagement, implementation science, quality improvement

1. Introduction

Engaging consumers of innovations (i.e., service users, end users) to facilitate equitable demand for and uptake of innovations is important across a wide range of settings (1–3). Consumers are the people who use, receive, or are most affected by an innovation, which could include new policies, treatments, or programs. Examples of consumers are patients in healthcare settings, students and families in education settings, and incarcerated individuals in criminal justice settings. When implementing an innovation in new settings, implementers—quality improvement personnel, implementation scientists, and practitioners—typically focus on changing dynamics within an organization, the processes within smaller units of local context, and the behavior of people delivering an innovation (4). "Consumer engagement implementation strategies," defined as those that focus on people who are direct recipients of innovations and practice changes, are less commonly used (5) and not robustly operationalized in the implementation science literature (4, 6).

Experts identified five consumer engagement implementation strategies to enhance uptake of innovations. They include (a) involving consumers or family members in implementation or quality improvement activities; (b) intervening with consumers to enhance their own uptake of and adherence to an innovation; (c) preparing consumers to be more active participants in their own services; (d) increasing consumer demand for innovations; and (e) using mass media to disseminate information about innovations (4). Unpacking the first type—involving consumers in implementation or quality improvement activities—might include having consumers serve on advisory councils (7), be practice change agents who assist with innovation implementation (8), marketing, or dissemination (9); and/or participate in user testing of consumer-facing products (10). What these strategies have in common is their direct involvement of consumers to inform and/or participate in the implementation strategies used to spread uptake of an innovation. Although implementers may want to involve consumers in implementation activities, implementers do not always feel confident in how to do so. Despite increasing requirements by payers and organizations to engage consumers in implementation or quality improvement (1, 11–13), using consumer engagement implementation strategies, alone or in conjunction with strategies targeting deliverers of innovations and their organizations, appears to be uncommon (14, 15). When engaging consumers in implementation activities, implementers face numerous challenges, such as uncertainty about usefulness of engaging consumers, confusion about terminology, lack of role clarity, or lack of funding to do so (1, 16, 17).

To increase the use of consumer engagement implementation strategies and specifically to clarify *how* to involve consumers in implementation or quality improvement activities, we engaged in a multi-step, systematic process to develop a compendium of tools called Consumer Voice. Designed to support implementers, Consumer Voice was developed within the context of implementing a suicide prevention intervention—Safety Planning Intervention—in rural primary care settings to reach rural U.S. military veterans in Arkansas, as suicide rates are double among rural-dwelling (vs. urban) veterans (18, 19). However, Consumer Voice tools were designed with generalizability in mind and can support uptake of any innovation in any setting. We believe using Consumer Voice would likely result in either (a) greater use of other types of consumer engagement implementation strategies by implementers (e.g., increasing demand for innovations) or (b) consumers assisting or leading the design/delivery of other implementation strategies. In this paper, our goal was to describe our developmental process, key content principles for consumer engagement in implementation, and how what we learned in each stage informed key design decisions for final tools.

2. Developmental process overview

2.1. Guiding framework

We developed Consumer Voice from April 2021 to November 2022 using a multistep, iterative process combining health services research and human-centered design methods. Our process was consistent with the Discover, Design, Build, and Test human-centered design framework for implementation (20). This framework suggests four phases in developing solutions to implementation problems, each with a different focus. The first is to discover targets for change or of need by identifying needs and perspectives of people involved and the context for implementation. The second and third phases are focused on design—synthesizing information learned in the Discover phase and then coming up with ideas and principles for potential solutions—and then building prototypes of solutions. Activities can cycle back and forth between Design and Build phases new data gathered through user testing is used to modify or redesign

solutions. The final Test phase involves evaluating high-fidelity prototypes in a real-world implementation context. In this paper, we describe activities in the Design, Discover, and Build phases of Consumer Voice—see Figure 1, incorporating co-creation with potential end-users with limited tools in constrained time settings (akin to alpha testing) as well as a step in which actual end-users interacted with the tools in their own environment (akin to beta testing).

2.2. Research and design team roles in decision making and prototyping

We had a research team and a design team that served distinct functions and contained overlapping members. The research team designed and executed data collection and analysis using traditional health services research methodologies in each step. The design team then synthesized research data in the context of their lived or professional experience related to the topic, generated key insights from data related to Consumer Voice development, and brainstormed and made decisions about prototype solutions to address those topic areas. The research team made all prototypes and refinements. The research team consisted of the principal investigator of this study, a doctoral-level clinical psychologist (ENW), a research assistant with a bachelor's degree in sociology (IAB), and a qualitative methodologist trained in implementation science (KLD). The design team consisted of the research team plus another clinical psychologist and implementation researcher (RSS); one consumer as a co-design participant—a military veteran consultant who was a former seaman in the U.S. Navy as well as engaged in women veterans outreach and certified in health benefits administration (CS); a second consumer as a co-design participant—a military veteran consultant with a juris doctorate who was a retired colonel in the U.S. Army and National Guard (DC); a psychiatrist and implementation researcher (JEK); and an anthropologist who engages community members in implementation science (CW).

2.3. Participants and recruitment

We engaged participants with diverse experiences throughout our multistep development process. Participants included members of the target end user group, which included those with knowledge of and/or need for safety planning to prevent suicide in rural Arkansas, as well as individuals with knowledge that would generalize to consumer engagement or implementation in any setting. Specifically, we recruited: (1) veterans living in rural Arkansas who experienced suicidal thoughts or attempts; (2) Arkansas community members involved in suicide prevention (e.g., state Veterans Service Officers, community organizers who were also veterans); (3) mental health leadership at VHA rural clinics; (4) suicide prevention providers and champions at the main central Arkansas VHA medical center, and at the national level; (5) implementers who would theoretically use Consumer Voice in their work; and (6) community engagement experts in any area.

Using a respondent-driven, non-probabilistic approach, we reached out to relevant professional groups, community organizations, or established veteran contacts in the community via email or social media, asking them to suggest potential participants. After generating a list of people who might meet criteria, the research team made phone calls to screen for

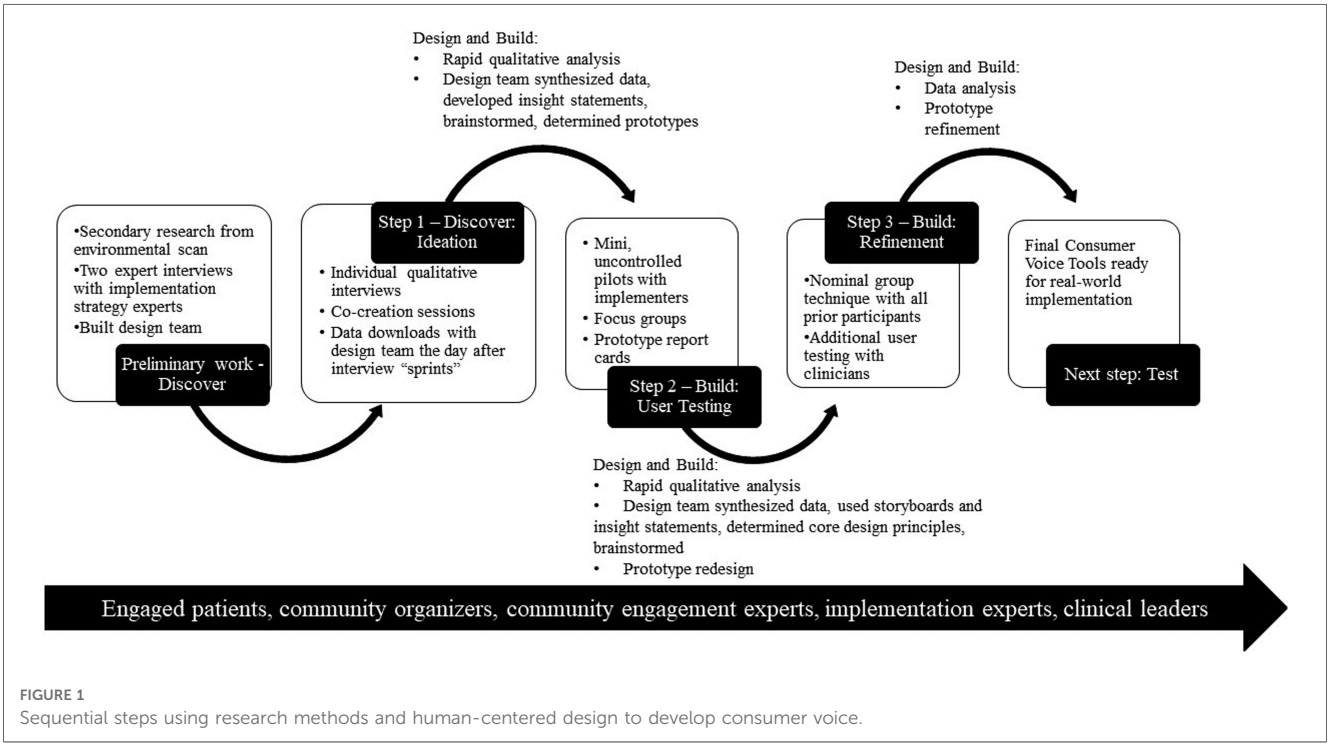

FIGURE 1
Sequential steps using research methods and human-centered design to develop consumer voice.

eligibility. We screened for eligibility using simple questions consistent with the inclusion criteria shown in Table 1 (e.g., For implementers, "Do you have practical experience implementing new treatments/programs into practice and considered or attempted to engage consumer groups in this process?"). For veterans with lived experience, we used multiple questions about (1) their military status, (2) their zip code, and (3) whether they ever thought about ending their life, planned to end their life, or attempted suicide before. We compared their zip code to the Rural Urban Community Area (RUCA) code database to determine if their residence was considered rural (21). Veterans were eligible for our study if they lived in an area with a RUCA code 4–10, indicating large, small, and isolated rural towns. Veterans were not eligible for the study if they appeared to have trouble remembering key parts of the screening conversation or demonstrated memory impairments that could be due to cognitive or substance use issues, as we believed this compromised their ability to give informed consent. We were also prepared to exclude Veterans who were high risk for suicide using a suicide risk protocol, although no one met this criterion.

If participants were eligible, we then assessed if they wanted to participate in the study. If they agreed, they were enrolled. These individuals were recruited for either Step 1 qualitative interviews and co-creation of tools or Step 2 focus groups. Finally, all were recontacted for participation in Step 3 nominal group technique processes for final refinement of tools.

Individuals were engaged in an informed consent process and compensated for each step in which they participated. Consumer and community members were compensated $30 per hour (up to $90 dollars total) and professional implementers and community engagement experts outside VHA were compensated $100 per hour (up to $300). VHA hospital employees were not compensated for research activities when occurring during their official work hours per VHA policy. The study was approved by the Central Arkansas Veterans Healthcare System Institutional Review Board.

3. Multistep process and key insights

3.1. Preliminary work—discover

3.1.1. Process

We based initial prototypes on themes from preliminary work in an environmental scan from May 2019 to April 2022 on what implementers had already done to engage consumers in implementation efforts in U.S. healthcare systems (6). In the environmental scan, we synthesized data from published literature, publicly available webinars, and surveys or interviews with seven implementers. We also interviewed two implementation strategy experts about how they preferred to learn to consider how best to "teach" consumer engagement strategies to other implementers.

Using human-centered design methods, the design team engaged in a synthesis process by reviewing data from activities, developed key insights from the data, prioritized important concepts, and then collectively brainstormed how to prototype those concepts. Any potential solutions to teach implementers to use consumer engagement implementation strategies were (1) prioritized by the design team and (2) based on "key insights" gleaned from data generated in each step—see key insights from this step below.

3.1.2. Key insights

We generated and prioritized five key insights from our preliminary work. Those five insights were:

1) There are many ways to engage consumers in design/delivery of implementation strategies and not all consumers nor implementers want the most intensive engagement. Environmental scan data showcased a range of intensity of consumer engagement activities, including lower intensity activities such as obtaining unidirectional feedback from

TABLE 1 Participant groups' inclusion and exclusion criteria and sample size for steps 1, 2, and 3.

Participant group	Inclusion criteria	Exclusion criteria	Step 1	Step 2[a]	Step 3[b]
Veterans with lived experience and community members	Veterans living in rural Arkansas who experienced suicidal thoughts or behavior or their caregivers, family, or peers; Arkansas community members involved in assisting with preventing Veteran suicides (e.g., clergy, state Veteran Service Officers)	Acutely high risk for suicide at the time of study activities; cognitive impairment or substance use that impedes study activities	$N = 10$	n/a	$N = 8$
Implementers and implementation experts	Persons with research or practical experience implementing new treatments/programs into practice who have considered or attempted to engage consumer groups in implementation, VHA or non-VHA settings; can reside in any country	Have not considered or attempted to engage consumers in implementation	$N = 5$	$N = 11$[a]	$N = 1$[c]
Community engagement experts	Persons of any discipline trained and experienced in engagement of consumers, communities, and other patient-level stakeholders in research or implementation, VHA or non-VHA settings; can reside in any country	No experience in consumer or community engagement	$N = 3$	n/a	$N = 2$
VHA personnel including suicide prevention champions in rural clinics	Persons employed in VHA, in a national or local role related to suicide prevention or safety planning intervention; included rural clinic mental health leaders	Not employed in VHA, general mental health researcher or employee with no clear expertise in suicide prevention	$N = 8$	n/a	$N = 3$

[a]These are 11 participants unique from participants in Step 1.
[b]These participants were from the same sample as recruited in Step 1.
[c]We sampled much fewer implementers in Step 3 than prior steps because they represented a group with more exposure to consumer engagement in implementation activities and by Step 3, we wanted to sample a group with less exposure to this topic for their "real-world" reactions to Consumer Voice tools.

consumers about an implementation strategy and higher intensity activities such as using patient and family advisory councils in hospitals, in which patients were voting members on hospital committees where decisions were made about policy or process. Some implementers wanted more intensive engagement, but got feedback that it was neither feasible nor of interest to consumers.

2) There is a recognized need for mentoring and coaching for learning to use consumer engagement implementation strategies. Implementers may not know how to engage consumers in implementation meaningfully. Engaging consumers may be something they have never considered nor been taught. Therefore, it would be important to seek out people who have experience engaging consumers (early adopters) to ask for information on their processes and skillset. Solutions might involve may be of lower intensity (e.g., shadow other experts) or more formal mentorship or longitudinal processes (e.g., ongoing consultation, learning collaborative).
3) Structures and processes to engage consumers need to be empowering for them. Consumers often have the least amount of legitimate power in the implementation process. Implementers usually belong to a health care system or organization that consumers are accessing for their needs to be met. There may be concerns about speaking up on how to improve these systems and how it may impact their care or services. To actively engage in power sharing, it is important to develop a sense of psychological safety, rapport, and activities where consumers are centered and heard, e.g., allowing consumers to select location of meetings, soliciting input from consumers on meetings processes, or co-leading meetings with consumers.
4) It is important to clarify whose voice we are hearing and who they represent. Consider who is the most likely to speak up during the implementation process and who is the most likely to have their feedback listened to and heard. Often the voices most heard during the implementation process are those with more power (e.g., leadership). There may be social characteristics of voices associated with the majority that are most often heard (e.g., cisgender, white, men). It is helpful to check in during the implementation process and ask ourselves and our implementation teams (1) who are we not hearing from? and (2) how can we bring them into the conversation?
5) We are not sure what the best solution is yet to support implementers using consumer engagement strategies. Existing resources to learn about this topic are not synthesized anywhere currently. Another challenge is the innate societal power structures encountered in consumer engagement work. Although we may provide recommendations and ways to consider minimizing power imbalances, those power structures are still in place and implementers often belong to institutions that may have a history of real and perceived harm toward consumers.

With these insights in mind, we agreed to compile prototypes in one location, providing easy and central access to implementers. The design team voted to prioritize and develop two low-tech prototypes that were used as a starting point in Step 1. The prototypes addressed building psychological safety in an implementation team where consumers would be present (insight #3) and building regular check-ins for an implementation team on how they are working together and if consumer voices are being heard (insight #3).

3.2. Step 1—discover: ideation (individual interviews and co-creation sessions)

3.2.1. Process

Then, in formal Step 1 of our study, we completed 1-hour interview and co-creation sessions with 26 participants via video conference or telephone from June to September 2021. Inclusion/exclusion criteria and sample size for Step 1 interviews are listed by participant group in Table 1. Sessions were audio recorded, and one interviewer took detailed notes using a template. The purpose of the interview sessions was to refine operational definitions of what tasks might be preferable in "involving consumers or family members in implementation or quality improvement activities," describe barriers to and facilitators for using these methods, and technical resources needed for Consumer Voice tools. We had two prototypes from our preliminary work we initially showed participants in Step 1, and they suggested new ones as well, so we co-created by either making or refining prototypes with participants during these interview sessions as well (22). We shared video screens in an online platform, consulting participants on what they wanted changed, their response to certain visuals or words, all while making refinements in real-time.

We asked questions about preferred types of consumer engagement and technical or logistic resources needed for consumer engagement in implementation activities. We presented a hypothetical scenario about consumer engagement in implementation activities, asking open-ended questions to inquire into their reactions. We often followed up on responses by probing with "five whys," posing the question "Why?" five times, thus prompting the participant to share very specific motivations or needs that are not always clear in their initial answer (23). See our supplemental file for interview guide.

Within 4–6 weeks of collecting data from Step 1 interviews, the research team analyzed the qualitative data using a rapid assessment process relying on audio recordings, notes, and summary templates in Microsoft Word software (24). This analytic technique is useful for studies in which there is a time-sensitive demand for creation/modification of a product, yet need for rigor (25). The qualitative analysis team included two coders (ENW and IAB) and a consulting researcher (KLD). The coders were a research assistant who completed a short course in rapid assessment processes for qualitative analysis and a PhD researcher who had taken part in the same short course and had training in other qualitative methodologies (e.g., grounded theory). The consulting researcher was a PhD anthropologist with extensive training and experience using qualitative analysis.

We blended inductive and deductive approaches, first reviewing audio recordings and notes from each interview, importing data into a written template with domains based on our specific interview questions to guide analysis deductively. We integrated new domains as emerging topics were mentioned repeatedly by participants. Before listening to recordings, two coders met to review note summaries and adapted the template as needed, eventually forming a blank master template. For the first five interviews, two coders listened independently to the audio recording, sorting data into the template categories. The coders met and discussed concepts after each interview to develop consensus and agreement and create a final master template for each participant. The coders then divided the remaining interviews between them, each templating all 26 interviews assigned to them independently. One coder reviewed all templates, asking and resolving questions from the other coder, creating a final set of individual templates.

Together, the coders synthesized data from individual templates from each participant across three matrices that addressed different topics: (1) operationalizing consumer engagement in implementation (i.e., who should be involved, how, when, where, and why); (2) suggestions for tools to teach others how to engage consumers in implementation (e.g., online platforms, reading materials, worksheets); and (3) barriers and strengths to anticipate when using the tools, with resources for reference. Within each matrix, coders organized data by participant type to identify patterns within groups (e.g., community members and organizers, implementation experts). The design team met, digested data from each matrix, then synthesized key insights and brainstormed potential solutions to each insight, listed below.

3.2.2. Key insights

We identified five key insights from our Step 1 activities. The insights shared a common theme related to building trusting between consumers and implementers. Specifically, insights included:

1) Implementers need to be prepared to really listen to consumer input and perspectives by responding empathically to consumer concerns. Implementers should resist defending one's practice and/or institution, and instead think about how they would want to be responded to in their own healthcare delivery. Lowering defensiveness would require increasing comfort with consumers seeing the "*dirty laundry*" behind the scenes when implementing innovations. Openly allowing criticism of the practice and/or institution can lead to trust building. Implementers need to use or develop skills to regulate themselves when receiving negative feedback.
2) There are several ways to recruit and engage consumers in implementation efforts. Options include, but are not limited to, using technology to overcome divides among consumers dispersed geographically, setting up feedback loops for local community members to express needs confidentially, providing resources for consumers to attend meetings (e.g., bus passes, tablets), meeting outside traditional work hours and locations, having specific tasks consumers can do in the effort, following through on tasks identified as key by the implementation team, and being thoughtful about how people are arranged to work together to minimize power differentials and increase engagement. Ongoing engagement is one way to build trusting relationships and overcome mistrust.
3) Implementers must work with diverse groups of people involved in the problem to garner different perspectives on the issue and form a more complete understanding of problems and potential solutions. People representing consumers in the implementation process need to be representative of specific populations who are target users of the innovation or evidence-based practice to be implemented. Consumers who had negative experiences with the topic or institution should be included also to fully understand their concerns and glean insights into how to become credible again (e.g., "dissatisfied customers").
4) Implementers need to showcase how consumer input is valuable to the implementation effort. If there is no discussion or follow through on consumer feedback on how/when/what implementation strategies should be used, it can lead to disengagement and mistrust. Examples of showing how consumer input is valuable included saying explicitly to consumers their voice matters and to please share, moving forward with action based on their input, and providing consumers with feedback of what happened with the input they shared.
5) Implementers must clarify roles of all team members and expectations. Examples included working on formal or informal agreements that communicate clear expectations regarding roles, time commitment, and how work will get accomplished for all involved. This also includes a clear and full orientation for consumers to what work needed to get done, when, how, and why.

Based on the above insights and prototypes voted on by the design team, the research team created new and refined existing prototypes to support implementers. One prototype that was created from our preliminary work was refined further in co-creation sessions with participants, which expanded on practical tips for implementers in creating and assessing for psychological safety among consumers (insight #1). Another prototype provided practical tips for implementers prepare to receive and respond to negative feedback from consumers (insight #1). A third prototype focused on using a visual spectrum to showcase a range of low-to-high intensity engagement strategies, such as one-time brief interactions to long-term equal partnerships (insight #2). A fourth focused on helping implementers balance a greater diversity of consumers involved with a small enough group format to enhance engagement (insight #3). Each insight did not yield a prototype in each step because the design team did not prioritize it above the other insights.

3.3. Step 2—build: user testing (with implementers)

3.3.1. Process

In Step 2, we asked implementers to pilot the prototype of Consumer Voice tools briefly in their own work and share feedback through focus groups. We recruited 11 participants to use full prototypes of Consumer Voice tools; focus groups were hosted May–June 2022. Using experience sampling (26), participants comprised implementers who would theoretically use Consumer Voice in their work inside VHA or outside VHA settings. Participants were given 2–4 weeks to use the Consumer Voice tool prototypes developed in Step 1 however they wanted. Although not required, we also asked participants to take notes specifically on the following questions as they used the tools: "Can you use this in your job?" and "What is missing?" Four participants provided written feedback.

Across focus groups, we asked participants the same three questions: "Could you actually engage consumers in your planning using these tools, and why or why not?" "What about the format needs to change and how?" "Did you feel confident about selecting modules, and why or why not?" Participants responded verbally. We used a qualitative rapid assessment process similar to what we used in Step 1, although with the goal to capture all feedback in a comprehensive manner rather than identify repeating ideas. Coders used note summaries and audio recordings from focus groups to populate one master template for all focus group qualitative and written data. The template captured: things they liked, things that were missing or needed changing, formatting, and other tools we might create. We summarized user feedback in an 11-page, single-spaced document including feedback on aspects they liked, things that needed improvement, and minor wording or formatting changes. The design team synthesized the data and generated additional insights and brainstormed prototype changes. Ultimately, we made every change the user testers suggested prior to showing the revised tools to users again in Step 3 rather than only prioritizing key insights.

3.3.2. Key insights

Users in Step 2 liked that the tools that were communicated via slide sets and word documents. They felt that tool content was almost comprehensive, and they perceived the value of the tools to help with meaningful engagement with consumers. As one participant said, "*If someone uses the materials, it's going to protect [consumers] from being invited to be a part of this in a tokenistic way*." Examples of aspects users did not like included being unsure how to start, as they felt the materials were overwhelming at first. They also felt there was not enough detail on assessing for power differentials between consumers and implementers. They identified key content that was absent from existing tools, such as information on how to compensate consumers for their contributions to the implementation process. By this step, we also had enough data from multiple perspectives to clarify our "design principles"—core elements that our solutions should follow in terms of how they presented materially. Our design principles were as follows:

- Materials must be "bite-size"—just enough to learn something, then have depth and examples for people who want to dig deeper.
- Simpler is better regarding web functionality and wording.
- Do not be prescriptive—give options for how to work with consumers.
- Use examples to showcase application of concepts.

Based on user feedback about content, we added new prototypes and refined existing ones. One new prototype was written guidance and a templated worksheet for implementers to consider and decide how to compensate consumers who help design or deliver implementation strategies. Another prototype was an entirely new module entitled "How to Use Consumer Voice" to address the concern that materials were overwhelming and needed more orientation. Based on user feedback about design principles, we added a real-world example to every module showcasing how to apply a concept, and ensured new prototypes adhered to the above design principles.

3.4. Step 3—build: refinement (focus groups using nominal group technique)

3.4.1. Process

In Step 3, we attempted to reconvene all participants from prior Steps 1 and 2 to share updated Consumer Voice tools and conduct a nominal group technique process to vote on the most feasible and important components of final prototypes (21, 22). Participants from all prior steps were invited to independently review revised tools and participate in a 1-hour group feedback session November–January 2023. See **Table 2** for participant demographics. To reduce power differentials and dual relationships with each other, feedback sessions were conducted separately for professionals and for consumers or community members. To increase participant inclusion and generate feedback from every participant, we used a nominal group technique process. Nominal group technique included the following steps. First, we asked one open-ended exploratory question: "What are the areas we need to improve upon in the Consumer Voice tools?" Participants had 5–10 min of quiet time to independently generate ideas. Second, participants reported their ideas orally to the larger group without discussion. Third, the group facilitator invited participants to ask questions to better understand an idea another participant had shared or elaborate upon their own comment. Finally, each person voted publicly on their top ideas to prioritize for impact. In the final step, we also collected demographic information from participants. We audio recorded feedback and took written notes. We ended each session with a list of prioritized recommendations.

Coders compared recommendations across all groups and created a matrix comparing recommendations between consumer/community members and professionals. The goal was to capture a subset of priority feedback areas rather than to comprehensively capture all feedback. Quantitative analysis was used to count final votes and to sum the frequency and percentages of votes.

TABLE 2 Demographic characteristics of 14 participants who completed steps 1 and 3[a].

Demographic characteristic	*N* (%)
Age	*Mean* = 41 years, *Range* = 34–51 years
Military veteran status	
Enlisted, non-commissioned officer, discharged	3 (37.5%)
Retired	1 (12.5%)
Part of professional organization serving veterans	2 (25%)
Family member or friend of veteran	1 (12.5%)
Other	2 (25%)
Gender identity	
Man	3 (38%)
Woman	5 (63%)
Disability status (mental, physical, cognitive)	
Yes	4 (50%)
No	3 (37.5%)
Did not report	1 (12.5%)
Racial identity	
Asian	1 (12.5%)
American Indian or Alaska Native	2 (25%)
White	6 (75%)
Sexual identity	
Straight or heterosexual	6 (75%)
Bisexual	1 (12.5%)
Lesbian, gay, or queer	1 (12.5%)
Geographic location	
Rural	2 (25%)
Urban	5 (62.5%)
Did not report	1 (12.5%)

[a]We did not collect demographic data from participants in Step 2 who were all implementers or implementation experts.

3.4.2. Key insights

Our nominal group process yielded a prioritized set of 8 refinements for the tools, four of which focused on content and four focused on usability. Content refinements included:

1. Emphasize which content helps build a trusting relationship with consumers and include more content on assessing power imbalances.
2. Reframe sections on "leading meetings" to clarify that people who share negative feedback are not "obstructive" but offer critical feedback based on legitimate lived experiences.
3. Emphasize content conveying that there are multiple avenues to engage consumers and avenues used should be sensitive to consumers' time limits, literacy, physical ability, etc.
4. Create a brief exercise for people to share with each other their own histories of engagement or work within their organization to help understand motivations and skills early.

Refinements focused on improving usability of the tools through better design included:

1. Condense content without removing any substantive details—one idea was to use audio voiceovers for slides.
2. Provide additional guidance to orient the user and help them know where to start.
3. Incorporate more examples from settings other than healthcare.
4. Make titles of modules more specific and action oriented.

We incorporated those suggested improvements into a final version of Consumer Voice tools, which are currently freely available to users outside VHA online (27) and users within VHA on a Sharepoint website (28). See **Figure 2** for evolution of key insights and prototypes over research and design activities.

4. Discussion

We blended human-centered design approaches with health service research methods to design a compendium of tools, Consumer Voice, to support implementers of new innovations in how to "involve consumers or family members in implementation or quality improvement activities" in a centralized location. Through discovery from multiple data sources and repetitive cycles of designing and building prototypes, we built the same, free compendium of tools on two different online platforms—one within VHA server (28) and one for people outside VHA on a cloud-based server (27). We identified principles for designing solutions (e.g., how the tools should function and what they should be like) and essential content (e.g., there are multiple ways to recruit consumers into implementation efforts, find a diverse set of consumers representative of the population you are trying to serve). The tools are modular and nonlinear tools allowing for self-guided learning tailored to beginner, intermediate, or advanced experience with consumer engagement.

Consumer Voice tools offer great specificity on the "what to consider" and "how to" for the consumer engagement implementation strategy "involving consumers or family members in implementation or quality improvement activities" (4). In other words, Consumer Voice offers multiple suggestions for implementers to engage consumers in the design/delivery of implementation strategies, which might include other consumer engagement implementation strategies (e.g., using mass media) or system-facing implementation strategies (e.g., redesign workflow, shadow other experts). It would be helpful for implementers using Consumer Voice to track strategies that emerged from their use of the tools.

Consistent with the Discover, Design, Build, and Test framework for human-centered design in implementation efforts, we will continue this work with a formal test of Consumer Voice. At the time of this publication, we are conducting a feasibility and acceptability assessment of Consumer Voice tools in the context of improving reach and quality of safety planning intervention among rural Veterans at moderate risk for suicide in VHA (29). We will combine Consumer Voice tools with Implementation Facilitation to address all levels of the implementation context. Another next step for research on consumer engagement in implementation, whether using Consumer Voice or other tools, is to assess their impact on implementation and effectiveness outcomes. The need for data on consumer-level outcomes of involving consumers in the design/delivery of implementation strategies was noted in a systematic review on this topic, which found that outcomes were typically reported for clinic/hospital/system of care but not for patients' experiences, behaviors, or health (30).

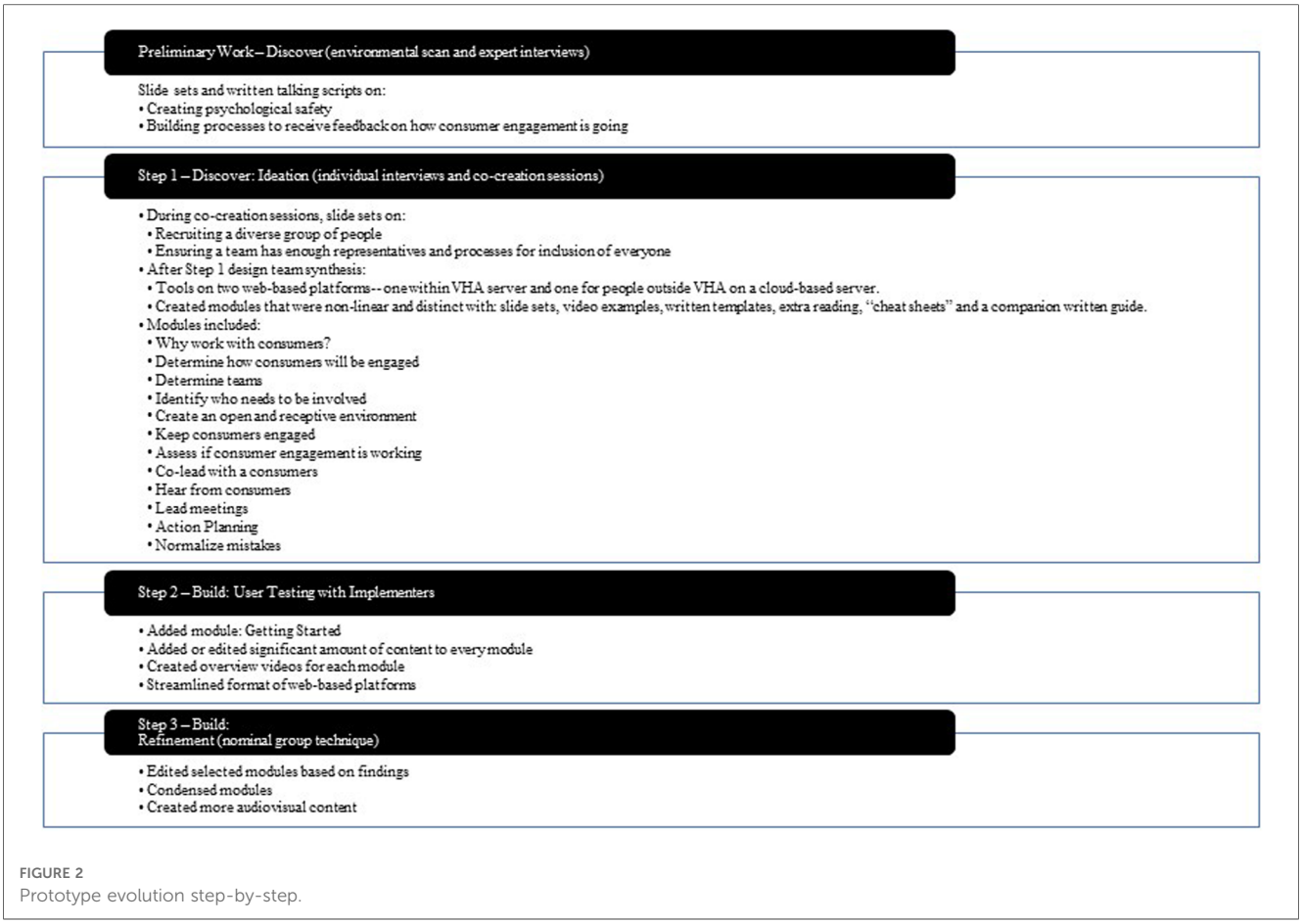

FIGURE 2
Prototype evolution step-by-step.

One interesting finding was that almost all key insights generated by the design team from the environmental scan and individual interviews with co-creation sessions explicitly served to build trust between consumers and professionals representing institutions. This is especially noteworthy if implementation activities are to reduce healthcare disparities and improve health equity through enhanced trust for consumers who have experienced significant neglect or harm from institutions providing services (e.g., 31–33). Key insights that ultimately informed Consumer Voice tools align well with a recent proposed theory of change related to trust-building in implementation efforts (34). Authors of this theory propose that to build trust during implementation efforts, implementers must focus on *what* (technical strategies) they do to engage with others and *how* (relational strategies). Specifically, technical trust-building strategies involve frequent interactions, responsiveness, demonstrating expertise, and achievement of quick wins; while relational strategies involve showcasing vulnerability, authenticity, bi-directional communication, co-learning, and empathy-driven exchanges. Many of our prototyped tools suggest these very technical strategies (e.g., make community agreements, discuss tactics to keep engagement confidential, compensate consumers) and ways to embody the relational strategies (e.g., balancing group discussion with options for anonymous or individual feedback, emotionally regulating oneself before a meeting when asking for critical feedback). An interesting next step in research would be to assess the impact of consumer engagement in implementation activities on trust, specifically, or assess trust as a moderator of change in other consumer-level or organizational-level outcomes.

Some design principles favored efficiency and clarity, which were not surprising given busy settings where people work. One design principle—do not be prescriptive about how consumers should be engaged, but instead, give options—is consistent with documented examples of consumer engagement in implementation efforts. There is a range of intensity of implementation activities, and the most intensive consumer engagement implementation strategy is not always feasible or ideal to either consumers or implementers, given the context (35). In Bombard et al.'s (2018) systematic review, intensity of engagement appeared to influence outcomes of the quality improvement or implementation effort. Discrete products such as brochures or policy documents typically derived from low-level (consultative) engagement, whereas care process or structural outcomes such as enhanced care or shared governance typically occurred when there was high-level (co-design) engagement (30). Lower intensity consumer engagement (in research, not implementation), such as consultation with unidirectional feedback, have been considered by other scholars to represent even non-participation or something symbolizing participation by consumers without meaningful contribution (36). Our results supported this conclusion and yet, also, recognized there is

variability across implementers *and* consumers regarding their ability and interest in higher intensity consumer engagement implementation strategies.

4.1. Limitations

This study has limitations. For one insight garnered in Step 1, "There is a recognized need for mentoring and coaching of learning," we did not design any solutions yet, as we believed the other insights could be addressed initially through a compendium of tools and we did not have the person or financial capacity to develop an ongoing mentoring or coaching program. Our qualitative analysis used rapid extraction and templates, rather than using written transcripts or deeper coding, so it is possible we missed some more nuanced viewpoint from participants. And yet, the rapid assessment process was generally well-suited as a data extraction method (vs. true qualitative coding and thematic analysis) because the questions and data generated from interviews were more straightforward feedback about the topic. Also, the design process took place in the U.S. state of Arkansas and focused on strategies to engage consumers in safety planning to prevent veteran suicide. Although we believe our process is applicable to other patient populations and settings, we also cannot speak to how the product generated through our human-centered design approach would compare to products generated using other strategies. We also collected demographics from participants in the final Step 3, resulting in missing demographic descriptors of some participants who contributed to Steps 1 and 2. Future testing of the effectiveness of Consumer Voice in multiple settings and with larger samples of implementers and consumers is needed prior to widespread adoption.

4.2. Conclusions

Including consumers in design/delivery of implementation strategies is increasingly recognized as essential for achieving equitable implementation and effects of innovations. Yet, there is still a great omission of principles and practical tips to engage consumers in implementation activities, which is essential if consumer engagement implementation strategies are going to have their desired effects. This study fills this gap by using a "consumer focused" approach to develop much-needed guidance for implementers to use as they begin to include consumers engagement implementation strategies, informed through meaningful consumer input, in their future implementation efforts. Although the resulting product, Consumer Voice, was developed in the VHA healthcare context and specifically focused on including rural Veteran patients in improving implementation of a suicide prevention intervention, our process included participants outside VHA and mental health care settings to increase applicability to other settings or health topics.

Data availability statement

The original contributions presented in the study are included in the article/**Supplementary Material**, further inquiries can be directed to the corresponding author.

Ethics statement

The studies involving human participants were reviewed and approved by Central Arkansas Veterans Healthcare System IRB, Little Rock. The patients/participants provided their written informed consent to participate in this study.

Author contributions

EW conceptualized the study, design and executed all data collection and analyses, led the design team, and contributed to writing this manuscript. IB collected and analyzed data, participated in the design team, and contributed results to this manuscript. CW helped conceptualize this study and its methods, training others as needed, participated in the design team, and contributed to writing this manuscript. RS participated in the design team, helped refine results, and contributed to writing this manuscript. CS participated in the design team, helped refine results, and contributed to writing this manuscript. DC participated in the design team and helped refine written results presented in this manuscript. KD helped conceptualize and guide analysis. SL helped conceptualize the study and guide methods. LH helped conceptualize the study, guide methods, and contributed writing to the manuscript. JK helped conceptualize the study, participated on the design team, and contributed writing to the manuscript. All authors contributed to the article and approved the submitted version.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Publisher's note

Supplementary material

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/frhs.2023.1124290/full#supplementary-material

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Implementing AI in healthcare—the relevance of trust: a scoping review

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Background: The process of translation of AI and its potential benefits into practice in healthcare services has been slow in spite of its rapid development. Trust in AI in relation to implementation processes is an important aspect. Without a clear understanding, the development of effective implementation strategies will not be possible, nor will AI advance despite the significant investments and possibilities.
Objective: This study aimed to explore the scientific literature regarding how trust in AI in relation to implementation in healthcare is conceptualized and what influences trust in AI in relation to implementation in healthcare.
Methods: This scoping review included five scientific databases. These were searched to identify publications related to the study aims. Articles were included if they were published in English, after 2012, and peer-reviewed. Two independent reviewers conducted an abstract and full-text review, as well as carrying out a thematic analysis with an inductive approach to address the study aims. The review was reported in accordance with the PRISMA-ScR guidelines.
Results: A total of eight studies were included in the final review. We found that trust was conceptualized in different ways. Most empirical studies had an individual perspective where trust was directed toward the technology's capability. Two studies focused on trust as relational between people in the context of the AI application rather than as having trust in the technology itself. Trust was also understood by its determinants and as having a mediating role, positioned between characteristics and AI use. The thematic analysis yielded three themes: individual characteristics, AI characteristics and contextual characteristics, which influence trust in AI in relation to implementation in healthcare.
Conclusions: Findings showed that the conceptualization of trust in AI differed between the studies, as well as which determinants they accounted for as influencing trust. Few studies looked beyond individual characteristics and AI characteristics. Future empirical research addressing trust in AI in relation to implementation in healthcare should have a more holistic view of the concept to be able to manage the many challenges, uncertainties, and perceived risks.

KEYWORDS

trust, artificial intelligence, implementation, healthcare, scoping review

1. Introduction

Artificial intelligence (AI) can be understood as "a computerized system that is equipped with the capacity to perform tasks or reasoning processes that we usually associated with the intelligence level of a human being" (1). These systems have the potential to transform healthcare at many levels and solve many of its current challenges (2–4), e.g., by reducing

costs and workloads, improving efficiency and quality, as well as by making earlier and more accurate diagnoses (2, 5). The expectations on AI are high and the European Union (2) and the European Commission are making significant investments in AI (6).

Despite the rapid development of AI and its potential benefits when implemented in healthcare, the process of translation into practice has been slow (7). AI systems tend to be complex, unpredictable, lack evidence, and difficult to grasp, hence the many uncertainties and risks related to its use, e.g., patient harm, bias, and lack of privacy (2). Trust in AI and its trustworthiness have therefore been regarded as important aspects to address (6, 8, 9). Based on literature from other scientific fields, trust is fundamental for a functioning health system (10) where patients are in vulnerable situations since it is known to increase the tolerance of uncertainty, as well as to reduce the perceived complexity (11). Trust is understood as a way of dealing with uncertainty (12), and according to Luhmann (13), trust is an attitude which leaves room for risk-taking behavior. To be trustworthy is a characteristic of someone who is competent to perform an action and has the moral attitude toward those who depend on the performance (14, 15). Being trustworthy helps in gaining trust but does not imply trust *per se* (16, 17).

Most research in AI in healthcare has so far been primarily focused on AI's performance (18), fairness, trustworthiness (8, 19–22), legal and ethical issues (21–27), and transparency and explainability (19–22, 24, 27).

Aspects such as AI's influence and interaction with the context in which it is implemented are also important to consider for successful implementation of AI (28). There appears to be a general lack of empirical research investigating implementation processes in relation to AI in healthcare (7, 28, 29). Health professionals are trusted and authorized to give advice and treatment based on their profession and expertise (30–33), and an implementation of AI into practice is believed to disrupt healthcare by questioning these health professionals' existing authority, as well as influencing organizational structures, roles, and practices (1, 7, 29). The many challenges, uncertainties, and perceived risks reflect the importance of trust in AI in relation to implementation in healthcare.

In order to successfully implement AI into routine applications in healthcare and change clinical practice, an understanding of trust in AI in relation to the change processes is needed. No previous studies exploring the concept trust in AI in relation to implementation in healthcare have to our knowledge been performed, which implies there could be a lack of conceptual clarity. Without a clear understanding of trust in AI, it could be difficult to identify implementation strategies, which means that AI will not advance despite the significant investments and possibilities. The aim of this paper was thus to explore the scientific literature regarding how trust in AI is conceptualized in relation to implementation in healthcare and what influences trust in AI in relation to implementation in healthcare.

2. Methods

2.1. Study design

We chose a scoping review methodology to explore all relevant literature addressing trust in AI in relation to implementation in healthcare, since this methodology is useful for identifying knowledge gaps, scoping a body of literature, or clarifying concepts (34). We used the methodological framework developed by Arksey and O'Malley (35) and followed the five stages: (1) identifying the research question, (2) identifying relevant articles, (3) selecting articles, (4) charting the data, and (5) collating, summarizing, and reporting the results. The review followed the recommendations in the Preferred Reporting Items for Systematic Reviews and Meta-Analysis for Scoping Reviews (PRISMA-ScR) checklist (34), and since it was based on publicly available studies there was no ethical consideration related to the handling of personal and sensitive information. A review protocol based on Arksey and O'Malley's (35) framework was developed, and the final version of the protocol can be found in **Data Sheet 1**.

2.2. Identifying the research question

To address the aim, we formulated two research questions:

1. How is trust in AI conceptualized in relation to implementation in healthcare?
2. What influences trust in AI in relation to implementation in healthcare?

2.3. Identifying relevant articles

A thorough search for published literature was developed and carried out together with an experienced librarian. Search terms included a combination of terms related to implementation, AI, and healthcare. We used standardized subject headings describing the terms and subcategories provided by the databases. Truncation of words allowed for alternative endings and were used for implementation, improvement, innovation, and intervention. The term trust had to be specific since the aim was to explore how trust was conceptualized in AI in relation to implementation in healthcare. The electronic database search was recorded in a table (**Data Sheet 2**). An initial search was carried out in CINAHL and PubMed to identify keywords and subject headings, which were then included in the search strategy for the selected databases. Five electronic databases (PubMed, CINAHL, PsychINFO, Web of Science and Scopus) were systematically searched to identify relevant scientific literature. In addition, reference lists of the identified research articles were reviewed manually.

The eligibility criteria ensured that the content of the included studies was relevant to the research question (36). The focus was on

trust in AI in relation to implementation in healthcare, and there was no restriction placed on the type of methodology used in the paper (e.g., qualitative, quantitative, mixed methods or theoretical). To be included, articles had to: (a) address "trust" in AI in (b) relation to implementation in healthcare. Although there are closely related terms for trust, we found it important to be specific since the aim was to conceptualize "trust" in AI in relation to its implementation in healthcare. Articles were excluded if they were non-English, not available in full text, not peer reviewed or published before 2012 (Table 1). The decision to exclude articles published before 2012 was made to allow a focus on more recent development of AI, due to its fast-changing nature. AI was uncommon in healthcare settings prior to 2012 (3).

We defined implementation as "An intentional effort designed to change or adapt or uptake interventions into routines", which was based on a definition used by two earlier reviews with a focus on implementation of AI into healthcare practice (7, 28). We also made a distinction between trust and trustworthiness, and we excluded studies that were only mentioning trust without giving it further attention or dealing with it in relation to implementation in healthcare.

2.4. Selecting articles

The eligible articles were uploaded into Endnote X9 software where duplicates were removed, and thereafter imported into Rayyan. The initial screening of titles and abstracts was conducted in collaboration between two reviewers (authors 1 and 2), who communicated and met regularly to discuss any disagreements or uncertainties regarding which articles to include or exclude based on selected criteria. If agreement could not be reached, the other authors were consulted through discussions. The full article was read if focus of an article was unclear based on title and abstract. In the next step, the same two reviewers (authors 1 and 2) independently conducted the full-text review on the remaining articles, and disagreements and uncertainties were again resolved through discussion with the other authors.

2.5. Charting the data

First, we developed a standard data charting form, following the guidelines by Arksey and O'Malley (35), based on characteristics of the articles: (1) country; (2) publication year; (3) methodological design; (4) healthcare setting; (5) aim of the study; (6) application area; (7) intended user; (8) definition of trust (Table 2). Two reviewers (authors 1 and 2) extracted the data from the articles and thereafter confirmed with the other authors. The aim was to explore all relevant literature rather than provide a quantitative or qualitative synthesis. The methodological quality or risk of bias of the included studies were therefore not reviewed, which is consistent with guidance on the conduct of scoping reviews (35, 37).

TABLE 1 Inclusion and exclusion criteria.

Inclusion criteria	Exclusion criteria
- Studies addressing trust in relation to implementation of AI in healthcare. - Peer reviewed	- Abstract missing. - Published before 2012. - Not in English. - Only mentioning trust.

2.6. Collating, summarizing, and reporting the results

We then used a thematic analysis with an inductive approach to analyze data associated with the research questions, how trust in AI is conceptualized in relation to implementation in healthcare and what influences trust in AI in relation to implementation in healthcare. We followed the guide of Braun and Clarke (50) with six phases: (1) data familiarization; (2) initial code generation; (3) generating themes; (4) theme review; (5) theme defining and naming; (6) and report production. The first step involved reading and rereading the articles, as well as making notes. Two reviewers (authors 1 and 2) reflected individually and generated independently lists of codes from words and phrases, which were coded regarding trust in AI in relation to implementation in healthcare. The reviewers then compared their codes and interpretations, and the relationships between the codes were discussed, which were referred to as subthemes. The conceptualization of trust was either clearly defined or defined by its determinants. The subthemes were then analyzed, and three overarching themes were generated. All authors discussed continuously the data analysis to enhance its quality and validity. No qualitative data analysis software was used.

3. Results

A total of 815 articles were retrieved from the five databases. Three articles were identified through manual searches of reference lists. The number of articles for review was reduced to 454 after duplicates were removed. 426 of the 454 (93.8%) were excluded in the title and abstract screening, for reasons highlighted in Figure 1. The term trust was often only mentioned, but not further addressed ($n = 170$). 235 articles investigated trust but not in AI in relation to implementation, thirteen articles were not in the healthcare setting, six articles were published before 2012 and two articles had no abstract. This resulted in a high number of excluded articles. Only 28 articles remained for full text review. Twelve of these articles were excluded because they only mentioned trust and did not further address or elaborate on the concept in the full text, and eight articles were excluded because they did not address trust in relation to AI implementation in healthcare. A total of eight articles met all criteria and were included in the study.

3.1. Study characteristics

The included studies were published between 2018 and 2022. Most articles were from the United States ($n = 3$), two from

TABLE 2 Characteristics of included studies .

Author(s)	Country of origin	Methodological design	Healthcare setting	Aim of the study	Application area	Intended user	Definition of Trust
Datta Burton et al. (38), 2021	The United Kingdom	Opinion paper, with empirical support	Neurology	To explore questions of trust between patients and clinicians and between clinicians and researchers.	Brain modelling	Clinicians (unspecified)	A triangle of trust; "relationships between patients and clinicians, and between clinicians and researchers" (38).
Choi et al. (39), 2020	The United States & Canada	Opinion paper, without empirical support	Radiology	To outline several ethical and practical concerns in integrating AI with human cognition in the real-world: bias and pitfalls of AI, ethics of trust and risk regarding AI, and design of the human—AI interface.	Image recognition	Clinicians (radiologist)	"A human's propensity to submit to vulnerability and unpredictability, and nevertheless to use that automation, as measured by intention expressed in speech or writing, or by measurable bodily actions to actually use the automation" (40).
Esmaeilzadeh et al. (41), 2021	The United States	Quantitative: survey study	Healthcare, general	To examine how potential users perceive the benefits, risks, and use of AI clinical applications for their healthcare purposes and how their perception may be different if faced with three healthcare service encounter scenarios.	Diagnosis and treatment	Patients (with acute or chronic conditions)	"Trust can be defined as trust in clinicians and the clinical tools they use (such as AI clinical applications)" (42).
Fan et al. (43), 2018	China	Quantitative: survey study	Hospital	To explore the adoption of artificial intelligence-based medical diagnosis support system by integrating Unified theory of user acceptance of technology and trust theory.	Diagnosis	Clinicians (unspecified)	"The beliefs about a technology's capability rather than its will or its motives." (44).
Liu & Tao, (45), 2022	China	Quantitative: survey study	Healthcare service delivery	To examine the roles of trust and three AI-specific in public acceptance of smart healthcare services based on an extended Technology Acceptance Model.	Smart healthcare services	The general population	"The degree to which an individual perceives that smart healthcare services are dependable, reliable, and trustworthy in supporting one's healthcare activities" (45).
Prakash & Das, (46), 2021	India	Mixed methods	Radiology	To develop and test a model based on theories of Unified Theory of Acceptance and Use of Technology, status quo bias, and technology trust.	Diagnosis	Clinicians (radiologist)	"The willingness of a party to be vulnerable to the actions of another party…" (47).
Roski et al. (48), 2021	The United States	Opinion paper, without empirical support	Healthcare, general	To describe how AI risk mitigation practices could be promulgated through strengthened industry self-governance, specifically through certification and accreditation of AI development and implementation organizations.	AI, general	N/a	N/a
Yakar et al. (49), 2021	Netherlands	Quantitative: survey study	Radiology, dermatology, and robotic surgery	To investigate the general population's view AI in medicine with specific emphasis on three areas that have experienced major progress in AI research in the past years, namely radiology, robotic surgery, and dermatology.	Diagnosis, communication, and surgery	The general population	N/a

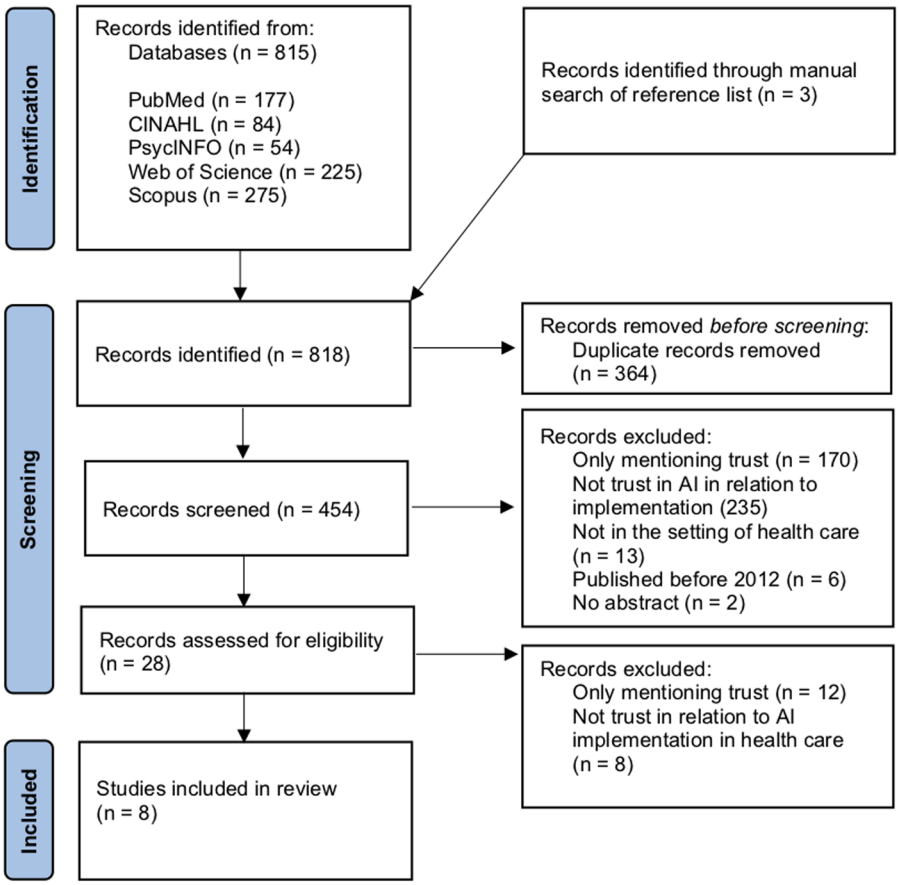

FIGURE 1
PRISMA-ScR flowchart.

China, and the remainder from the United Kingdom ($n = 1$), India ($n = 1$), Canada ($n = 1$) and Netherlands ($n = 1$). Many of the studies ($n = 6$) were conducted in hospital settings (neurological practice, radiology, dermatology, and robotic surgery), except for two studies which involved healthcare management at home and healthcare in general. AI was often used for diagnosis ($n = 4$). Other application areas were brain modelling (1), image recognition (1), smart healthcare services (1), treatment (1), surgery (1), communication (1). One study was too general to have a specific purpose. Four studies were based on quantitative studies, three were opinion papers, and one mixed method. The studies examined the perceptions of different intended users: clinicians ($n = 4$), general population ($n = 2$), and patients ($n = 1$). The characteristics of the included studies are shown in **Table 2**.

3.2. How is trust in AI conceptualized in relation to implementation in healthcare?

Six out of the eight studies provided a definition of trust (**Table 2**). Most empirical studies had an individual perspective where trust was directed toward the technology's capability ($n = 4$), e.g., describing trust as human's propensity or willingness to submit to the vulnerability of the technology's capability (39, 43, 46) or the perception of AI as being dependable, reliable, and trustworthy in supporting healthcare activities (45). Two studies had a contextual perspective and focused on trust as relational between people in the context of the AI application rather than having trust in the technology itself. Datta Burton et al. (38) argued that it is necessary to develop the human side of these tools, which represents a triangle of trust relationships: between patients and clinicians, and between clinicians and researchers. Esmaeilzadeh et al. (41) focused on care encounters and understood trust as the degree to which an individual believes that the clinical encounter is trustworthy and referred to Reddy et al. (42) who understood trust as "Trust is in the clinicians and the clinical tools they use". Two studies only defined trust indirectly by describing trust determinants (48, 49).

3.3. What influences trust in AI in relation to implementation in healthcare?

The inductive coding yielded three themes regarding what influences trust in AI implementation in healthcare, which could be understood as interconnected: *individual characteristics, AI characteristics, and contextual characteristics*. These themes were based on 10 subthemes and 34 codes (**Table 3**).

TABLE 3 Influences of trust in relation to implementation of AI in healthcare based on inductive thematic analysis.

Themes	Subthemes	Codes	Articles
Individual characteristics	Demographic characteristics	Age, education, sex/gender, geographic origin, and employment.	(43, 45, 46, 49)
	Knowledge	Usage experience, tacit knowledge, and tech skills.	(38, 43, 45, 46, 49)
	Personal traits	Cognition and positive attitude.	(43, 46, 49)
	Health condition	Health condition and healthcare consumption.	(41, 49)
AI characteristics	Individualization	Personalization, privacy, and anthropomorphism.	(41, 45)
	"Black box"	Self-learning, non-transparent, and autonomous.	(38, 39, 41, 46, 48)
	Technical objectivity	Data-driven, accurate, lack of moral values, and lack of empathy.	(38, 39, 41, 46, 49)
Contextual characteristics	Healthcare culture	Medical area, task complexity, "skilled clinician", professional expertise, custodians, and opinion of important others.	(38, 41, 43, 46, 49)
	Interpersonal relations	Collaboration, personal interactions, and mutual understanding	(38, 41, 48, 49)
	Governance	Policies, guidelines, and standards/regulation.	(38, 39, 41, 48)

3.3.1. Individual characteristics

The individual characteristics capture those qualities that make the individuals different from each other, such as age, sex/gender, personality. These characteristics influence individuals' trust in AI in relation to an implementation in healthcare. *Demographic characteristics* such as gender, age and education were found to relate to trust by moderating the relationship between antecedents and behavioral intention ($n = 4$). For example, being male, higher educated, employed or student, and with Western background were predictors of trust in AI among the general population (49). Disposition to trust technology (a person's general tendency to be willing to depend on technology) varied among clinicians based on their living experiences (43) and cultural background (43, 46). *Knowledge* and technological skills were found to influence trust in AI ($n = 5$), which emphasized the need for education and training (49). Four studies understood trust as influenced by earlier usage experience or technological skills (38, 43, 45, 46), e.g., radiologists were used to highly complex machines in their routine clinical practice, and ease of use may therefore not be a concern in the adoption-related decision making (46). *Personal traits* such as cognition and having a positive attitude were associated with higher levels of trust ($n = 3$), e.g., disposition to trust technology was related to trust in AI use (43, 46), and understood as influenced by the individual's cognition and personality (46). *Health conditions* and healthcare consumption were also something that influenced trust ($n = 2$), e.g., individuals with chronic conditions may not trust AI clinical applications if no physician interaction were included in healthcare delivery (41) and individuals who utilized less healthcare were associated with a higher level of trust in AI (49).

3.3.2. AI characteristics

Trust in relation to the characteristics of AI was frequently mentioned in the literature, where aspects such as its performance, capacity, and trustworthiness were focused on. AI's ability to *individualization* was shown to enhance trust, which was understood as care tailored to the patients' unique needs ($n = 2$). Personalization was based on patients' health information, which required sharing sensitive personal data and caused concerns such as risks of privacy breaches (41, 45). AI's anthropomorphic characteristics enhanced trust in AI in relation to an implementation since it generated a sense of social presence. It was referred to as the perceived level of humanlike characteristics such as human appearance, self-consciousness, and emotion (45). AI characteristics such as "*black box*", self-learning, non-transparent and autonomous characteristics brought uncertainty and threatened trust in the implementation of AI ($n = 5$), since inputs and operations were not visible to the user. *Technical objectivity*, which included characteristics such as data-driven, accuracy, lack of moral values, and lack of empathy, was also related to trust ($n = 5$), since they in some cases could produce results that were more accurate and reliable than those of even the most skilled diagnostician (38).

3.3.3. Contextual characteristics

The theme contextual characteristics concerned the influence on trust in AI in relation to implementation in healthcare regarding the context in which individuals and AI are embedded. The contextual characteristics in relation to implementation of AI in healthcare consisted of the following subthemes: *healthcare culture, interpersonal relationships, and governance. Healthcare culture* included medical area, professional expertise, and opinion of important others ($n = 5$). For example, a "skilled clinician" was considered someone who had embodied tacit knowledge through years of experience in a community of experts (38). Opinion of important others, such as clinicians, colleagues, and seniors, shaped individuals' initial trust (43, 46). Trust in AI in relation to implementation in healthcare depended also on the medical area, e.g., the perceived risks of using AI in radiology and dermatology compared to robotic surgery (49). *Interpersonal relationship,* collaboration, personal interactions, and mutual understanding were found to influence trust ($n = 4$), especially between different stakeholders (38, 48). Thus, reduced communication in relation to AI implementation was believed to result in less trust among patients (41, 49). Yakar et al. (49) investigated trust in AI in the areas of radiology, surgery and dermatology, and the results showed that those who found personal interactions important had less trust in all three areas. *Governance,* including policies, standards, and guidelines had to be defined to enhance trust in AI ($n = 4$). The lack of clear guidelines in medical context was believed to lead to more uncertainties and less trust (41). Roski et al. (48) highlighted the importance of different stakeholder-consented framework and goals to enhance trust, which was also a condition for self-governance. Datta Burton et al. (38) suggested policies that encourage greater clinician engagement in the evaluation of a computational model that would lead to more responsible adoption.

4. Discussion

This study was conducted to explore the scientific literature regarding how trust in AI is conceptualized in relation to implementation in healthcare and what influences trust in AI in relation to implementation in healthcare. Only eight studies were found to meet the strict inclusion criteria. The results showed that the conceptualization of trust in AI differed between the studies, as well as what they accounted for as influencing trust. We identified three themes that influenced trust in AI in relation to implementation in healthcare: individual characteristics, AI characteristics and contextual characteristics. Most research focused on the individual characteristics or AI characteristics, and the focus was rarely on the context or implementation processes.

AI in healthcare is a relatively new endeavor but the use of AI has become more common in healthcare setting during the past decade (3). Studies on the implementation of AI in healthcare are therefore fairly new research areas. This could explain the low number of included studies, which all were recently published and mostly from high income countries. Another explanation for the low number could be that trust is rarely mentioned in implementation science frameworks, theories, or models (51). The findings showed that the intended users were often clinicians (38, 39, 43, 46), which also aligns with implementation science where the focus is on clinicians rather than patients. Most of the empirical studies were cross-sectional where questionnaires were used to measure trust as the individual's attitudes and perceptions of AI's capability (41, 43, 45, 49) rather than considering other influencing variables. These studies discussed AI at a general level where the individuals had no or very little experience with practical AI tools, instead of addressing trust where the tools have been implemented and used over longer periods. One should thus be careful in using these perspectives in the development of implementation strategies to avoid building strategies on opinions, perceptions, and potential misconceptions rather than on actual experiences. Moreover, these fairly superficial perspectives on trust in AI in relation to implementation give little insight since they do not consider the context and the underlying values.

The conceptualization of trust in AI in relation to implementation in healthcare differed between the included studies. Some studies focused on individual characteristics and AI characteristics (39, 43, 45, 46, 49), and other studies concentrated on the relations between people (38, 41). Trust in AI in relation to implementation in healthcare did not always have a specific definition. Instead, it was understood indirectly as influenced by different characteristics or determinants, and as having a mediating role, positioned between perceptions of AI characteristics and AI use. These different approaches to trust in AI reveal its complexity and the need of having a holistic understanding of the concept spanning different levels and dimensions.

The three themes that was found to influence trust in AI in relation to implementation in healthcare can be compared to implementation science, which emphasizes the determinants that influence the implementation by understanding the context in which they are used (52, 53). In line with Leeman et al. (54). The determinants to facilitate implementation need to be known for appropriate strategies to be chosen. The themes are well-aligned with the Consolidated Framework for Implementation Research (CFIR), which is one of the most widely used determinant frameworks in implementation science (**Figure 2**). Trust could be placed in the assessment category in CFIR, situated between determinants and outcomes, where also the concepts of acceptability, appropriateness, feasibility, implementation readiness and implementation climate are placed (55).

The theme individual characteristics such as an individual's circumstances was shown to influence trust in AI (38, 41, 43, 45, 46, 49). The result showed that individuals in vulnerable positions (less educated people, unemployed, people with non-Western immigration background, older people, and patients with chronic conditions) had low degree of trust in AI (49). Hence, the relationship between trust and the individuals' perception of control or empowerment. This may be consistent

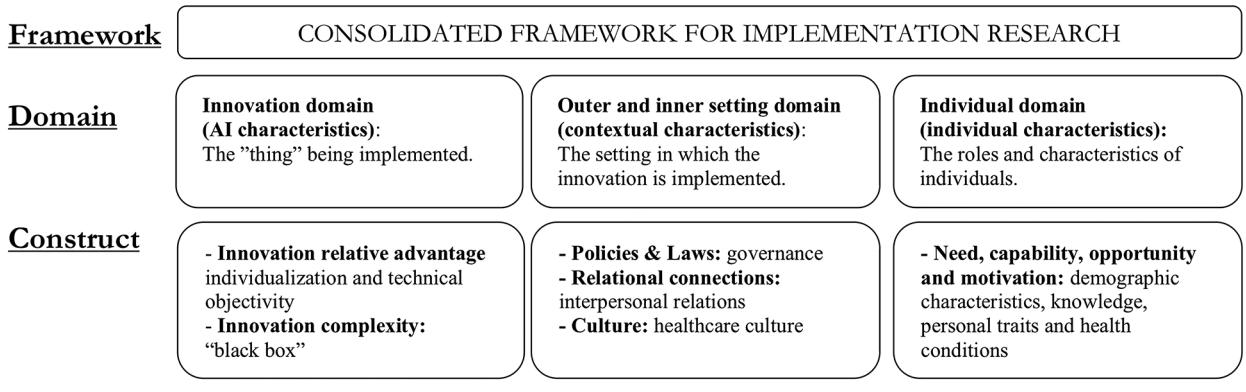

FIGURE 2
The determinants associated with trust in AI in relation to implementation in healthcare mapped onto CFIR domains and Constructs (55).

with Luhmann (11) who argued that people are willing to trust if they possess inner security. Moreover, perceptions of AI characteristics such as being a non-transparent "black box" with autonomous and self-learning capacity were related to lack of trust in AI since these characteristics obstruct the understanding of its decisions. Knowledge and technological skills were other aspects that were shown to enhance trust in AI, which may also be understood as related to control or empowerment.

This study showed that trust in AI in relation to implementation in healthcare may be related to knowledge within a context. People's perception of AI as meaningful, useful, or valuable contributed to trust (38, 39, 41, 43, 45, 46). The results showed that trust in AI was not only influenced by its "technical" objectivity, efficiency, and accuracy. For example, person-centered care does not only consider medical competence as technical skills but also relational moral competency, empathy, compassion, and trust (41), which could explain why AI's anthropomorphic characteristics and personalization enhanced trust in AI (45). Healthcare culture is based on knowledge within a context and could be why the individuals' trust in AI was often shaped by important others (43, 46, 49), as well as why interpersonal relationships, collaboration and common understanding were found to influence trust (38, 41, 48, 49). It also explains the importance of governance and the need of common guidelines (38, 39, 41, 48).

Knowledge within a context and its influence on trust in AI in relation to implementation in healthcare could be compared to Normalization Process Theory (NPT), another widely used theoretical approach in implementation science. The theory understands implementation as a possible challenge toward individuals' existing ways of working or thinking about care (56). NPT suggests that people need to make sense of AI together to understand their specific roles and responsibilities in relation to AI use in healthcare, and the importance of new agreements and values that give meanings to their actions (57). This could be explained by our ability to contextualize information through narratives (58), which is also in line with Luhmann (11) who viewed trust as possible only in a familiar world.

Only considering AI's technical aspects when implementing AI in healthcare is not enough. AI tools should not be understood apart from the context and the people using them. Existing values and understanding of care can become barriers to trust in AI in relation to implementation in healthcare if there is a lack of coherence. There is thus a need to understand the context in relation to implementation (59) to be able to align AI to existing values (38, 57). Differences in values must be considered for trust to be present when implementing AI in healthcare. The use of AI could thus add value to clinical reasoning rather than competing with it according to Datta Burton et al. (38).

4.1. Strength and limitations

The study has some strengths that are worth highlighting. The search was designed together with a librarian and the selection of relevant studies were conducted independently by two reviewers with consensus. We used a comprehensive search strategy and adhered to a structure for scoping reviews outlined by Arksey and O'Malley (35).

The study also has shortcomings that must be considered when interpreting the findings. Trust in AI in relation to implementation in healthcare relates to a young research field, and we found it therefore necessary to include any type of methodology in this study. This means the conceptualization of trust in AI was based on both results and reflections. The study was limited to the published literature in English, and we did not search wider grey literature where we may have identified additional relevant literature. Only a small number of articles met the strict inclusion criteria since many of the articles were excluded because they only mentioned trust or did not address trust in AI in relation to implementation in healthcare. Most of the included studies were conducted in high-income countries and the results may therefore not be relevant to other countries.

4.2. Implications and suggestions for future work

This scoping review showed that there were different approaches to trust, which demonstrates that trust can be understood at different levels and dimensions. Only considering one aspect could mean that inappropriate strategies are used to support implementation. For example, there were few empirical studies that addressed trust beyond individual characteristics and AI characteristics. Future empirical studies thus need to have a holistic view on trust. The results also showed that in order to establish trust in AI in relation to implementation in healthcare, it is important to align AI to existing values and to take account of social interactions and negotiants of values in relation to care. This scoping review also found that trust in AI was often influenced by the opinion of important others (43, 46). Future studies could therefore investigate how these important others facilitate trust in AI in relation to implementation in healthcare. Three of the included studies mentioned that trust grows with time and maturity (39, 43, 46). However, none of these studies investigated this change empirically. There is therefore also a need for a better understanding of how trust in AI changes during implementation in healthcare.

5. Conclusions

Findings from the scoping review revealed that there is a variation in the scientific literature how trust in AI in relation to its implementation in healthcare has been conceptualized. Trust is often conceptualized by its determinants and having a mediating role, positioned between characteristics and AI use. There were also differences in what was believed to influence trust in AI. We found three themes that influenced trust in AI in relation to implementation in healthcare: individual characteristics, AI characteristics and contextual characteristics. Today, most research focuses only on one or two perspectives,

for example the individual characteristics or the AI characteristics. Future studies addressing trust in AI in relation to implementation in healthcare should have a more holistic view on trust to be able to manage the many challenges and develop appropriate strategies to support the implementation of AI in healthcare.

Data availability statement

The original contributions presented in the study are included in the article/**Supplementary Material**, further inquiries can be directed to the corresponding author/s.

Author contributions

ES conceptualized the study with input from author PN, PS and JN. All authors contributed to the study design. ES retrieved the records from the databases. Authors ES and ES participated in the screening process and the extraction of the data. Data analysis was performed by authors ES and ES, and then discussed with all authors. The manuscript was drafted by ES with input from the other authors. All authors thereafter drafted and revised the manuscript and approved the final version.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

The author PN declared that they were an editorial board member of Frontiers, at the time of submission. This had no impact on the peer review process and the final decision.

Publisher's note

Supplementary material

The Supplementary Material for this article can be found online at https://www.frontiersin.org/articles/10.3389/frhs.2023.1211150/full#supplementary-material

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Toward a more comprehensive understanding of organizational influences on implementation: the organization theory for implementation science framework

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Introduction: Implementation is influenced by factors beyond individual clinical settings. Nevertheless, implementation research often focuses on factors related to individual providers and practices, potentially due to limitations of available frameworks. Extant frameworks do not adequately capture the myriad organizational influences on implementation. Organization theories capture diverse organizational influences but remain underused in implementation science. To advance their use among implementation scientists, we distilled 70 constructs from nine organization theories identified in our previous work into theoretical domains in the Organization Theory for Implementation Science (OTIS) framework.

Methods: The process of distilling organization theory constructs into domains involved concept mapping and iterative consensus-building. First, we recruited organization and implementation scientists to participate in an online concept mapping exercise in which they sorted organization theory constructs into domains representing similar theoretical concepts. Multidimensional scaling and

Abbreviations
CFIR, consolidated framework for implementation research; CPCRN, cancer prevention and control research network; EPIS, exploration, preparation, implementation, sustainment; OTIS, organization theory for implementation science; TDF, theoretical domains framework.

hierarchical cluster analyses were used to produce visual representations (clusters) of the relationships among constructs in concept maps. Second, to interpret concept maps, we engaged members of the Cancer Prevention and Control Research Network (CPCRN) OTIS workgroup in consensus-building discussions.

Results: Twenty-four experts participated in concept mapping. Based on resulting construct groupings' coherence, OTIS workgroup members selected the 10-cluster solution (from options of 7–13 clusters) and then reorganized clusters in consensus-building discussions to increase coherence. This process yielded six final OTIS domains: organizational characteristics (e.g., size; age); governance and operations (e.g., organizational and social subsystems); tasks and processes (e.g., technology cycles; excess capacity); knowledge and learning (e.g., tacit knowledge; sense making); characteristics of a population of organizations (e.g., isomorphism; selection pressure); and interorganizational relationships (e.g., dominance; interdependence).

Discussion: Organizational influences on implementation are poorly understood, in part due to the limitations of extant frameworks. To improve understanding of organizational influences on implementation, we distilled 70 constructs from nine organization theories into six domains. Applications of the OTIS framework will enhance understanding of organizational influences on implementation, promote theory-driven strategies for organizational change, improve understanding of mechanisms underlying relationships between OTIS constructs and implementation, and allow for framework refinement. Next steps include testing the OTIS framework in implementation research and adapting it for use among policymakers and practitioners.

KEYWORDS

organization theory, implementation, determinant framework, concept mapping, consensus-building

Introduction

Individual healthcare providers' behaviors are often constrained by factors that are beyond their own control (1). The assumption that all behaviors are largely under conscious control has taken a "theoretical battering" due to research showing the importance of non-conscious processes that operate in organizations (2). Research suggests that many healthcare provider behaviors that are repeatedly performed become non-reflective and more or less automatic (3). Individual behavior is also constrained by factors at collective levels (1). Collective levels include interpersonal (e.g., relations between healthcare providers), group (e.g., healthcare professionals providing care in a breast medical oncology practice), intraorganizational (e.g., hospital culture), and interorganizational (e.g., accreditation standards). Collective-level influences may also be largely non-conscious, having become internalized and taken for granted (e.g., norms and values of a professional culture) (1).

Various implementation determinant frameworks include factors at the organizational level. For example, the Consolidated Framework for Implementation Research (CFIR) and the Exploration, Preparation, Implementation, Sustainment (EPIS) Framework include inner setting (i.e., intraorganizational) and outer setting (i.e., interorganizational) domain (4, 5). Domains are comprised of constructs (i.e., explanatory concepts that cannot be directly observed but can be inferred from observed data) (6). Organization-level domains include constructs such as *structural characteristics* ("the social architecture, age, maturity, and size of an organization"), *cosmopolitanism* ("the degree to which an organization is networked with other external organizations"), and funding ("fiscal support provided by the system in which implementation occurs") (7–9). The Theoretical Domains Framework (TDF) similarly includes the environmental context and resources domain, which includes constructs such as *material resources* and *barriers and facilitators* (10).

Commonly used implementation determinant frameworks encourage implementation scientists to consider organizational influences on implementation; however, the scope of organization-level constructs described in extant frameworks is limited. Furthermore, determinant frameworks often lack explanations of the mechanisms underlying the relationships between organization-level constructs and implementation. Extant frameworks' limited scope impedes progress in implementation science by obscuring the influence of organization-level constructs that may drive implementation outcomes. A substantial body of work in industries other than healthcare provides evidence of the significant influence of organizational influences on implementation, pointing to high-leverage strategies to promote organizational change. Organization theory has been applied to educational and budgetary reform, elucidating the critical importance of addressing power dynamics among leadership and fostering positive change culture to facilitate implementation (11, 12). In the non-profit industry, organization theory can be used to build capacity, assist with decision-making, narrow target populations, and clarify organizational needs (13).

Failing to account for the critical influence of organization-level constructs on implementation introduces omitted variable bias–i.e.,

the faulty attribution of the influence of the omitted variable(s) to variables that were included (14). In the case of implementation research, this may amount to, for example, attributing the influence of organizational inertia (i.e., resistance to change) to a construct that is related but distinct (e.g., readiness for implementation) or an unrelated construct (e.g., individual provider motivation). The misattribution of omitted organization-level constructs to the constructs that extant implementation frameworks include has important implications for subsequent stages of implementation research, such as selecting and identifying strategies to target the constructs influencing implementation.

Many extant implementation determinant frameworks are conceptual frameworks, in that they offer a menu of constructs thought to influence implementation, but they do not address how change takes place or any causal mechanisms, which is critical for falsifying hypothesized relationships through empirical study (15). The ability to falsify hypothesized relationships between constructs depends on explanations of the mechanisms underlying relationships between constructs that are derived from theory (16). The constructs in conceptual frameworks such as the CFIR derive from a combination of theory and empirical studies. For example, the CFIR *peer pressure* construct derives from Institutional Theory, but *patient needs and resources* derives from a combination of empirical evidence and other conceptual frameworks rather than theory.

In contrast to conceptual frameworks, theoretical frameworks are based on theories, which propose mechanisms underlying the relationship between constructs and implementation. One commonly used theoretical framework in implementation science is the TDF. As a theoretical framework, the TDF can be used to identify mechanisms proposed in included theories; however, the TDF does not offer nuanced insight into organization-level influences on implementation. The TDF's environmental context and resources domains contains constructs that derive from several theories that are identified as organization theories; however, many of the included theories are not in fact organization theories (e.g., decision-making theory). As such, the TDF is limited in its contributions to understanding organization-level influences on implementation.

Organization theories provide explanations for the complex interactions within and between organizations and their context (environment, surrounding policies, cultural norms). These theories not only describe and explain these interactions, but can also be used to predict implementation outcomes based on contextual factors. Organization theories have the potential to explain how policies, institutions, funding, and workforce dynamics affect implementation outcomes (17). Organization theories have been historically used to an explanatory tool in fields of education, nonprofit organizations, management, and health services research, dating back to the 1950 s (11–13, 18, 19). These theories, while widely used and published, remain largely inaccessible outside of organization science. Organization theories provide their own inventory of constructs, which often require significant training to apply with fidelity.

To equip implementation scientists with understanding of a broader scope of organization-level constructs and their hypothesized influence on implementation, a comprehensive yet accessible framework of organizational influences on implementation is needed. In this paper, we describe the development of the Organization Theory for Implementation Science (OTIS) framework, which summarizes constructs from nine organization theories identified as relevant to implementation in preliminary studies (20). Our overarching goal is to increase implementation scientists' familiarity with and conceptualization of the myriad organizational factors that influence implementation through mechanisms clearly articulated by organization theories.

Materials and methods

We developed the OTIS framework using a combination of concept mapping and iterative consensus-building, with support for interpretation from members of the Cancer Prevention and Control Research Network (CPCRN) OTIS workgroup (21). CPCRN is a national network of academic, public health, and community partners whose work focuses on reducing the burden of cancer within specific workgroup and interest group projects. CPCRN OTIS workgroup members include investigators conducting research at the intersection of implementation science and cancer prevention and control. This study was approved by the Wake Forest University School of Medicine IRB (IRB00072134) on 6/2/21.

Concept mapping

Recruitment and sampling

We used a purposive sampling approach to recruit approximately 25 scholars with expertise at the intersection of implementation and organization science to participate in an online concept mapping exercise via the Concept Systems Global MAX™ web platform (22). The premise of our sampling approach for the survey on organization theories of relevance to implementation science that provided the foundation for this study was that scholars with primary training in implementation and organization science had the knowledge required to identify organization theories with relevance to implementation science. For this study, we purposively included a more diverse group of scholars with implementation and organization expertise with the objective of generating a framework that would reflect the perspective of targeted users of the OTIS framework. Between 20 and 30 sorters have been found to maximize concept mapping fit consistency, yielding results similar to concept mapping by several hundred participants (23). Members of the study team identified potential participants from their respective professional networks in Canada, the UK, and the USA, as well as professional organizations such as the VA QUERI Implementation Research Group. We sent up to three emails offering potential participants a $50 incentive to engage in the concept mapping exercise.

Procedure

To identify conceptually distinct categories (domains) of constructs, we asked participants to sort virtual cards for each of the 70 constructs from nine organization theories relevant to implementation identified in previous work (20), accompanied by their definitions, into piles as they deemed appropriate. We then asked participants to name each pile. Participants could engage in the activities in the order of their choosing and could do so over multiple online sessions, at their convenience, until their responses were complete.

Analysis

Data analysis involved the use of multidimensional scaling and hierarchical cluster analyses to produce visual representations of the relationships among the constructs (23). Specifically, multidimensional scaling was used to generate a point map depicting each of the constructs and the relationships between them based upon a summed square similarity matrix. Constructs frequently sorted together were placed closer together on the point map (23). Hierarchical cluster analysis was used to partition the point map into non-overlapping clusters (i.e., domains) (23). The Concept Systems Global Max^{TM} suggested potential cluster labels based upon participant responses. Model fit was assessed using the stress value, an indicator of goodness of fit between the point map and the total similarity matrix. Cross-study syntheses of concept mapping studies have consistently found mean stress values of 0.28 (24). The stress value of the concept map represents goodness of fit of the configuration, demonstrating how close the solution is to the original groupings made by the participants. Lower stress values indicate a better fit than higher stress values (24).

Consensus-building

Recruitment and sampling

We invited members of the CPCRN OTIS workgroup to review concept mapping results and provide feedback. All CPCRN OTIS workgroup members were eligible to participate.

Procedure

To build upon the results of the concept mapping activity, CPCRN OTIS workgroup members provided their expertise in reviewing results of the concept mapping activity. Participation occurred over the course of three months, beginning with the CPCRN Annual Meeting and continuing through regular workgroup meetings.

Analysis

During a hybrid meeting held in May 2022, CPCRN OTIS workgroup members (6 in-person; 4 virtual) considered a range of potential cluster solutions, ranging from seven to 10 clusters, to determine which solution best suited the purposes of the current study. Each member identified the cluster map that they deemed most conceptually clear based on their knowledge of the field. The group then discussed their choices and worked to reach consensus on what the group believed to provide the most conceptually clear map and moved constructs to clusters that provided the best fit. The group also discussed and altered the automatically generated labels created by Global Max^{TM}. Following the initial analysis, two workgroup members reviewed notes, and a third member reconciled discrepancies, suggesting additional shifts of constructs among clusters. Finally, the lead investigator revised clusters based on extensive knowledge of organization theory. The resulting clusters were again reviewed, revised, and approved by CPCRN OTIS workgroup members during workgroup meetings until a consensus was reached.

Results

Concept mapping

Twenty-four scholars participated in the concept mapping exercise. Participant demographics are described in Table 1.

TABLE 1 Concept mapping participant demographics.

Characteristic	Percent Total
	N = 25
Education	*N* (%)
PhD	21 (84.0)
MD	1 (4.0)
Other	3 (12.0)
Academic Title	*N* = 24
Assistant professor	6 (25.0)
Post-doctoral fellow	5 (20.8)
Professor	5 (20.8)
Associate professor	4 (16.7)
Other	2 (8.3)
Did not respond	2 (8.3)
Organization	*N* = 24
University	19 (80.0)
Government Agency	2 (8.0)
Other	2 (8.0)
Research Institute	1 (4.0)
Field, Specialty, or Discipline	*N* = 24
Multidisciplinary	7 (29.2)
Health policy and management	3 (12.5)
Implementation science	3 (12.5)
Social work	2 (8.3)
Behavioral science/public health	2 (8.3)
Health care management	1 (4.2)
Health services research	1 (4.2)
Sociology	1 (4.2)
Clinical psychologist	1 (4.2)
Behavioral science	1 (4.2)
Healthcare	1 (4.2)
Organizational behavior	1 (4.2)
Content Expertise	*N* = 23
Multidisciplinary	13 (56.5)
Cancer (prevention, control, survivorship)	4 (17.4)
Mental health	2 (8.7)
Health services research	1 (4.3)
Health and social care	1 (4.3)
Digital technology in healthcare	1 (4.3)
Maternal and child health	1 (4.3)

Most participants (84%) held a PhD degree and worked in an academic institution (80%). The plurality of participants had multidisciplinary training (29%), and the majority had multidisciplinary expertise (57%).

All 24 participants completed the sorting exercise. We confirmed that sorts were valid by checking 5 participants' responses to ensure that criteria were sorted into generally logical categories. The stress value was 0.32, demonstrating poor fit. Our consensus-building process was designed to address poor fit by developing a more coherent solution.

Consensus-building

Workgroup members ($n = 18$) participated throughout in-person and virtual discussion sessions. Participant demographics are described in Table 2. The concept mapping software produced multiple cluster options, ranging from 7 to 13 clusters. CPCRN OTIS workgroup members narrowed the clusters to 8–10 (Figures 1–3), ultimately selecting the 10-cluster solution to use as a starting point for the consensus-building process. Workgroup members then reorganized the clusters to increase coherence, yielding six final OTIS framework domains: organizational characteristics; governance and operations; characteristics of a population of organizations; tasks and processes; knowledge and learning; and interorganizational relationships. The final solution was informed by the 10-cluster solution. A total of 70 constructs are organized across the six domains. Supplementary File S1 organizes constructs by domain and includes brief descriptions/definitions for each, as well as the source theory.

TABLE 2 Consensus gathering participant demographics.

Characteristic	Total
	$N = 18$
Education	N (%)
PhD	13 (72.2%)
MD	0
Other	5 (27.8%)
Academic Title	$N = 18$
Assistant professor	4 (22.2%)
Post-doctoral fellow	1 (5.6%)
Professor	5 (27.8%)
Associate professor	3 (16.7%)
Other	5 (27.8%)
Organization	$N = 18$
University	18 (100%)
Government Agency	0
Other	0
Research Institute	0
Field, Specialty, or Discipline	$N = 18$
Multidisciplinary	5 (27.8%)
Health policy and management	0
Implementation science	7 (38.9%)
Social work	1 (5.6%)
Behavioral science/public health	5 (27.8%)
Health care management	0
Health services research	0
Sociology	0
Clinical psychologist	0
Behavioral science	0
Healthcare	0
Organizational behavior	0
Content Expertise	$N = 18$
Multidisciplinary	6 (33.3%)
Cancer (prevention, control, survivorship)	8 (44.4%)
Mental health	1 (5.6%)
Health services research	3 (16.7%)
Health and social care	0
Digital technology in healthcare	0
Maternal and child health	0

Organizational Characteristics (number of constructs = 6) refers to the features of an organization that may predispose it to governance, operations, interorganizational relationships, etc. Included constructs relate to change dynamics (e.g., inertia; adaptability), orientation to operations (e.g., professionalization; specialization); and dominance within its population [e.g., age; size (i.e., indicators of viability; on average, older, larger organizations are more likely to survive than younger, smaller organizations)].

Governance and Operations ($n = 7$) refer to the rules and operating procedures that govern an organization. An organization's rules and operating procedures may be established explicitly (e.g., intentionally, by a governing body) or implicitly (e.g., passively, through repeated operations). Constructs include approaches to operating (e.g., governance structure; internal arrangements) and structures that characterize an organization's operations (e.g., internal arrangements; feedback loops).

Characteristics of a Population of Organizations ($n = 16$) refer to the features of a group of organizations of which the referent organization is a member (25). The institutions that comprise an organization's population may vary depending on the objective or problem in question. That is, a referent organization may be part of several populations. For example, a hospital's population may be defined as local healthcare organizations with respect to competition for physicians and patients, but with respect to adherence to government regulations, a hospital's population may be defined as all of the country's hospitals. Constructs included in the *Characteristics of a Population of Organizations* domain are features of the population as a whole rather than features of the organizations that comprise the population. Constructs relate to change within the population (e.g., dynamism; stability); competition (e.g., competition; selection pressure); variation within the population (e.g., isomorphism; spatial variation); and availability of resources (e.g., munificence; constraint).

Tasks and Processes ($n = 16$) characterize the work that an organization pursues and the conditions that influence its approach to accomplishing the work. Included constructs refer to features of the processes used to accomplish tasks (e.g., un/programmed coordination task structure; transaction costs); features of the environment in which tasks are accomplished (e.g., dependence; excess capacity); and features of the task (e.g., frequency of transactions; technology cycles).

Knowledge and Learning ($n = 5$) refers to the information available to an organization in pursuing its goals and the

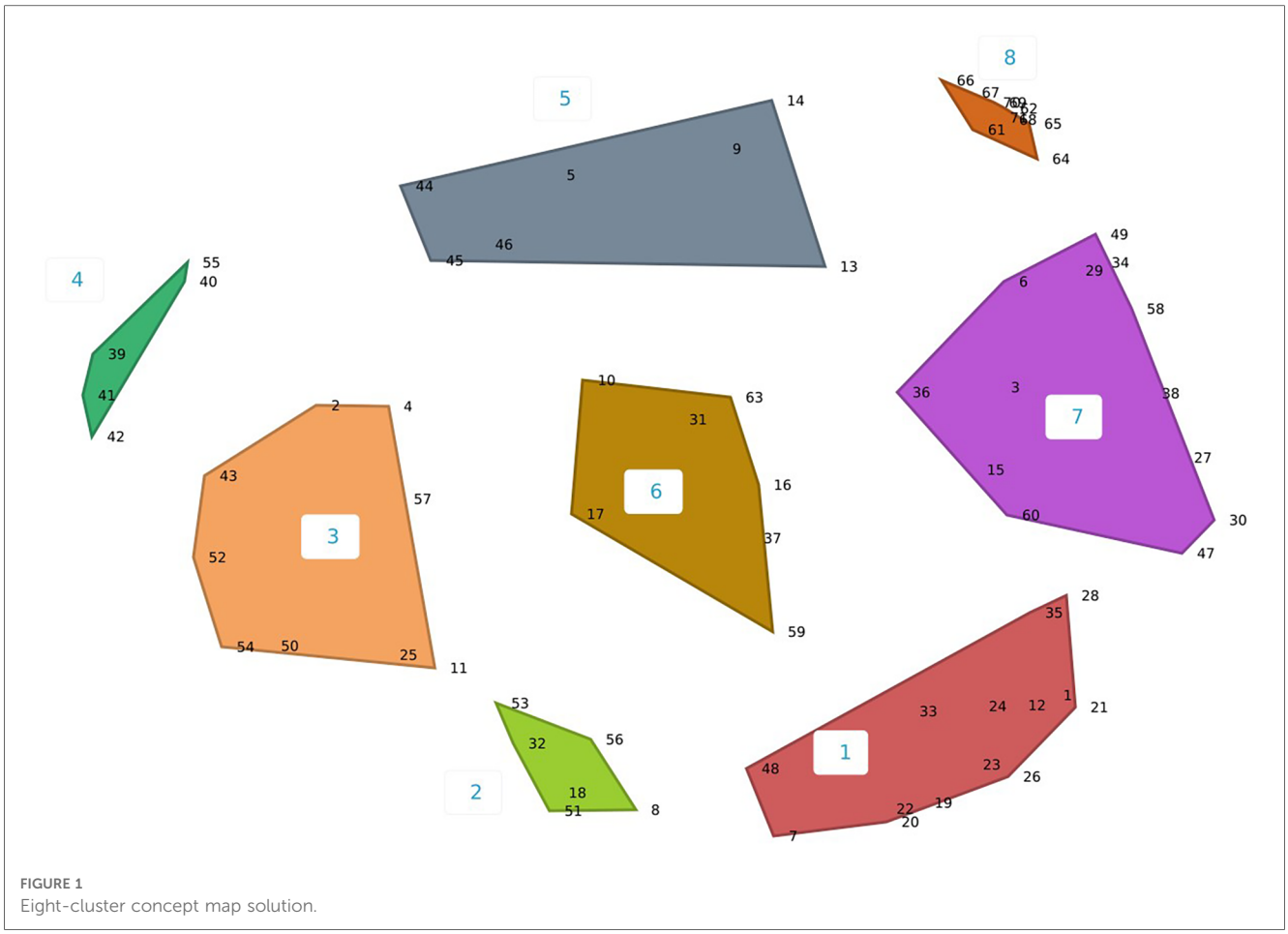

FIGURE 1
Eight-cluster concept map solution.

processes used to acquire the information. Included constructs relate to characteristics of knowledge (e.g., tacit and implicit knowledge) and approaches to acquiring knowledge (e.g., learning (sub)processes; sense making).

Interorganizational Relationships ($n = 20$) refer to characteristics of the interactions that an organization has with other institutions. In contrast to the *Characteristics of a Population of Organizations* domain, which refers to features of a population of organizations as a whole, the *Interorganizational Relationships* domain characterizes communal (e.g., communication) or exchange (e.g., monetary or other resource exchange) interactions (26). Included constructs characterize an organization's dependence on other institutions (e.g., interdependence; community interdependence); the pressure that organizations exert on each other (e.g., normative, mimetic, and coercive pressure; dominance; power).

Discussion

This study describes how we created the OTIS framework to increase implementation scientists' familiarity with and conceptualization of the diverse set of organizational influences on implementation. Increasing implementation scientists' conceptualization of organizational influences may contribute to more comprehensive understanding of the key drivers of implementation and, in turn, our ability to identify and select strategies to accelerate the translation of evidence into practice, as found in other industries, such as business and education (11, 12, 17, 18). Our efforts yielded six conceptually distinct domains, encompassing 70 constructs from nine organization theories with relevance to implementation. Distilling many constructs from several theories into a limited number of domains limits the burden on implementation scientists to account for the vast array of potentially important organizational influences on implementation. The six domains that we identified in this study reflect concepts that are central to organization theory, including power, structure, autonomy, control (20), but which are less commonly addressed in implementation science. The concepts reflected in the OTIS framework offer perspective on key questions in implementation science, such as how and why organizations adopt, implement, and sustain evidence-based practices—or resist doing so.

The OTIS framework considerably expands upon existing implementation determinant frameworks' conceptualization of organizational influences on implementation. OTIS includes constructs such as *specialization*, which is not explicitly captured in the CFIR or EPIS frameworks, but which may influence the decision to adopt an evidence-based practice. For example, a study of determinants of low-value use of computed tomography

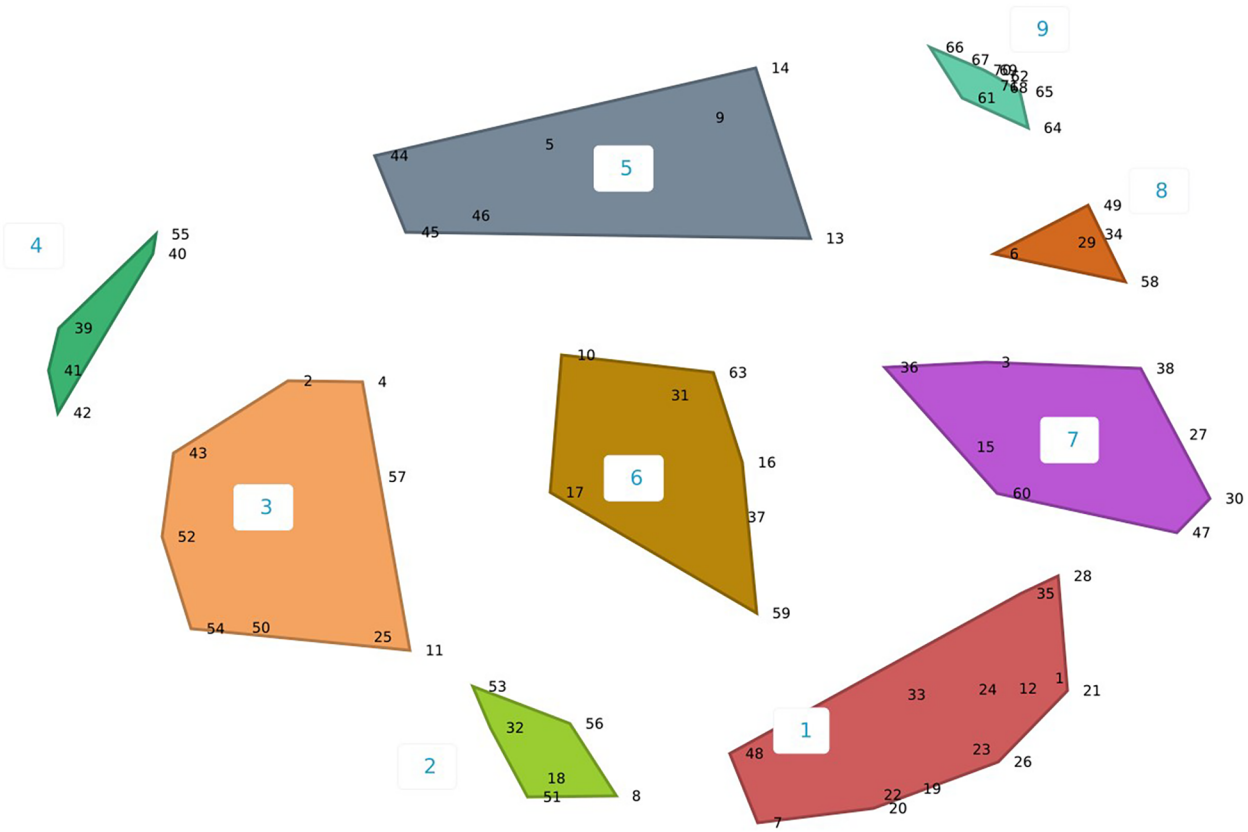

FIGURE 2
Nine-cluster concept map solution.

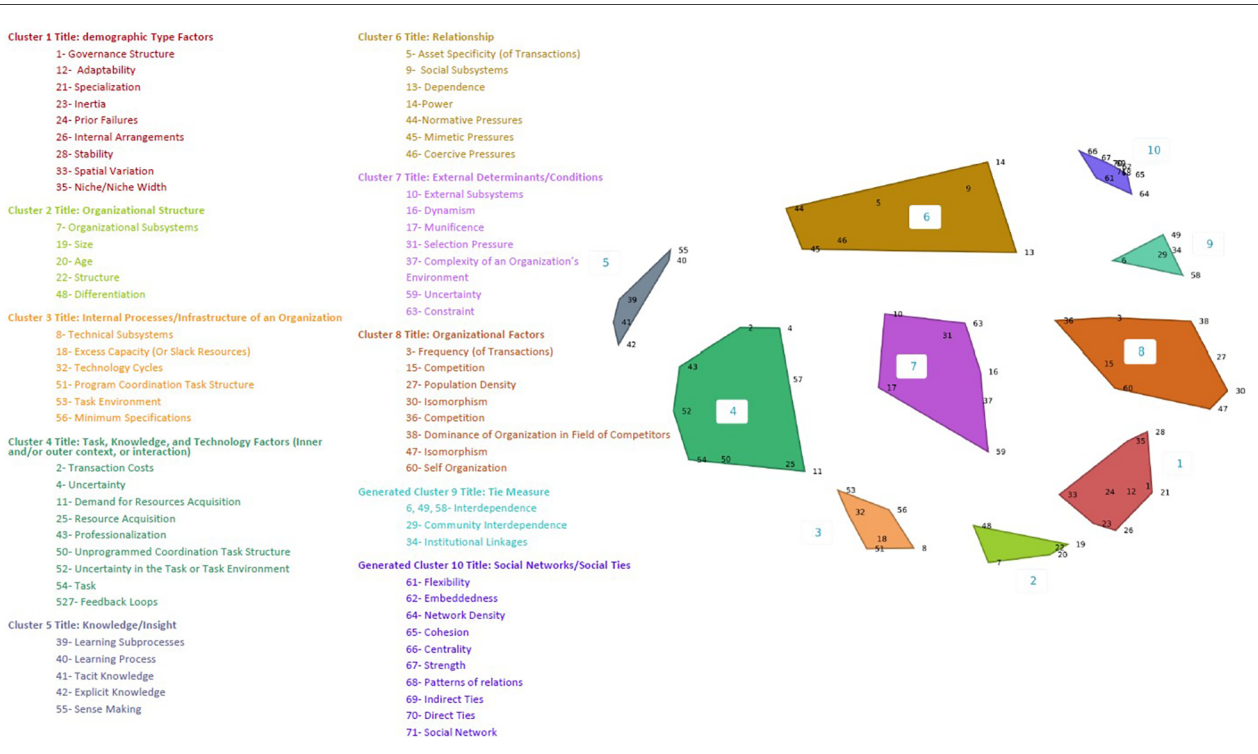

FIGURE 3
Ten-cluster concept map solution and constructs.

to evaluate microscopic hematuria found that, while urologists' evaluation practices changed following the American Urological Association's revised guidelines, primary care providers' evaluation practices often went unchanged, highlighting the need to tailor strategies for the various specialties involved in implementation (27, 28). OTIS greatly expands upon the TDF's organization-level *environmental context and resources* domain with more nuanced domains, such as *interorganizational relationships*. Future efforts should systematically map OTIS onto extant determinant frameworks to clearly articulate OTIS's unique contribution. For example, OTIS's Governance and Operations and Tasks and Processes domains include several constructs that may add critical nuance to EPIS's Funding/Contracting construct. Before systematic mapping of OTIS onto extant frameworks, OTIS may be used in its current form in conjunction with other frameworks, such as the CFIR and TDF, which are increasingly used in combination and already capture intra-organizational constructs, such as climate and leadership (28). For example, some OTIS domains or constructs that appear not to be captured in CFIR (e.g., tasks and processes; stability of the population of organizations; normative pressures) could be included in implementation determinant studies.

OTIS also expands upon commonly used implementation frameworks by allowing users to access organization theories articulate the mechanisms underlying relationships between included constructs and implementation. For example, the EPIS framework identifies sociopolitical influences on implementation (e.g., legislation; monitoring and review); however, EPIS does not articulate *how* or *why* these constructs influence implementation. In contrast, OTIS's basis in theory allows users to identify hypothesized relationships between included constructs and implementation, as clearly articulated in publicly available OTIS abstraction forms (28). Specifically, users may consult the *propositions* section of OTIS abstraction forms to identify mechanisms underlying included constructs. For example, OTIS describes how coercive influences of governments and accrediting bodies exert normative pressure (Interorganizational Relationships domain) on healthcare organizations to comply with legislation and monitoring by virtue of organizations' dependence on these governing bodies for permission to operate. Therefore, OTIS could be used in conjunction with extant frameworks to explain the mechanisms underlying constructs' influence on implementation (29). Clearly articulated mechanisms are critical for identifying strategies that are best-suited to influence the construct identified as influencing implementation.

Members of the CPCRN OTIS workgroup are currently applying the OTIS framework in the following projects: Project 1 a) tests the conceptual validity and applicability of the OTIS framework in community oncology practices and b) develops, tests, and disseminates tools using OTIS in implementation research, including a qualitative interview guide and codebook. Project 2 is an American Society of Clinical Oncology collaborative study on Sexual Orientation and Gender Identity data collection. OTIS will be used in this project to a) reanalyze data that have been previously analyzed using the CFIR, and b) compare results between CFIR and OTIS findings. Project 3 applies OTIS to a CDC-funded U01 cooperative agreement to reduce health inequities for cancer survivors in the District of Columbia. OTIS will be used to a) to build community coalitions of approximately 10 organizations to improve infrastructure and communication and b) to think consider power dynamics and the elimination of disparities and health inequalities. Some limitations of our study should be noted. Concept mapping requires participants to have pre-existing knowledge and experience with the topic they are mapping, limiting the pool of potential participants. There is a limited population of researchers with the required familiarity of organization theories and implementation science to participate in concept mapping. As a result, our purposive sampling approach was necessary to increase the likelihood that participants would understand included constructs enough to sort and rate them. However, it is possible that participants lacking refined expertise in implementation or organization science would have valuable perspective on included constructs. For example, hospital administrators may lack fluency in the terminology included in organization theories, but they may have unique insight into how, for example, normative pressure from professional organizations influences implementation. Future work should refine the language used in OTIS to increase its accessibility to an audience without expertise in organization science. Additionally, the clusters that Global Max generated, in many cases, lacked coherence as indicated by the stress value of 0.32, suggesting variation in concept mapping participants' interpretation of the constructs and their relationships. To address this concern, OTIS workgroup members used their expertise to reorganize many clusters in our consensus-building process, potentially suggesting the limited utility of concept mapping for developing the framework. We view the OTIS framework as a living document to be revised through application. For example, implementation scientists may find through qualitative interview data collection that study participants describe OTIS constructs in combinations not reflected in the domains identified in this study. Future iterations of the OTIS framework will be revised to reflect empirical evidence.

Despite these limitations and the need for continued development, OTIS may be used in its current form in implementation research. OTIS could be used to inform data collection or analysis. For example, OTIS could be used to develop guides for interviews with cancer program leadership to understand the potential influence of participation in quality improvement networks, professional norms, and the ability to recruit providers influence compliance with cancer program accreditation standards (30). We plan to use OTIS to analyze data that were previously collected regarding factors influencing cancer programs' implementation of exercise interventions. In each of these cases, OTIS offers researchers the tools necessary to understand the mechanisms underlying factors that influence implementation, pointing toward strategies to facilitate implementation (e.g., strengthening or reorganizing quality improvement networks to support compliance with accreditation standards).

Conclusions

We distilled 70 constructs from nine organization theories into six domains in the OTIS framework. The OTIS framework has several potential benefits. First, OTIS may enhance implementation scientists' consideration of organization-level constructs, which to date has been insufficient (17). Second, OTIS adds nuance to relatively limited conceptualizations of organizational influences in extant implementation determinant frameworks, such as the CFIR, EPIS, and TDF. Third, OTIS may increase the use of theories in implementation science. Evidence suggests that the use of theories, models, and frameworks in implementation science is inconsistent and often inappropriate (31). Unlike conceptual frameworks, which offer a menu of constructs thought to influence implementation, theoretical frameworks including OTIS are based on theories, which propose mechanisms underlying the relationship between constructs and implementation. OTIS links implementation scientists to theories that may explain the phenomena underlying complex implementation problems, such as slow uptake or poor sustainment. Future efforts should include expanding extant frameworks with OTIS's unique domains and constructs; refining OTIS's language to increase its accessibility to an audience without expertise in organization science; and revising OTIS to reflect empirical evidence.

Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation by reasonable request to the corresponding author.

Ethics statement

This study was approved by the Wake Forest University School of Medicine IRB (IRB00072134) on 6/2/21. Written informed consent for participation was not required for this study in accordance with the national legislation and the institutional requirements.

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Some of the data analyzed during this study have been previously published and are available from (20).

Author contributions

SB: contributed to the study conception and design, drafted the manuscript, and participated in the data collection, analysis, and interpretation of results; CW and AP: drafted the manuscript and participated in the data collection, analysis, and interpretation of results; MK, JB, PA, MF, MM, TH, ML, MW, PN, MB, MC-B, GR, and AR: participated in the analysis and interpretation of concept mapping results; LK contributed to the study conception and design and participated in the data collection, analysis, and interpretation of results. All authors contributed to the article and approved the submitted version.

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The authors PN, TH, MEF, and PA declared that they were an editorial board member of Frontiers, at the time of submission. This had no impact on the peer review process and the final decision.

The remaining authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Publisher's note

Supplementary material

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Translating evidence-based knowledge objects into practice

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This paper aims to show how organizational translation theories and models may supplement implementation science with a new process perspective on how knowledge objects such as Cochrane reviews, clinical guidelines and reference programs are implemented in practice in healthcare organizations. They build on Bruno Latour's idea about translation that states that the spread in time and space of anything—including knowledge objects—is in the hands of people and that each of these people may act in many different ways, letting the token drop, modifying it, deflecting it, betraying it, adding to it, or appropriating it. Implementation science theories, models and frameworks often try to identify general aspects of processes and variables that influence implementation processes. In contrast, translation theories and models build on a process view that uses the sequence of events, activities and choices by translators situated in time as well as in space to explain how outcomes of translation/implementation processes came about. The paper develops some implementation relevant propositions about translation of knowledge objects in healthcare organizations that may inform further research. Moreover, it discusses how organizational translation studies and implementation science may supplement each other.

KEYWORDS

translation, knowledge translation, organizational translation, implementation, Cochrane review, clinical guideline, translation theories, translation models

1. Introduction

A knowledge object is a piece of knowledge held in a well-defined and structured format, such that it is easy to replicate and disseminate. It typically contains explicit evidence-based knowledge but may also contain some elements of human knowledge (KM Glossary, skyrme.com). Examples of knowledge objects in healthcare organizations include Cochrane reviews, reference programs and clinical guidelines. Generally, knowledge objects in healthcare organizations are intended to inform practitioners about the latest evidence-based knowledge related to certain types of patients and diagnoses and to support and improve their decision-making concerning these patients. They contain an assembly of evidence-based knowledge and ideas about "what to do" with certain types or categories of patients. In order to assure that evidence- based knowledge objects have an impact on practice, they need to be implemented or, as assumed in this article, "translated".

The translation perspective on organizational change has developed in organization studies in recent years among researchers who study the movement of management and organizing ideas as well as other tokens in organizations (1–3). It focuses on understanding how different types of ideas/tokens move within as well as between organizations. The types of tokens that organizational translation researchers have studied include the translation of new management and healthcare ideas, of strategies, policy ideas, the movement of knowledge, translation in relation to socio-technical co-construction and design of IT-systems as well as in relation to the creation and translation of ideas and knowledge during innovation processes (3). This article will focus on what implementation science researchers may learn about implementation

processes related to knowledge objects from the theories and models of translation that have been developed in organization studies (1–3). It offers a new view on implementation as translation processes that may supplement and—if further researched—develop especially the process dimension of existing frameworks in implementation science.

So, what is translation in organization studies? Many different definitions exist. One of the most famous ones suggests that

> *"….the spread in time and space of anything—claims, orders, artefacts, goods—is in the hands of people: each of these people may act in many different ways, letting the token drop, or modifying it, or deflecting it, or betraying it, or adding to it, or appropriating it."* (4)

Latour's (4) definition suggests that the fate of any token, an idea, a concept, a knowledge object like an evidence-based reference program, a clinical guideline, or a systematic Cochrane review, depends on what the people who move them choose to do with them. They may choose to be loyal to the token or they may choose to drop the token, modify, deflect, betray, add something to it, or appropriate it. This view on organizational translation processes suggests that tokens, including those mentioned above, move geographically- that is physically—from one place to another, they move semiotically—that is in relation to what these tokens mean—and they move politically as receivers of the tokens may have interests that affect what they choose to do with the tokens (2). Therefore, in an organizational translation perspective you will expect that:

1. The translation of tokens unfolds through an uninterrupted translation chain where the token that you want to implement needs to be continuously given new energy and moved by people in a chain of translations to be implemented.
2. That the token will be adjusted and changed through the translation process because the token and what counts as knowledge in relation to it will not just be transferred but also translated and politically negotiated as it moves.

The implementation of a token in healthcare organizations—for instance an evidence-based knowledge object as a reference program, a clinical guideline, or a systematic Cochrane review—will thus demand that people and according to some translation researchers also material/physical objects are mobilized and influenced to "act" on behalf of the token (4–6). To make people and objects "act" on behalf of and through those actions in practice "realize" a token is, however, not easy. It depends on and requires that a lot of different and typically locally unique types of translation work are done before a token may be "implemented". Giving an overview of all the insights that organizational translation studies may offer implementation science researchers is not possible in a short article. Readers interested in that may explore these issues further in Scheuer (3). Instead, the article will focus on answering the following research questions:

1. What are the implications of selected organizational translation theories and models for processes related to implementation of evidence-based knowledge objects in healthcare organizations?
2. Which conditional propositions about translation of knowledge objects may be derived from them?

The theories and models that will be discussed in the article are selected in order to demonstrate some key questions that organizational translation theories and models raise, that may interest implementation science researchers and give some new views on what may characterize implementation processes (see **Table 1**). The selected theories and models address questions that have been identified as important for the translation of management, organizing ideas and knowledge by organizational translation researchers that may have important implications for implementation researchers, too. Some conditioned propositions are developed on the basis of these theories and models that may inform further research of implementation science researchers. A conditional proposition consists of two simple statements joined by the words "if" and "then" (if today is Friday, then tomorrow is Saturday). A conditional proposition asserts that the antecedent implies the consequent that is: the consequent is true if the antecedent is true (9).

The implementation relevant questions that are derived from the selected organizational theories and translation models and on the basis of which the conditional propositions presented in the article are developed are: (1) What are the consequences if the knowledge object (for instance a Cochrane review or a reference programme) is considered a text that a translator needs to translate to the receivers of it? (2) What if humans/groups of humans do not just transfer knowledge/the knowledge object but also translate and politically negotiate it? (3) What if not just humans but also physical objects (non-humans) are needed to do work to implement the knowledge object? (4) May the travel of the knowledge object from one time-space context to another influence the translation of it?

In the first section of the article, the theme and research questions are presented and the concept of knowledge object is defined. In the second section, the concepts of theory and models as well as the concept of conditional propositions are explained and defined. Moreover, the phenomena and implementation situations the selected translation theories and models relate to as well as the process and inclusion and exclusion criteria used for selecting theories and models are presented. In the third section, the selected

TABLE 1 Selected translation models.

Theories	Linguistics	Symbolic interactionism	Actor-network-theory Ventriloquism[a]	Neo-institutional theory
Models	Holden et al.'s Knowledge translation model	Carliles' knowledge translation model	The idea-practice-translation model	The travel of ideas model
Authors	Holden et al. (7)	Carlile (6)	Scheuer (3)	Czarniawska and Joerges (5)

[a]Ventriloquism was developed by the organization studies researcher Cooren (8). He based his theory about the communicative constitution of organizations partly on actor-network-theory. The idea-practice-translation model builds on its ontological and epistemological assumptions about organizations.

translation theories and models are presented and discussed, and some implications and conditional propositions are suggested on that basis. In the fourth section some reflections concerning the contributions of organizational translation studies to implementation science (and vice versa) are presented. Finally, in the fifth section, some conclusions are drawn.

1.2. Knowledge objects in healthcare

A knowledge object is a piece of knowledge held in a well-defined and structured format, such that it is easy to replicate and disseminate. Although they contain predominantly explicit (often evidence-based) knowledge, they may also contain some elements of human knowledge (KM Glossary, skyrme.com). You find many types of knowledge objects in healthcare organizations, systematic Cochrane reviews summarizing the latest evidence related to treating certain health conditions, evidence-based reference programs and clinical guidelines. Cochrane reviews attempt to collate all empirical evidence that fits pre-specified eligibility criteria in order to answer a specific research question. It uses explicit, systematic methods that are selected with a view to minimizing bias, thus providing more reliable findings from which conclusions can be drawn and decisions made (10, 11) (1.2.2 What is a systematic review? (cochrane.org)). In Denmark evidence-based reference programs are presented as a way to search for, summarize and translate scientific research results to systematic recommendations (sst.dk). According to The Institute of Medicine, clinical guidelines are "systematically developed statements to assist practitioners and patient decisions about appropriate health care for specific clinical circumstances" (12). Knowledge objects in healthcare are thus intended to inform practitioners about the latest evidence-based knowledge related to certain types of patients and diagnoses and to support and improve their decision-making concerning these patients. You may suggest that the use of knowledge objects to diffuse evidence-based knowledge to practitioners builds and depends on at least two assumptions: (1) Research-based knowledge may be stored in physical objects/texts which may then be transferred and reproduced by others/the receivers in an objective and thus non-subjective way. (2) The content of the knowledge objects may be transferred from the sender to the receiver and may be implemented without being changed by the activities and processes of the actors involved in the movement of the knowledge objects. As it will be demonstrated, the translation perspective in organization studies questions these assumptions.

2. Introduction to theories and models

2.1. From theories and models to conditional propositions

A theory may be defined as an explanation of relationships among concepts or events within a set of boundary conditions (9). A theory simplifies and explains a complex real-world phenomenon and describes the who, what and where of a phenomenon being investigated, but also explains the how, when and why it occurs (13). They consist of terms (concepts, constructs, variables, or events), relationships among terms (propositions and hypothesis) and assumptions (boundary conditions within which these relationships hold in time, space, and value contexts), and explanations (arguments that provide reasons for the expected relationships) (9). The primary phenomenon of interest for organization theorists and researchers are organizations, which includes different kinds of organizations as well as organizing activities and processes (14). Historically, many theories about organizations have developed that have then been used to develop ideas about how to change them in organization studies. As a consequence, many theories about organizations and typologies of change strategies and models based on them have been developed in organization studies (15, 38, 39)[1]. This approach has also characterized organizational translation studies and organizational researchers' attempts to theorize and model change processes in organizations as translation processes (3).

As pointed out by Nilsen (40), models involve a deliberate simplification of a phenomenon or aspect of a phenomenon and need not be completely accurate representations of reality to have value (41, 42). Morrison and Morgan (43) argue that models serve as mediators between theories and data. They may not be derived entirely from theory or from data because they are neither one thing nor the other, neither just theory nor data, but typically involve some of both (and often additional "outside elements"), so that they can mediate between theory and the world (43). The organization researcher McKelvey (44) thus suggests that social scientists do not directly observe or test theories; instead, they examine models, and models may be seen as partial representations or maps of theories. Therefore—as pointed out by Nilsen (40)—models are closely related to theory and the difference between a theory and a model is not always clear.

When referring to translation "theories and models" in this article, it refers to the above-mentioned definitions and understandings of these concepts. Several of the approaches to translation and organizational change that have been included in this paper are embedded within and draw upon the basic assumptions of well-known and accepted theories in organization

[1]An example of such typologies is Demers (15) book "Organizational Change Theories" where she presents organization theories and the change strategies that may be derived from them using contingency theory (16–20), organizational life-cycle theory (21), population ecology theory (22), institutional theory (23), configurational theories (24, 25), organizational psychological theory (26, 27), organizational culture theory (28, 29) theories about organizations as political systems (30), behavioral and adaptive learning theory (31, 32), evolutionary theory (33, 34), complexity theory (35–37) and many more.

studies like institutional theory (the idea model) (5) and symbolic interactionism (6), Actor-network Theory (4, 45, 46) and Ventriloquism (the idea-practice-translation model) (8, 47). Other theories and models draw upon linguistic theories that model translation processes as characterized by translation of texts (which may be both written and/or spoken by the translators) (7). An overview of the theories and models included is shown in **Table 1**.

The selected theories and models referred to in the article are used to formulate a number of conditional propositions concerning implementation processes. A conditional proposition consists of two simple statements joined by the words "if" and "then" (if today is Friday, then tomorrow is Saturday). A conditional proposition asserts that the antecedent implies the consequent that is: the consequent is true if the antecedent is true (9). In the article, some selected theories and models are referred to that organizational translation researchers suggest identify some key characteristics of the way management ideas, knowledge and other tokens have been translated in organizations. In this article, some conditional propositions are deduced from them and it is suggested that if these (the above-mentioned) propositions are relevant to the translation of management ideas, knowledge and other tokens in organizations, then they might be relevant to implementation of knowledge objects in healthcare organizations, too. Here it should be noticed that propositions and hypotheses differ by levels of abstraction: propositions are relationships among theoretical concepts or constructs, while hypotheses are relationships among concrete observable variables or events (9). Thus, in order to test the relevance of the conditional propositions put forward in this article for implementation processes, they need to be translated into hypotheses, observable variables and events and tested empirically in later studies.

The selected theories and models theorize and model the translation process differently and are based on different ontological assumptions (1–3). In organizational translation studies, this has made some researchers discuss whether these issues might suggest that the theories and models focus on different phenomena and belong to separate and perhaps incompatible research traditions (2, 3). They conclude, however, that they do not believe this to be the case. Instead, they suggest that the theories and models focus on different aspects of translation processes, and do so with different emphasis and terminology. They moreover conclude that they are complementary and try to say something about the same phenomenon: How an object changes from one state to another within and across organizational settings (2, 3).

2.2. Inclusion and exclusion criteria

The inclusion criteria used when selecting the theories and models were their ability to demonstrate some questions that organizational translation theories and models have identified and raise, which may interest implementation science researchers and give some new views on what may characterize implementation processes and make implementation of evidence-based knowledge objects difficult (these questions are described in the introduction). They represent different views on what may affect the translation of a token like a management concept or idea or as hypothesized here; a knowledge object as it moves through translation chains of people and/or groups of people in or between organizations. Translation theories and models thus offer a process view (48) on organizational change and implementation that may be considered an alternative to existing process views in implementation science (see section 4 below for a discussion of this).

The selection of theories and models was based on an in-depth literature review of organizational translation theories and models that was performed by the author when writing his latest book: How Ideas Move—Theories and Models of Translation in Organizations, Routledge (3). The research for the book started out from existing reviews of the research literature in organizational translation studies including reviews by O'Mahoney, Scheuer, Wæraas and Nielsen and Wedlin & Sahlin (1, 2, 49, 50). These reviews were supplemented with an additional literature review conducted especially to support the research done when writing the book. In this literature review, the most cited theories and models in different areas of organizational translation studies were identified as well as theories/models that represented different definitions and understandings of translation and the translation process in organization studies.

Concerning the exclusion criteria, some organizational translation theories and models were excluded from the article due to lack of space or relevance [an overview of other translation theories and models in organization studies may be found in Scheuer (3)]. Another research stream that was excluded was linguistic studies of the translation of texts—primarily those focusing on the translation of texts (books, instructions, user manuals, etc.) from one language to another rather than on translation of tokens between groups of people in organizations aimed at being implemented and causing organizational change. The linguistic theory about knowledge translation in organizations that was included in the article (7), thus has an explicit focus on translation of texts and knowledge aimed at being implemented and causing organizational change.

2.3. What do the selected theories address and in which situations are they relevant?

The selected translation theories and models presented in this article build on the assumptions that were mentioned in the introduction and try to theorize and model how translation processes unfold in different situations. Each of the selected theories and models focus on phenomena that may make the movement (and thus implementation) of knowledge objects difficult in healthcare organizations. The theories and models that have been selected address:

- The consequences of viewing translation of knowledge objects as a linguistic translation of texts that may include good, bad,

wrong translations and depend on translators' translation competences (7).
- Translation processes as characterized by not just transfer but also intergroup translation and negotiation of the content and knowledge related to the knowledge object (6).
- Translation processes as dependent on both humans and physical objects' (non-humans') work and thus—according to some translation researchers—complex, locally situated socio-technical design and translation processes (3).
- The travel and physical disembedding, re-embedding and translation of knowledge objects from one time-space context to another that may be caused by rational human actors trying to make their organizations more effective and efficient but is often also caused by other things: What translators happen to attend to, characteristics of the knowledge objects themselves, normative pressures and influence from fashion trends (5, 51–53).

Each of the above-mentioned theories and models focus on different situations where an evidence-based knowledge object needs to be translated in order to be moved and thus implemented—and where some difficulties may arise in order to succeed with such an endeavour. These situations include situations where:

- Translators of an evidence-based knowledge object (a Cochrane review, a reference programme, a clinical guideline) try to translate the knowledge object in the form of a document or a text to practice in their local organization/department/unit.
- Situations where different groups having different cultures and languages try to transfer, translate, and negotiate what should count as knowledge in relation to the knowledge object at encounters between the groups.
- Situations where not only humans but also "non-humans" i.e., material objects of different sorts need to be included in the translation process in order to succeed with implementation (as when you develop and introduce diabetes monitoring IT-systems at hospitals which makes both humans and IT-systems an object of design efforts)
- Situations where local, socially embedded translators in healthcare search for and may direct their attention toward relevant evidence-based knowledge objects (as many health care scientists and practitioners think they are supposed to) but may also just as well direct their attention elsewhere when trying to identify solutions to their local problems.

3. Translation theories and models

3.1. Translation as translation of text objects

As pointed out by Malmkjær (54) linguistics is the academic discipline that focuses on languages, and translation can be seen, in Catford's (55) words as "an operation performed on languages", and as pointed out by the knowledge translation researcher Holden (7) "translation…is by far the oldest universal practice of conscientiously converting knowledge from one domain (i.e., a language group) to another". Holden et al. (7) thus point out that human languages differ in relation to their syntax (the way in which words are arranged and combined grammatically), in their morphology (that is in how they are used in certain contexts), in their lexis (which refers to the vocabulary items of a language) and in their phonology (which refers to the speech sounds of a language). He moreover points out that these four elements deviate from each other among languages and that language may be seen as a repository of knowledge, experience and impressions and a device for facilitating social interaction. The challenge of the translator in finding equivalence as he/she translates between groups is then not just to render the words of one language into a second one, but also to re-express psychological and related factors within the terms of reference of that second language (7). They therefore conclude that:

- Knowledge transfer in organizations, like literary translation, is a sense-making activity.
- Knowledge transfer, like translation, is literally concerned with personal cognition and the inter-lingual transfer of knowledge from head-to-head and into social networks.
- Knowledge transfer, like translation, is subject to constraints, which affect not just transfer, but rather transferability: the extent to which knowledge can be transmitted to others.

As summarized by Scheuer (3), Holden et al.'s (7) model (see **Figure 1**) theorizes the factors that influence knowledge translation processes when knowledge moves between cross-cultural teams [see (7)]. The first factor is the lack of cultural understanding, uncertainty and thus ambiguity related to the source of the knowledge that leaves room for interpretation by the receiving group or team. Other factors are interference and lack of equivalence, which refers to the errors of translation that may occur because of differences in the use of words, grammar or pronunciation between the source and target language and the (possible) lack of corresponding words and concepts between the languages of the sender and the receivers. Other factors that influence the knowledge translation process are:

1. The ability of the translators or receivers of new knowledge to make tacit knowledge that is necessary for the functioning of the knowledge and is acquired through socialization explicit,
2. The translators' and receivers' ability to combine new and local explicit knowledge in relevant ways and
3. Their ability to internalize and make this new explicit knowledge tacit again.

Moreover, the knowledge translation process is influenced by the translatability and convertibility of the knowledge that is being translated. The translatability of the knowledge concerns the properties of the knowledge and whether the translator is a domain expert both in terms of the languages between which he needs to translate and in terms of the subject matter of the text/knowledge being translated. The convertibility of the knowledge will depend on whether domain experts/translators as well as other receiving team/group members find it useful and choose to implement it. Finally, when the knowledge has been through this process the translated knowledge may be converted into social networks (the receiving teams/groups) in at least 4 different

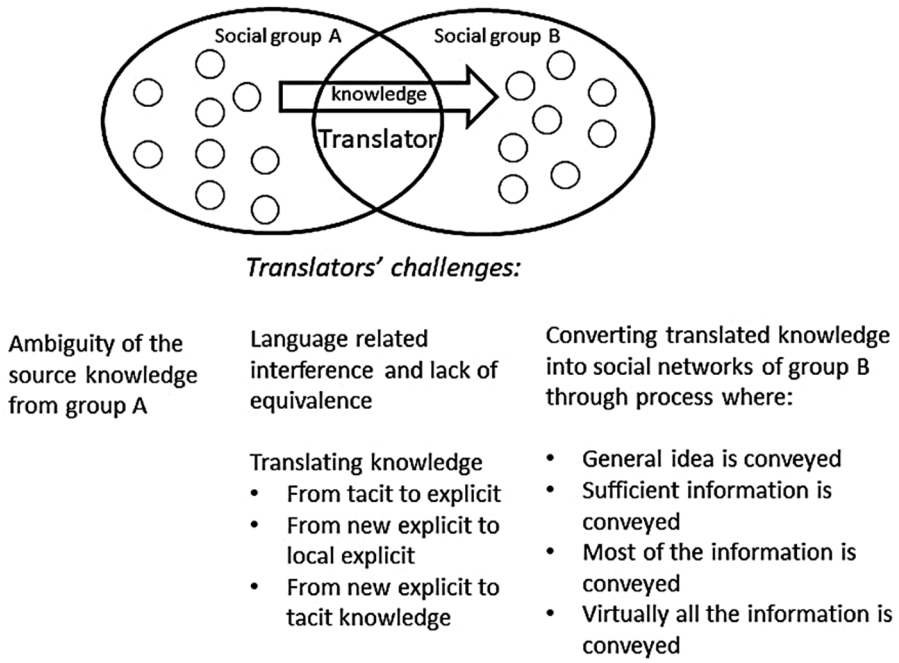

FIGURE 1
Extended model of knowledge transfer as translation. Source: developed by the author from Holden et al. (7).

ways: (1) The general idea is conveyed, (2) sufficient information is conveyed, (3) most of the information is conveyed and finally, (4) virtually all the information is conveyed.

3.1.1. Implications and conditioned propositions

The implications of what was mentioned above for implementation of text-based knowledge objects (like Cochrane reviews or guidelines) are that those who receive them need to have very similar cultural backgrounds and use language in very similar ways for the knowledge object to make as much sense to them as it did to the senders of it. Moreover, those who implement (translate) it need to be able to identify and handle both explicit and tacit aspects of the knowledge object that are necessary to "make it work" in the receiving group and if it doesn't; to improvise in a way that ensures that it does. Finally, both characteristics of the knowledge object itself, its usefulness for the receivers and how information about it is communicated may play a role.

The conditioned propositions that may be derived from what was mentioned above concerning implementation of evidence-based knowledge objects in healthcare organizations are that: (1) Implementation of knowledge objects as text-objects may need to be translated from one language and cultural group to another as it moves through and between groups of people in healthcare organizations, (2) this movement may depend on the types of language, learning and culturally related factors that Holden et al. (7) point out, (3) the implementation and adaptation of an evidence-based knowledge object may be studied by researching how it is translated and put into (written and spoken) words by different people and groups of people as it moves through the translation chain and, (4) effects related to the knowledge object may be assumed to relate to how this is done.

3.2. Translation as intergroup transfer, translation, and negotiation

Some researchers in organizational translation studies build on the ideas of symbolic interactionism (56). In this view, humans' capacity for thought is shaped by social interaction. It is assumed that people learn the meanings and the symbols that allow them to interpret and act in meaningful ways in different situations through their actions as well as interactions with other humans. People and groups examine possible courses of action related to a situation, assess their relative advantages and disadvantages, and then choose one that seems appropriate given the situation at hand (57). As a consequence of this view, some translation studies researchers theorize organizational translation processes as an intergroup transfer, translation and negotiation process (6, 58, 59). Translation is theorized as happening between people and groups of people belonging to different social worlds (56). These social worlds are often remote from each other culturally, language-wise, in relation to interests as well as in time and space. This now creates problems whenever collaboration and coordination of several groups of people are needed in order to achieve common social goals (as for instance when "implementing" an evidence-based knowledge object).

As explained by Scheuer (3) the knowledge translation model of Carlile (6, 59) (see **Figure 2**) suggests that if social worlds A and B are similar in their language, culture and interests, knowledge about (for instance) a knowledge object may just be **transferred**. The knowledge will be relatively easy to communicate and will be relatively easily accepted by the receivers and storage and retrieval technologies may be used to store the knowledge for later use. If there is a greater distance between the two groups in their language, culture, and interests,

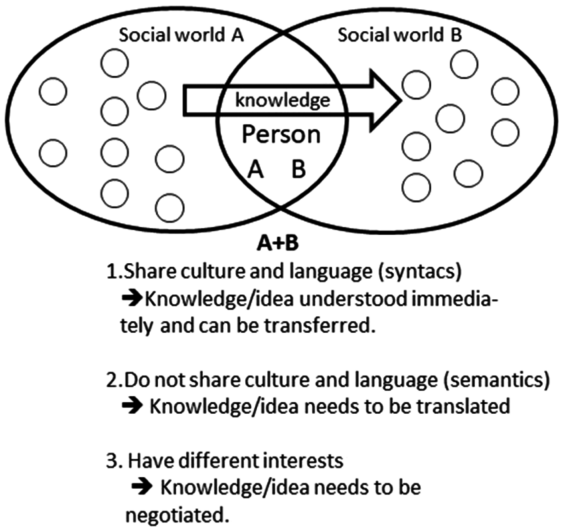

FIGURE 2
Carliles knowledge translation model. Source: developed by the author from Carlile (6).

however, the knowledge (object) also needs to be translated and politically negotiated.

The reason is that if something new is created or presented during an innovation or translation process, it is not sufficient to share and assess knowledge across a boundary. In that situation, a new situation arises that creates a semantic boundary that necessitates a **translation** or interpretive approach. Novelty thus generates some differences and dependencies that are unclear—different interpretations exist. Common meanings are developed to create shared meanings and provide an adequate means of sharing and assessing knowledge at the boundary. In that situation, the different communities of practice engage in translating knowledge in order to create shared meanings. During this process, the techniques used are development of the different groups' semantic capacity, cross-functional interactions, and teams as well as boundary spanners and translators and according to some translation researchers also "boundary objects" (58).

Carlile (6, 59) points out that being able to create common meanings and to be able to share and assess knowledge, you often need to take differences in interests between members of group A and group B into account and make new political agreements. Novelty thus potentially generates different interests between actors that impede their ability to share and assess knowledge. Common interests are therefore developed to transform knowledge and interests and provide an adequate means of sharing and assessing knowledge at a boundary. Knowledge is therefore not just translated but also negotiated and through that political process **transformed**. The techniques required by actors involve an ability to be pragmatic, to use prototyping and other kinds of boundary objects that can be jointly transformed. To share and assess knowledge thus requires significant practical and political effort.

Finally, Carlile points out that several iterations are needed. Addressing the consequences of knowledge (a knowledge object) cannot be resolved by group A and B with one try but requires an iterative process of sharing and assessing knowledge, creating new agreements, and making changes where needed. As the actors participate in each iterative stage, they get better at identifying what differences and dependencies are of consequence at the boundary; they improve at collectively developing a more adequate common lexicon, meanings, and interests (6).

3.2.1. Implications and conditional propositions

The implications of Carlile's (6) knowledge translation model for implementation of evidence-based knowledge objects in healthcare organizations are that a knowledge object will be easier to transfer if the receivers of it shares the language, culture and interests of the senders of the knowledge object in question. If they do not, however, more translation and negotiation work will probably be needed. Another implication is that if more groups along a translation chain are involved, even more translation and negotiation work is needed, and even more uncertainty may be introduced in relation to how the knowledge object is translated. As a consequence, it may be assumed that it is more likely that the knowledge object/the knowledge it communicates will be changed as it moves through these groups than it will remain the same.

The conditional propositions that may be formulated concerning the implementation of evidence-based knowledge objects in healthcare organizations based on this are: (1) An evidence-based knowledge object (the knowledge it represents) may just be transferred if the groups involved in the process are alike language-wise and in their culture and interests, (2) it will have to be translated and politically negotiated if it is not, (3) the more different groups of people in the translation chain, the more translation and negotiation work needs to be done, (4) the degree to which the original content of the knowledge object is preserved or changed through the process may be considered uncertain and an empirical question.

3.3. Translation processes as dependent on both humans' and non-humans' work

After having focused primarily on humans' work organization and science and technology studies researchers have increasingly recognized the importance of the work that physical objects and things (materialities) do in organizations. Thus, after having been ignored for many years, actor-network theory and science and technology (4, 45, 60, 61), process-study (62), learning (63) and communication researchers (47) in organization studies have accepted that both humans' and non-humans' (objects/things/materials) work is important in organizing processes[2].

[2]That this is the case seems obvious when developing IT-systems in hospitals. IT-systems developed to monitor diabetes patients in their homes from the hospital thus include attempts to design and construct

A Cochrane review of Arthroplasties (with and without bone cement) for proximal femoral fractures in adults (64) found that there is good evidence that cementing the prostheses in place will reduce post-operative pain and lead to better mobility. It points out some work that doctors (humans) in a department need to do to "implement" or rather translate the knowledge object; they should choose solutions where the prosthesis is cemented in place instead of other solutions. It also points out some work that non-humans seem to do more or less well in these situations (different artificial joints that doctors may choose from that include different shapes of the stem set into the bone; the incorporation of a secondary joint (bipolar joint); joints that replace only the ball part of the ball and socket hip joint (hemiarthroplasty) and those that also involve replacing the socket part of the hip joint (total hip replacement). As a consequence, to "implement" or rather to translate the above-mentioned knowledge object, translators receiving the Cochrane review in a local orthopedic surgery department need to design and construct new relations and types of interactions between both humans (the patients having hip problems, the doctors who perform hip operations in the department) and non-humans (the different types of prostheses available for such operations) in order to translate the knowledge object. The (performative) effects of the knowledge object will depend on whether a translator succeeds with this local translation and construction of new types of relations and interactions between humans and non-humans (artifacts/things/objects).

Scheuer's (3) "idea-practice translation model" was developed to theorize and model what happens in the encounter between a translator wanting to translate an innovative token (as an idea about a diabetes monitoring system or a knowledge object full of ideas about what to do with certain patients etc.) and a local context as it is translated. It is based on research-based insights from organizational research in actor-network theory (4, 45, 46), ventriloquist communication (8, 47), learning (65, 66) and design processes (67) as well as from research in organizational routines (68) and relational inertia (3, 69). It suggests that change processes in hospitals and other types of organizations are socio-technical (or socio-material) design and construction processes[3]. Scheuer (3) suggests that translation processes that "materialize" (and thus implement) tokens such as evidence-based knowledge objects have the following characteristics:

1. The token (knowledge object) has to be translated into an "actor-network" of humans and non-humans (objects/things/materials) that then do the work that materializes and thus "implements" it (4, 45, 46).
2. The organizing of the humans and non-humans necessary to translate the token (knowledge object) depends on communication and dialogues. In these (ventriloquist) dialogues (8, 47) translators may communicate that they think that certain humans and non-humans are necessary for translating the token. But also unexpected humans and non-humans may communicate and make the translators speak and act in certain ways in that connection (as when surgeons will not change their routines for some reason, or the cement used to cement a prosthesis in place does not fasten it enough and translators need to communicate and try to do something about both problems)
3. The translation process moreover depends on a socio-technical design process. It includes designing and constructing new relations and types of interactions between humans, objects, and contexts (as demonstrated in the example above) (67).
4. The translation process also depends on translators learning which humans, non-humans (objects/artifacts) and contextual factors are relevant for the translation and materialization of the token (the knowledge object) in a given translation situation. Here learning may originate from translators' interaction with locally present "body-external" humans, non-humans and contextual factors. Furthermore, it may originate from the translators' "embodied/internal" reflections about his/her former experiences from interacting with similar types of humans and non-humans in similar contexts, about his/her idea about the future goal of the process or about his/her own understanding of own identity and feelings (65, 70).
5. To be implemented the token (knowledge object) moreover has to be translated into new relations and interactions between humans and non-humans that are then stabilized (and thus become reproduced continuously across time). The stabilizing happens through a process where the translators connect an assembly of certain humans and non-humans, certain activities/actions and supporting artifacts with a narrative about the assembly that makes sense to the translators (68) ("in our department the operation of Arthroplasties for proximal femoral fractures in adults should involve these actors, who interact in this way following these procedures, using these prostheses based on these reasons" etc.).
6. Both symbolic and socio-material tools may be developed and used by the translators to translate the token (knowledge object) (65, 66). Symbolic tools **may be the Cochrane review mentioned above**, theories, models, calculations, or preliminary interpretations about how to design and construct the relevant assembly of humans and non-humans (objects/materials). Socio-material tools may include local experiments and development of prototypes where different assemblies of humans, their activities/types of actions, objects, and narratives about the token are tried out in practice.
7. Finally, the translation process (and thus the implementation of the token/knowledge object) depends on whether the relational

new relations between both humans (the patients, doctors and nurses supposed to monitor the patients) as well as non-humans (physical objects such as body-sensors, IT-modems, internet-connections, computers in the patients' homes as well as in the hospital, software systems, etc.). It moreover includes attempts to design and construct new types of relations and interactions between these humans and non-humans that may produce certain wished-for effects (a system that makes it possible to monitor and help diabetes patients with remembering to take their medicine and to keep them away from the expensive hospital beds).

[3]They are socio-technical/socio-material because they include and depend on both humans' and non-humans' (that is objects') work.

inertia (3, 69) that hinders the translation of the token is overcome. Relational inertia is produced by humans and/or non-humans not relating and interacting in the way they need or are supposed to if the token (knowledge object) is to be materialized realized/implemented). Overcoming relational inertia therefore depends on translators' ability to somehow—through appropriate strategies—solve the conflicts and controversies with all these humans and/or non-humans.

The idea-practice translation model (3) (see **Figure 3**) builds on these assumptions and suggests that the translation of a token (as a knowledge object) will unfold as follows:

Innovative ideas (as those related to knowledge objects) are first noticed and introduced by the translator(s) in the local ecology of (pre-existing) humans and non-humans (things). They identify, communicate with, relate to and interact thereafter with body external as well as embodied actants (humans and non-humans) in order to learn how the ideas/knowledge object may be materialized in their specific local setting. They try to design and construct new relations and interactions between people, things and their local context which have the outcome effects they pursue. They develop symbolic and socio-material tools during the process that help them with this, just as they work with overcoming the relational inertia that hinders the forming of a token-related performative actor network that consists of humans, certain types of interactions and performances, supporting artifacts and a narrative about the assembly that explains it. The outcome of the translation process may be that

1. A new assembly/an actor network (of humans and things) that—through their collective work—realizes the token (knowledge object) is constructed.
2. The assembly/actor network remains dynamically stable and thus keeps producing its local outcome effects over time.
3. A part of the assembly/actor network changes whereby the outcome effects of the assembly change
4. The relations and interactions between the humans and non-humans (objects) in the assembly dissolve whereby the effects of the token/ideas/knowledge object cease to exist in the organization.

3.3.1. Implications and conditional propositions

So, what are the implications of the idea-practice translation model for the implementation of evidence-based knowledge objects in healthcare organizations? The idea-practice translation model assumes that a change like the introduction of an evidence-based knowledge object (a Cochrane review or guideline) will take place in an ecology of locally already existing humans and non-humans where some of them may be relevant to realizing/materializing the knowledge object/its ideas while others will not (3). The translator (perhaps a doctor) who wants to translate the knowledge object will bring his/her experiences from similar situations and their "life history" with them into the situation as well as their ideas about what the future goals are with introducing the knowledge object. They will "draw in" actants from these experiences which they assume are relevant in relation to translating (implementing) the knowledge object into their local context. These may concern humans or non-humans that according to their experiences may be relevant to implementing/translating the knowledge object, they may concern reflections about what may influence wished-for future states when introducing the knowledge object or personal experiences or feelings that the translator has about what may be needed or what may be a barrier to the introduction of the knowledge object in their specific context. As the translator(s)

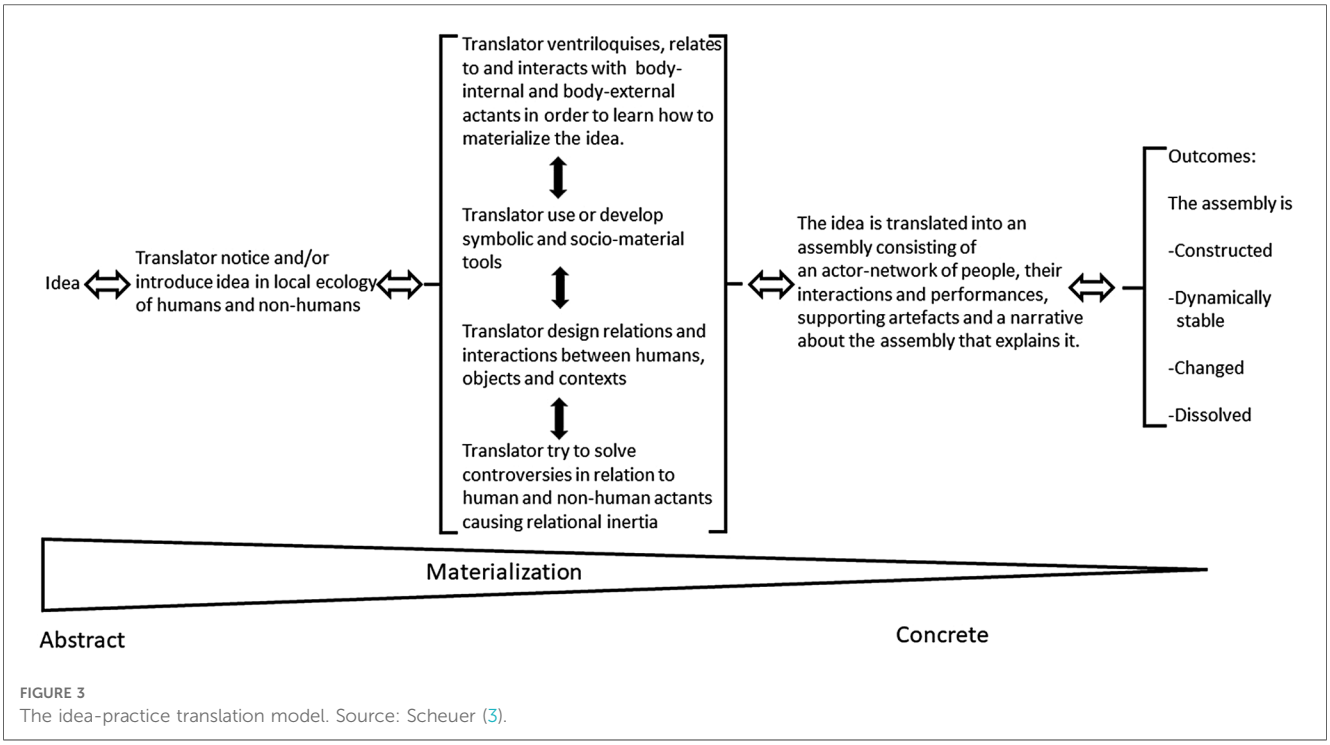

FIGURE 3
The idea-practice translation model. Source: Scheuer (3).

starts to implement the knowledge object, all the above-mentioned types of (unique) experiences will make him/her speak (ventriloquize them) in certain ways about what is needed to implement the knowledge object.

But other things will influence and make him/her speak, too. As the translator starts introducing the knowledge object, he/she will start communicating, interacting with and start trying to design and establish new types of relations and interactions between local humans and non-humans that the translator (according to his/her experiences) thinks are relevant to translating (implementing) the knowledge object. He/she may learn through this interaction process that some of them are indeed relevant to implementing (translating) the knowledge object and may be related and made start interacting in the way that the translator assumes. He/she may, however, also experience and learn that some of these humans and non-humans may not be related and made to interact in the necessary way and this will make him/her speak about these things (with other humans; doctors, employees etc.). Humans and non-humans (objects) not foreseen as relevant to the implementation of the knowledge object may also be "empirically" experienced to be relevant in unforeseen ways which will make the translator(s) speak about them; Rules and regulations may unexpectedly turn out to be in conflict with ideas presented in the knowledge object, the ideas about treatment of patients presented in the knowledge object may not fit the needs of all but only a certain group of the targeted hip replacement patients, economic restraints may make certain parts of the suggested treatment difficult because of limited economic resources in the department etc.).

All the controversies (difficulties) that the translator(s) experience with all these humans and non-humans are labelled "relational inertia" in the idea-practice translation model. Relational inertia is defined as "the accumulated and combined effect of conflicts and controversies that a translator meets and has to overcome as he/she tries to mobilize and assemble an actor network of humans and nonhumans making it possible to perform and thus realize a given innovative change idea and its related supposed and intended effects in an organization" (3). The relational inertia and controversies related to translating the knowledge object need to be overcome using whatever strategy or type of intervention that the translator finds necessary to do so. Symbol-based tools such as those developed by implementation science researchers in their theories, models and frameworks or theories and models developed in organizational change management research may be used to overcome controversies that hinder translation (implementation) of the knowledge object. Translators may also use local experiments as tools, too, to try out which relevant local humans and non-humans may or may not be related and made to interact in "wished-for ways" so that the knowledge object/its ideas may be realized.

Through this socio-material translation, design, construction and learning process the translator(s) gradually learn which humans and non-humans may or may not be relevant to translating (implementing) the knowledge object in his/her local context/ecology of humans and non-humans. If he/she succeeds the knowledge object is translated into a local narrative about what the knowledge object "looks" like in our department which includes certain people, certain types of interactions between them and types of performances by them as well as certain types of interactions with supporting artifacts. The outcome may be a narrative that states that "in our department the operation of Arthroplasties for proximal femoral fractures in adults should involve these actors (humans), who interact in this way following these procedures, using these prostheses and this type of cement (non-humans) based on these reasons" etc. Here an important point is that this narrative does not just represent an interpretation but is literally a representation of the performative actor network of humans and non-humans that was designed, constructed and made to interact and thus do "work" this way through the translation process in this specific department. This "assembly" of these humans, non-humans and the narrative about them may now be produced and reproduced through time and be stable, elements which are a part of the assembly may be changed whereby the assembly and its effects change, or the assembly may be dissolved whereby the knowledge object/its ideas cease to exist in the department.

The conditional propositions that may be derived from the idea-practice translation model are that: (1) A knowledge object in healthcare will not move by itself but will depend on translators doing the translation work necessary to make it move, (2) implementation of knowledge objects depends on local translators' ability to interact, communicate with and learn from their interactions with their own experiences as well as locally present humans and non-humans, (3) it will moreover depend on translators' ability to—through appropriate strategies/interventions, tools and handling of relational inertia—assure that an actor network of humans and non-humans doing the work realizing/materializing the knowledge object is established, (4) if successful, the outcome of the translation of the knowledge object/its ideas will be a performative actor network that consists of humans, certain types of interactions and performances, supporting artifacts and a narrative about the assembly that explains it.

3.4. The consequences of knowledge objects as travelling objects

At the time when organizational institutionalism emerged as a research stream in organization studies, organization theory was dominated by rational choice theory. Rational choice theory assumed that organizational change originated from bounded rational actors who adopted new management ideas, practices, and organizational forms because they wanted to make their organizations more efficient (71). However, research in neo-institutional theory showed that instead of being only rational, actors in organizations also adopted ideas, practices and organizational forms because they were embedded in social networks in institutional fields that—at a given point in time—considered these particular ideas, practices and organizing forms as legitimate (23, 72). Management ideas, practices and

organizational forms were thus not just adopted by managers because they were rational but many times also because they gave these managers legitimacy in the eyes of other network participants.

Scandinavian neo-institutionalists (5) developed the "travel-of-ideas model" to theorize and model how management ideas, practices and organizational forms travel from the organizational field level and into and become institutionalized in local organizations/organizational units. It also theorized and modelled how innovative ideas, practices and organizational forms travelled the other way, that is from an organizational unit/an organization and out into the organizational field (see **Figure 4**).

Czarniawska and Joerges (5) adopted Latour's (4) concept of translation as the key concept to describe how these types of tokens were moved and travelled in and between organizations. As pointed out by Wedlin and Sahlin (50) when summing up the evidence about "the circulation of management ideas" in organization studies it is emphasized that it is a key insight from this research that "not only are ideas subject to translation as they are being circulated, but these ideas also have an impact on other ideas and on those organizations involved in the diffusion and adoption of ideas. Hence, the translation of ideas and their embeddedness in organizational practices and actions should be understood as sets of dynamic and mutually influencing processes" (50).

According to neo-institutional translation researchers tokens/knowledge objects thus move in time and space when they are translated, or as they choose to phrase it; "they travel" (5). This may seem odd since we are used to talking about humans as travelling but not tokens like ideas and objects etc. But again—if we look closer—it becomes apparent that tokens like knowledge objects do indeed travel. As an example, the organizational healthcare field in Denmark includes these actors: The ministry of Health, The Danish Health Authority, the 5 regions, local councils, hospitals, general practitioners, the medical industry, The Danish Medical Association, medical societies in different specialties, Cochrane Denmark, patients and their interest organizations. If a new Cochrane review of Arthroplasties (with and without bone cement) for proximal femoral fractures in adults (64) has been produced by Cochrane, it needs to travel between some of these actors to be implemented. The review may travel through different communication channels: two-way dialogues among people or mass-media channels. It may be communicated through articles in the magazine of the Danish Medical Association, through presentations at a conference or a seminar or it may be communicated through information letters by a medical society or through new regulations presented by the Danish Health Authority referring to the knowledge object. As a consequence, in all of these situations the token/knowledge object needs to move and "travel" between people and/or groups of people in organizations to be implemented.

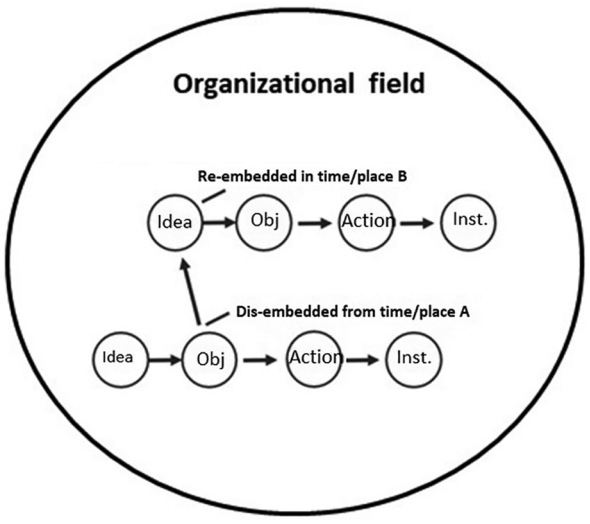

FIGURE 4
The travel of idea model. Source: developed by the author from Czarniawska and Joerges (5).

The neo-institutional organization researchers Czarniawska and Joerges (5) studied how management ideas travel in and between organizations in organizational fields where human actors construct each other as belonging to the same field (as in the healthcare field mentioned above) (23). In their "travel-of-ideas model" they offer the following understanding of a successful translation (implementation) process in organizations:

1. An idea is firstly selected and attended to in moment/place A?? (a person or group notices the new Cochrane review that contains new ideas about treating a certain type of patient)
2. The ideas are then translated into an object (a text, a picture, a presentation or a prototype that explains how these ideas may be realized in "our" department) which is then translated into
3. New types of actions derived from the ideas that are then repeated and stabilized into an institution (a pattern of interactions that persists and continuously produces and reproduces and thus "materializes" the ideas related to the review across time and space).

The researchers (5) suggest that the way ideas travel between organizations in organizational fields is that "objectified ideas" (that is ideas that have been described as objects—perhaps a text or a PowerPoint presentation as suggested under point 2 above) are dis-embedded from the local context in the organization it comes from (for instance Cochrane) and are then later re-embedded in a local context of the receiving organization (hospitals,and other organizations and institutions in the healthcare field). A Cochrane review of Arthroplasties (with and without bone cement) for proximal femoral fractures in adults may thus arrive at a hospital through the field-related social networks within which the hospital is embedded whose employees then translate it into a clinical guideline which then starts travelling to other hospitals through field-related social networks, where it then becomes translated into new forms of actions, that then, if repeated over time, become institutionalized.

However, Czarniawska and Joerges (5) and other neo-institutional organization researchers (51, 52) have suggested that other competing ideas to a travelling idea—for instance

those related to how to make Arthroplasties in the knowledge object—may exist and influence the travel of these ideas. Thus, instead of translators being rational or bounded rational in their decision-making they may also be influenced by other things. They may be motivated to adopt and translate new ideas about how to treat patients because they become fashionable (perhaps among surgeons) (52), because they serve their own or other people's interests (51) (surgeons who don't want to mass-produce based on standards but want to protect their professional autonomy as well as expertise by doing operations "their way") or because they correspond with someone's (perhaps their own) ideology, because they are forced to do so (by regulative pressures from authorities) (23) or because dominating and highly legitimate field actors (like the Danish Medical Association) or local innovators and opinion makers notice and start "speaking on behalf" of the ideas/the knowledge objects and make them the "legitimate ideas/objects" to adopt (53).

3.4.1. Implications and conditional propositions

Knowledge objects and the ideas they contain need to be translated into objects and actions in certain ways to make the impact and produce the effects that Cochrane researchers associate with them. As a consequence of what was mentioned above, however, neo-institutional organization researchers would expect that a loyal one-to-one translation of a Cochrane review (and guideline) and its treatment ideas in a local department in a hospital will be a rare and unusual case (that would need to be studied) rather than an expected outcome of the rational communication and implementation of it. Thus if a new review of Arthroplasties (with and without bone cement) for proximal femoral fractures in adults and a clinical guideline developed based on it has been produced by Cochrane, it is not at all certain that the potential receivers of this review/guideline and its ideas will notice it and do "the rational thing" and just implement it when it is communicated. If the review/guideline happens to be noticed, it may not "just be implemented" but rather find itself in competition with other ideas about how to treat patients that did not originate from Cochrane and that may influence the translation of it. What the outcome of that complex, multi-actor and geographically dispersed translation process will be may be considered an empirical question.

The conditional propositions that may be derived from the idea model and neo-institutional research are: (1) The knowledge object and the ideas it contains will be "materialized" (and thus implemented) by being translated into objects and actions by the local receivers of it where it may or may not become repeated over time and thereby institutionalized, (2) the knowledge object and the ideas related to it will probably be changed as it moves and is translated by people and groups of people in the social networks of the organizational healthcare field, (3) what will influence the direction and content of the translation of the knowledge object/its ideas may be difficult to foresee with certainty and may be considered an empirical question.

4. Relevance of translation theories and models for implementation science[4]

As explained by Scheuer (73), processes of organizational change may be studied using variance or process theories about organizational change (48). Variance theories use independent variables as necessary and sufficient causes of variation in dependent variables. It may for instance be suggested that more of *X* and more of *Y* produces more of *Z*. Process theories use the sequence of events, activities and choices situated in time as well as in space to tell a story which explains how outcomes came about: They did A and then B to get C (48). These two approaches to the analysis of organizational change may be associated with two different ontological views: being and becoming realism (74). Being-realism is a fundamental ontological posture which asserts that reality pre-exists independently of observation and as static, discrete, and identifiable "things", "entities", "events", "generative mechanisms", etc. In contrast becoming-realism gives primacy to a processual view of reality. How an "entity" "becomes" constitutes what that actual entity is so that the two descriptions of an entity are not independent. Its "being" is constituted by its "becoming" (74).

Often implementation science theories, models, and frameworks (40) seem to study organizational change processes using a variance theory approach. The emphasis is put on developing process models, theories and determinant and evaluation frameworks, which provide a detailed description of how implementation processes related to the implementation of

[4]Since the author of this article is not an implementation science researcher and the aim of this article is not to compare the translation perspective on change with the perspectives of change found in implementation science, it is not relevant or possible to cover all the dimensions where the translation theories and models may be similar to or different from implementation science theories, models and frameworks. Instead, the aim of the article is to offer some insights and conditioned propositions based on theories and models from organizational translation studies that may offer implementation science researchers some new views on and, if further developed by implementation science researchers, hypotheses about what may characterize implementation processes in healthcare organizations. As a consequence, the following discussion will have a limited scope and only cover the relevance of translation theories and models for a few selected theories and frameworks in implementation science as seen from an organization studies researcher's point of view.

evidence-based knowledge unfold (as for instance described in Graham et al.'s Knowledge-to-action model (75)[5], what variables or factors may enable or be a barrier during the implementation process as in the CFIR framework (78) and how implementation success may be measured [as in the evaluation frameworks by Glasgow (79) and Proctor (80)]. It is identifying the key aspects of processes and variables that influence the implementation process that is focused on, and it is the predictive potential of these theories, models, and frameworks for researchers as well as practitioners wanting to implement something that give them their scientific and normative value.

In contrast, translation theories and models build on a process and becoming-realist view that uses the sequence of events, activities and choices by translators situated in time as well as in space to explain how outcomes of translation/implementation processes came about. It is assumed that what a token—for instance a knowledge object—becomes is constituted by its becoming—that is by the translation process it goes through. Translation theories and models thus build on the "minimal" assumption that tokens in organizations—including management ideas, concepts and, as assumed here, knowledge objects—do not move by themselves but need to be moved by people (as suggested in Latour's (4) definition of translation above). To implement something necessitates construction of new relations and interactions between people and (for some translation researchers) things/objects (non-humans) that then—through their collective work—may (or may not) realize/materialize the token (3).

As a consequence, to foresee in advance what general variables may influence the translation/implementation process as well as what may enable or be a barrier to it (as in implementation science theories, models and frameworks) is "downplayed" in translation theories and models while developing a better processual understanding of how tokens (as a knowledge object, ideas, concepts, etc.) move and become "powerful" through the process of translation is given more attention.

Translation theories and models may thus offer implementation science researchers a new understanding of implementation as translation processes and some preliminary conditioned propositions about translation/implementation processes from which hypotheses may be developed and tested in future studies. On the other hand, implementation science researchers may offer organizational translation researchers insights into general theories, models, frameworks, concepts and variables concerning processes, enablers and barriers to translation/implementation that may make it possible for translation researchers and practitioners to identify in more detail what specific variables happen or happened to influence a particular empirical implementation/translation process. A few examples where the translation perspective may contribute to further developing implementation science and where implementation science may contribute to further developing organizational translation studies may be provided:

The CFIR (Consolidated Framework for Implementation Research) (78) was designed as a deterministic framework with the aim of creating a `one-stop shop' for clearly labelled and defined theoretical constructs to describe contextual factors that may have an impact on implementation success; specifically barriers and facilitators outside the evidence-based intervention that may hinder or facilitate efforts to integrate sustained change into clinical practice. It is comprised of five major domains: innovation characteristics, outer setting, inner setting, as well as characteristics of individuals and process. The process domain is related to stakeholders' perceptions of the success of the planning that took place when implementing an innovation including whether a context/needs assessment was completed, action items were developed and an implementation timeline, and whether implementation goals were set. The theoretical constructs describing contextual factors and what may hinder or facilitate implementation may inform translation researchers and give them a better understanding of which factors might influence the direction of translation processes. Translation theories and models may offer an alternative to the process understanding of the CFIR framework that does not focus on implementers planning processes but suggests that researchers should instead empirically follow and document how what translators along the translation chain do with a token—for instance a knowledge object—affect how that token is implemented and what the effects of that token turn out to be. This approach would make it possible to document empirically not just which planning factors and variables, but also which other contextual factors pointed out by the CFIR framework empirical data showed influenced the implementation (translation) of the token and its outcome. Moreover, it would make it possible to identify other variables not foreseen by the CFIR framework that may also have influenced the process and its (implementation/translation) outcome.

The above-mentioned translation approach to analyzing processes may also be relevant for The Theoretical Domains Framework (which is a determinant framework). It implies a system approach to implementation where the system is understood as an integrated whole composed of not only the sum of its components but also the

[5]Both knowledge translation and implementation science aim to bridge the gap between research and practice. Knowledge translation is about ensuring that knowledge users are aware of and use research findings in their decision-making. Implementation science studies the "black box" between research and practice to understand how evidence-based interventions can be successfully integrated into practice (76). However, implementation science and knowledge translation researchers do not seem to agree on a clear distinction between the two approaches. Nilsen (40) thus relates the knowledge-to-action model (75) to the process model category in his overview over theories, models and frameworks used in implementation science while the knowledge translation researchers Straus et al. (77) identify the same model as the key knowledge translation model in their introductory book: Knowledge Translation in Health Care - Moving from Evidence to Practice (Wiley Blackwell). It may therefore be suggested that the translation theories and models and the conditioned propositions derived from them in this article may be as relevant to knowledge translation researchers as they are to implementation science researchers. However, it should also be emphasized that whether that is the case will depend on further research.

relationships among those components (40, 81). It thus describes five interdependent determinants that are hypothesised to influence implementation processes and their outcomes;

- Characteristics of the implementation object,
- Influences at the individual healthcare professional level
- Patient influences,
- Collective-level influences,
- Effectiveness of implementation strategies to support implementation.

The framework, however, does not provide an understanding of through which types of processes these determinants become connected and end up producing certain outcomes during the implementation process. Here the translation perspective and its theories and models may contribute to a better understanding of these issues as they imply that a researcher needs to track and document how an implementation object becomes (or does not become) implemented/translated through translators' construction of new relations and interactions between people and (for some translation researchers) things/objects (non-humans) in certain contexts that then—through their collective work—does or does not realize/materialize the token/implementation object (3). By empirically tracking and documenting the translation process in this way, it would be easier for implementation researchers to identify and specify in more detail which types of influences affected or did not affect the process and how these influences did or did not come to do so.

An adaptation may be defined as a change to the content or delivery of an evidence-based intervention (EBI) that is designed to tailor the intervention to the needs of a given context (82). Adaptation researchers in implementation science have developed different types of frameworks to describe and identify the characteristics of adaptation processes; the Framework for Reporting Adaptations and Modifications -Expanded (FRAME) (83) and Moore et al.'s (84) framework. Kirk et al. (82) criticize these frameworks for only having a posthoc perspective which they consider shortsighted. They instead offer the "Adaptation-Impact Framework" which according to the researchers may be used to analyze the outcomes of adaptations after they have been finalized and implemented in the new context and used for proactive considerations of the potential impact of adaptations before they are finalized and implemented. The Adaptation-Impact Framework identifies three domains; (1) Adaptation characteristics which describe adaptations to the content and delivery as well as who delivered it and to whom, (2) possible Mediating or Moderating factors explaining why and how outcomes are achieved (through assuring fit and alignment of intervention with core components of intervention while considering the impact), (3) outcomes in relation to the intervention (client outcomes, service outcomes) and implementation (acceptability, appropriateness, adoption, feasibility, fidelity, cost, penetration, and sustainability) Kirk et al. (82) summarize the results of current adaptation research in this way:

"In general, research examining adaptation outcomes shows mixed results (85, 86): some adaptation efforts maintain or enhance outcomes of interest, whereas others diminish desired effects (87, 88) However, evidence is lacking regarding why and how adaptations produce demonstrated outcomes (that is, the pathways by which adaptations influence outcomes). Moreover, there is a lack of guidance and research on which outcomes (intervention or implementation outcomes) adaptations influence and how (that is, whether certain types of adaptations are more likely to influence certain types of outcomes, and what the total impact of adaptations will be" (82).

Here it may be suggested that using a process and becoming-realist translation view that uses the sequence of events, activities and choices by translators situated in time as well as in space to explain why and how adaptations produced certain outcomes seems highly relevant. It may be used to track and follow the pathway of translations through the translation chain making it possible to identify in more detail what influenced the direction and content of the adaptations that the translators made from point A to B and C etc. in time (and space).

Translation study researchers interested in how tokens change through translation processes may on their part learn a lot from the adaptation researchers in implementation science. Translation researchers in actor-network theory (4, 45, 46) suggest that both the token that moves (as an intervention or a knowledge object) and the humans that move it will change during the translation of it. Other translation researchers inspired by linguistic theory consider tokens (as interventions and knowledge objects) as texts (written or spoken) that need to be translated—ideally as loyal as possible—from a context A with one culture and language to another context B with another culture and language (7). Others try to theorize and model how such translation processes unfold as transfer, translation, and political negotiation processes (6) or complex socio-material design and construction processes (3). Here, however, implementation science adaptation researchers have a much richer vocabulary and several taxonomies describing which variables may influence and determine the content and direction of such processes that may be informative and contribute to translation researchers developing more refined perceptions of and ways to theorize these adaptive aspects of translation processes.

5. Conclusion

This article has discussed and identified some implications of organizational translation theories and models for processes related to implementation of evidence-based knowledge objects in healthcare organizations. It has also suggested some conditional propositions about translation of knowledge objects in such organizations that may be derived from them. It is concluded that organizational translation studies offer a new and different way of theorizing implementation processes in healthcare organizations. It is a way that assumes that the translation of tokens (including knowledge objects) unfolds through uninterrupted translation chains where the tokens need to be continuously given new energy and moved by people in a chain of translations to be implemented. The token will most likely be adjusted and changed through the translation process because the token and what counts as knowledge in relation to it will not just be transferred but also translated and politically negotiated as it moves. Finally, it may be concluded that in a

translation view people and, according to some translation researchers, also objects/materials will need to be mobilized and influenced to act on behalf of a token (as a knowledge object) to translate and thus implement it in a local context.

However, to make people and objects act on behalf of and through those actions in practice "realize" a token is—as demonstrated—not easy. It depends on and demands that a lot of different and typically locally unique types of translation work is done before a token may be "implemented". It may depend on translators' ability to introduce and adjust the token to a unique, pre-existing local context and ecology of humans and non-humans (objects/things) and it may depend on translators' ability to design and construct new relations and interactions between people and (for some translation researchers) things/objects (non-humans) that then—through their collective work—may (or may not) realize/materialize the token in the local context in focus (3) As a consequence the assumption that knowledge (ideas) may be stored in physical knowledge objects/texts which may then be transferred and reproduced by others/the receivers in an objective and thus non-subjective way seems questionable to translation study researchers. Moreover, they would suggest that the idea that the content of knowledge objects may be transferred from a sender to a receiver and may be implemented without being changed by the activities and translation processes of the actors involved seems if not unlikely then at least very uncertain.

It has been suggested that implementation science researchers seem to prefer a variance theory approach in their research that builds on a being-realist ontological posture where it is identifying the key aspects of processes and variables that influence implementation processes that are focused on and it is the predictive potential of these theories, models and frameworks for researchers as well as practitioners wanting to implement something that gives them their scientific and normative value. This was contrasted with the process and becoming-realist view of organizational translation study researchers who use process theories and the sequence of events, activities and choices situated in time as well as in space to tell a situated story about how outcomes of translation (implementation) processes came about. Here emphasis was ***not*** put on trying to theorize, model and foresee which variables may influence the change process in advance (as often seen in implementation science research) but on theorizing and modelling in more detail the process through which change comes about. The first approach suggests that a practitioner should build his/her implementation decisions on theories, models, and frameworks that general research evidence has shown influence implementation processes. The second approach proposes that the practitioner should focus on understanding the processes through which local changes come about but "downplay" his/her attempts to foresee in advance which other factors and variables may influence the content and direction of the (translation) process.

Consequently, it was suggested that translation theories and models may offer implementation science researchers a new understanding of implementation as translation processes and some preliminary conditioned propositions about translation/implementation processes from which hypotheses may be developed and tested in future studies. Implementation science researchers may on their part offer organizational translation researchers insights into general theories, models, frameworks, concepts and variables concerning processes, enablers and barriers to translation/implementation that may make it possible for translation researchers to identify in more detail what specific variables happen or happened to influence a particular empirical implementation/translation process in focus. Some examples of where implementation research may benefit from translation studies research and where translation studies research may benefit from implementation science research were provided.

Contribution to the field

The translation perspective on organizational change have been developed in organization and management studies in recent years. Recent reviews of this perspective and research on organizational change have been written by (1–3). The contribution of the article is to demonstrate how organizational translation theories and models may offer implementation science a new perspective on the processes through which knowledge objects as Cochrane reviews, clinical guidelines and reference programs are implemented in practice in healthcare organizations and on what the difficulties may be in that connection. The article thus hypothesizes that findings, theories and models from organizational translation studies may also be relevant for implementation science researchers and practitioners. A hypothesis and empirical question that will however- as stated in the article -depend on further research to be answered.

Data availability statement

The original contributions presented in the study are included in the article, further inquiries can be directed to the corresponding author.

Author contributions

The author confirms being the sole contributor of this work and has approved it for publication.

Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Publisher's note

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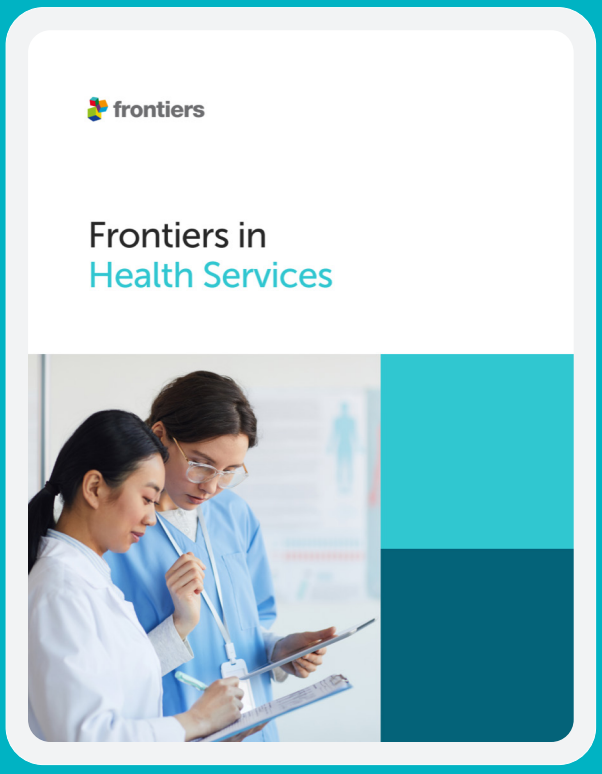

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