

Implementation mapping for selecting, adapting and developing implementation strategies

Edited by

Maria E. Fernandez, Byron J. Powell and
Gill Ten Hoor

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Implementation mapping for selecting, adapting and developing implementation strategies

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Editorial: Implementation Mapping for selecting, adapting and developing implementation strategies

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Editorial on the Research Topic

[Implementation Mapping for selecting, adapting and developing implementation strategies](#)

The development, or selection and tailoring, of strategies to implement evidence-based interventions (EBIs) is essential for closing the research-to-practice gap and improving health and health equity. Although Intervention Mapping (1) includes planning implementation strategies within its 6-step protocol for planning, implementing, and evaluating multilevel interventions, the standalone process for designing implementation strategies for existing EBIs via Implementation Mapping (IM) (2) was introduced in 2019. It is a helpful tool for guiding the design and tailoring of strategies to enhance intervention adoption, implementation, and sustainment. IM draws from the fields of health promotion and implementation science. It includes five tasks: (1) conduct a needs and assets assessment and identify program adopters and implementers; (2) state adoption and implementation outcomes and performance objectives, identify determinants, and create matrices of change objectives; (3) choose theoretical methods and select or design implementation strategies; (4) produce implementation protocols and materials; and (5) evaluate implementation outcomes. The tasks are iterative, with previous tasks revisited throughout to ensure all implementers, outcomes, determinants, and objectives are addressed.

IM addresses two priorities in implementation science by enhancing the design and/or tailoring of implementation strategies and facilitating a better understanding of the mechanisms through which implementation strategies work (3–5).

This Research Topic is dedicated to Implementation Mapping methods, with 15 articles representing a range of settings, topics, and applications (see Table 1).

Below, we highlight examples of the application of IM (by IM Task) in several of the published studies.

Task 1: Implementation Needs and Assets Assessment: Several articles in this issue describe the use of mixed methods to identify implementation determinants prior to designing strategies to address them. [Perkison et al.](#) conducted a needs and assets assessment among frontline staff in community health centers. They employed mixed methods to assess

implementation determinants for the National Diabetes Prevention Program (NDPP) by administering a 56-item online survey and conducting 1-h qualitative interviews. The assessments explored determinants at patient, provider, and organizational levels to inform a multilevel and multicomponent implementation strategy to improve adoption and use of NDPP.

Task 2: Adoption and Implementation Outcomes, Performance Objectives, Determinants, and Change Objectives: [Thackeray et al.](#) identified adoption and implementation outcomes for use of Coach2Move, a physical therapy intervention for

TABLE 1 Summary of included articles.

| Authors | Setting | Topic | Application of IM |
|--|--|---|--|
| Savas et al. | Clinical setting: Community Health Worker | Increase breast and cervical cancer screening—SEMM: Salud en Mis Manos | Development of strategies to accelerate and improve implementation fidelity, reach, and maintenance of the SEMM intervention. |
| Perkison et al. | Clinical setting: Primary care clinics | Adoption of the National Diabetes Prevention Program in primary care clinics | IM was used to systematically identify implementation barriers and facilitators, and design strategies to address those and to develop an adoption, implementation, and maintenance plan. |
| Valerio-Shewmaker et al. | Clinical setting: community health centers | Blood pressure control; adoption of the Target BPTM program | Identify barriers and facilitators for adoption and implementation of a blood pressure control program and develop strategies to increase program adoption and use. |
| Domlyn et al. | Urban setting: USA—FQHC | Implementing a computerized strategy of tobacco cessation | Case example for implementation practitioners; feasibility of using IM within an FQHC with limited funds and a 1-year timeline. |
| Thackeray et al. | Clinical setting: academic health system—physical therapy clinics | Physical activity behaviors among older adults | Development of implementation plan; identifying what physical therapist would need to implement the program, tailored to the needs of the target population. |
| Watson et al. | Organizational setting | Organizational readiness for implementation of sexual assault prevention | IM used to prioritize readiness goals and develop readiness strategies that will improve implementation of prevention evidence-based interventions for sexual assault prevention. |
| Markham et al. | School setting in native communities | Adoption and implementation of evidence-based sexual health programs in schools | IM was used to adapt an online decision support system, as well as applying innovative dissemination and implementation strategies. |
| Jolles et al. | Clinical setting: primary care | Screening for adverse childhood experiences | IM was used to engage diverse partners and guide them through a systematic process that resulted in the development of an implementation strategy. |
| Lovero et al. | Clinical setting: Primary care clinics of Maputo, Mozambique | Adolescent depression services in primary care | IM was used to design an implementation plan comprising 33 unique strategies targeting determinants at the intervention, patient, provider, policy, and community levels. |
| Odawara et al. | Organizational setting: small- and medium-sized enterprises in Japan | Prevention of non-communicable diseases | Combined CFIR and IM to develop implementation strategies tailored to the contextual factors identified in the formative study. |
| Hoskins et al. | Clinical & community setting | HIV medication adherence and care retention | IM used to design a menu of strategies for implementation of an adapted evidence-based intervention for HIV medication adherence and care retention, The process uncovered several challenges. Implementation and effectiveness of strategies developed with IM. |
| Dickson et al. | Urban setting: USA—FQHC | Improving implementation of two behavioral health programs in a Care Coordination Program | Applied IM for the selection and testing of implementation strategies and integrating additional implementation frameworks within IM. |
| Davis et al. | National setting: Uganda | Uptake of contact to find and treat individuals with active tuberculosis | Development of a new theory-informed implementation strategy, in combination with the COM-B (Capability-Opportunity-Motivation-Behavior) model and the Behavioral Change Wheel. |
| Schultes et al. | National setting: Switzerland | Ongoing organized colorectal cancer screening | Evaluation of current state of implementation. |
| Kang and Foster | Community setting | Community-based rehabilitation by occupational therapists | Applying implementation science in rehabilitation; identification of implementation determinants, mechanisms of action, implementation strategies, and outcome evaluation plans. |

older adults with a musculoskeletal condition. The team focused on adoption and implementation behaviors of clinic managers and physical therapists. They utilized the Consolidated Framework for Implementation Research to examine implementation determinants and described implementation actions (“implementation performance objectives”). They used this information to build a logic model that described the hypothesized mechanisms of action. They also created matrices of change objectives that considered both the specific actions that needed to be carried out to implement the program and determinants that influenced those actions. These matrices helped inform implementation strategy content.

Task 3: Selection of Theoretical Methods and Design of Implementation Strategies: [Lovero et al.](#) collaborated with community partners, including policymakers, providers, and representatives from local and non-governmental organizations, to design implementation strategies. They organized collaborative workshops to create implementation research logic models (6) and selected strategies aligned with Expert Recommendations for Implementing Change (ERIC) (7). They also identified new strategies for determinants not well-addressed by ERIC, tailored them to the specific context, and evaluated their priority and feasibility. They specified their strategies using Proctor et al.’s recommendations (8). Two other studies, [Savas et al.](#) and [Davis et al.](#), exemplified the use of theoretical methods in strategy selection. [Savas et al.](#) employed “A Taxonomy of Behavior Change Methods” (9) to guide their approach, while [Davis et al.](#) used COM-B and the Behavior Change Wheel (10). [Markham et al.](#) demonstrated how to effectively link determinants and change objectives, theoretical change methods (including parameters for their use), and implementation strategies (see Table 4 of that article).

Task 4: Production of Implementation Protocols and Materials: Informed Tasks 2 and 3, [Savas et al.](#) provided a design document for their implementation strategy, which provided details to the creative team on the objectives, determinants addressed, theoretical change method, and other guidance needed to develop the material. They also included protocols and final implementation materials.

Task 5: Evaluation of Implementation Outcomes: [Kang and Foster](#) used IM to develop implementation strategies for a rehabilitation goal setting and goal management intervention. The IM process informed evaluation plans to explore the impact of implementation strategies using a mixed-methods study. They used self-reported surveys to measure process outcomes, considering the change objectives identified in Task 2. The results of this evaluation can offer valuable insights into the mechanisms of implementation strategies and provide an example of how this information can inform further strategy refinement. An acknowledged limitation was that self-reported outcomes may not always align with objectively assessed performance.

Studies described in the special topics issue focused on various socio-ecological levels and settings including primary health care clinics, Federally Qualified Health Centers (FQHCs), businesses, organizations, schools, a university, and community implementation with community health workers. Two studies describe the application of IM on the national level, in Switzerland and Uganda. See [Table 1](#) for details.

Each article described the IM process, giving varied attention to stating implementation goals, identifying and changing

implementation determinants, applying strategies to promote dissemination and implementation, and acknowledging the role of relevant partners. Several studies used IM to integrate the application of several theories and frameworks.

The published articles in this issue show how IM can advance implementation science in several ways including the (1) use of theory in the development of implementation strategies, (2) use of logic models to identify mechanisms, (3) development of implementation research questions, (4) design of studies to evaluate implementation strategies, (5) integration of community engagement in planning strategies to enhance implementation, and sustainment, and (6) planning for broad scale-up and spread.

This Research Topic showcases how IM can contribute to bridging the research-to-practice gap to improve health and health equity. Too many EBIs are not put into practice or are implemented slowly, inequitably, or with poor fidelity. This compromises the potential of research findings in improving healthcare and health promotion efforts. IM outlines a practical method for planning implementation strategies that integrates community engagement, new data, theory and frameworks, and existing evidence. Just as the systematic planning of interventions has improved their effectiveness, IM holds promise for improving the appropriateness, quality, and impact of implementation strategies, which ultimately stands to yield improvements in population health.

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A Modified Implementation Mapping Methodology for Evaluating and Learning From Existing Implementation

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When empirically supported interventions are implemented in real-world practice settings, the process of how these interventions are implemented is highly relevant for their potential success. Implementation Mapping is a method that provides step-by-step guidance for systematically designing implementation processes that fit the respective intervention and context. It includes needs assessments among relevant stakeholders, the identification of implementation outcomes and determinants, the selection and design of appropriate implementation strategies, the production of implementation protocols and an implementation outcome evaluation. Implementation Mapping is generally conceptualized as a tool to prospectively guide implementation. However, many implementation efforts build on previous or ongoing implementation efforts, i.e., "existing implementation." Learnings from existing implementation may offer insights critical to the success of further implementation activities. In this article, we present a modified Implementation Mapping methodology to be applied when evaluating existing implementation. We illustrate the methodology using the example of evaluating ongoing organized colorectal cancer screening programs in Switzerland. Through this example, we describe how we identify relevant stakeholders, implementation determinants and outcomes as well as currently employed implementation strategies. Moreover, we describe how we compare the types of strategies that are part of existing implementation efforts with those that implementation science would suggest as being suited to address identified implementation determinants. The results can be used for assessing the current state of implementation outcomes, refining ongoing implementation strategies, and informing future implementation efforts.

Keywords: Implementation Mapping, implementation strategies, existing implementation, stakeholder engagement, implementation experience, tailored implementation

INTRODUCTION

When implementing empirically supported interventions in real-world settings, planning implementation processes that comprise a good fit between implementation strategies, the respective intervention, and context is a challenging task. Implementation Mapping is an approach based on Intervention Mapping (1) that provides practical guidance and supports

systematically planning implementation processes (2). As a participatory approach, it involves engaging intervention users and implementers in the respective setting. Implementation Mapping has been used for prospectively planning implementation in a variety of fields, such as cancer prevention and control (3) and chronic pain management (4). The process follows five steps: identifying stakeholders and conducting needs assessments, identifying implementation outcomes and determinants, designing implementation strategies, creating implementation protocols, and evaluating implementation outcomes (2).

Benefits of Implementation Mapping include a more transparent selection of implementation strategies that makes it easier to replicate selection processes in similar studies (3). Accordingly, reasons for choosing implementation strategies as well as these strategies' potential mechanisms of action are more explicitly documented (4), which is particularly helpful for presenting the results of the Implementation Mapping process to involved stakeholders (3). Working closely with and understanding the needs of stakeholders is another key element of Implementation Mapping (2). This approach provides practical and systematic guidance on how to do that and thus complements the description of implementation processes offered by implementation frameworks.

Originally, Implementation Mapping was conceptualized as a tool to prospectively guide future implementation actions. However, implementation processes often build on previous and ongoing implementation efforts. In this article, we discuss how to use Implementation Mapping for evaluating and learning from existing implementation to inform future implementation efforts. We define existing implementation as the entirety of processes and strategies that are currently or were previously employed in a system to implement an intervention. The strategies employed by existing implementation efforts may vary in the extent to which they are guided by practical expertise and/or current best evidence on quality implementation.

Evaluating existing implementation is especially relevant for interventions that have been part of a health system over long periods of time and for which implementation gaps have been identified. It is also relevant for interventions that have recently been introduced to practice, but for which resources were insufficient to conduct initial systematic implementation planning. When evaluating existing implementation, engaging stakeholders to build on their implementation knowledge and experience is highly important. Accordingly, the participatory approach that is central to Implementation Mapping is also central to this modified methodology.

Existing Implementation

So far, there has been no common terminology for describing existing implementation efforts. Lau et al. (5) contrast "investigator-driven implementation" with "system-driven implementation." Powell et al. (6) describe existing implementation processes as "implementation as usual" and emphasize a need for studies analyzing current implementation processes in relation to strategies that would be recommended by implementation science.

For describing previous or ongoing implementation efforts, we propose the term "existing implementation" since it points at implementation processes being targeted efforts by stakeholders in the system (5), although these might not be explicitly based on implementation science. For example, when evaluating existing implementation of empirically supported interventions in organizations specialized in autism spectrum disorders, Drahota et al. (7) found that agencies informally followed steps described in the EPIS framework (8), although a structured implementation was not reported.

Evaluating existing implementation can provide a useful overview of strategies that stakeholders already employ to implement interventions in their respective settings. For example, their feasibility, acceptability, or effectiveness can be assessed when planning refined implementation activities. At the same time, stakeholders' practical expertise that drives existing implementation can be harnessed to inform future implementation efforts. Moreover, building on existing implementation structures and processes when designing implementation strategies bears the potential of increased cost-efficiency. Descriptions of how to assess previous and ongoing implementation efforts are scarce. Here, Implementation Mapping can be used to systematically evaluate existing implementation efforts in a participatory process.

Stakeholder Engagement

When evaluating existing implementation, it is crucial to consider the experience and expertise of involved stakeholders, including decision makers, adopters, and implementers "on the ground." Although these stakeholders might not be experts in implementation science, they hold implementation expertise that relates to their respective role and setting. Accordingly, by working together with stakeholders, their practice setting expertise can be merged with the evaluation team's process expertise.

The relevance of engaging stakeholders to improve the design of processes is widely discussed in both implementation and evaluation research. For example, Ramanadhan et al. (9) highlight the benefits of stakeholder engagement in implementation research for an appropriate selection of interventions, developing effective recruitment and retention strategies and capacity building on the part of stakeholders and researchers. In evaluation studies, including stakeholders in decisions about design, desirable outcomes and measures leads to more positive attitudes toward the evaluation process and contributes to both a higher use of evaluation results and internal evaluation capacity building (10).

Identifying stakeholders for an Implementation Mapping process is most likely an iterative process that can include expert interviews, focus groups or snowball sampling (11). When assembling a group of stakeholders, their potential interests, influence, and support for or skepticism toward the intervention, implementation and evaluation process should be considered (11). In an interview study with stakeholders from different health system levels (12), the participants described engagement as starting early in the process, involving two-way communication and ranging from information sharing to

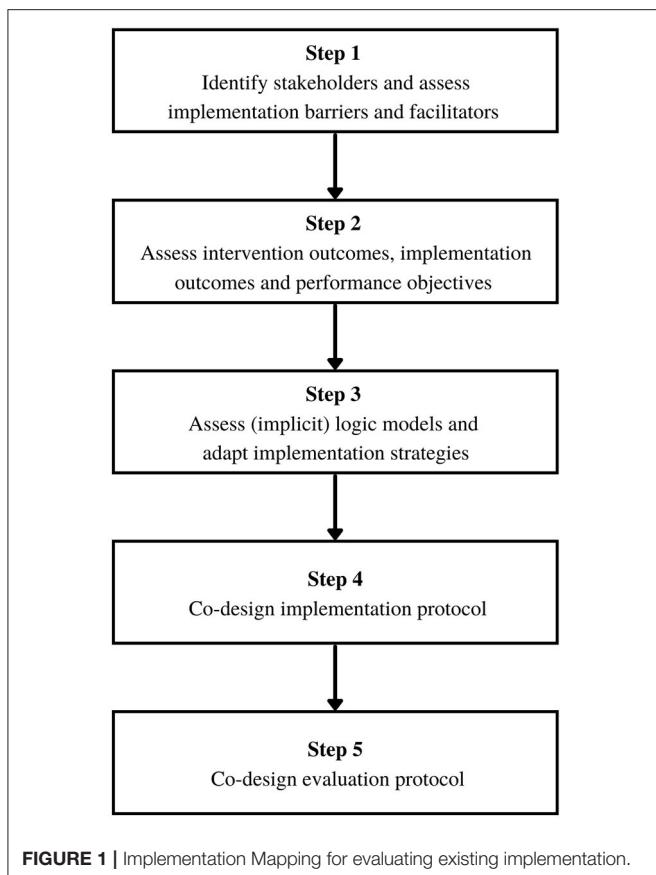


FIGURE 1 | Implementation Mapping for evaluating existing implementation.

shared decision-making. However, the processes and actions that stakeholder engagement entails have not been defined consistently in implementation science (12) and there is little practical guidance on how to include stakeholders' expertise in implementation processes (13).

IMPLEMENTATION MAPPING FOR EVALUATION OF EXISTING IMPLEMENTATION

In the following, we present a roadmap for applying Implementation Mapping to the evaluation of existing implementation. In our description, we assume that an external evaluation team is assigned to evaluate existing implementation of a particular intervention and to improve the implementation process together with stakeholders. **Figure 1** displays the steps of the adapted framework.

(1) Identify stakeholders and assess implementation barriers and facilitators:

The purpose of step 1 is to gain an overview of stakeholders' implementation experience with an intervention and their needs for continuing the implementation. The evaluation team identifies stakeholders who have been involved in the implementation process so far. Here, it is essential to

identify intervention champions and formal as well as informal implementation leaders (14). For this purpose, a stakeholder mapping procedure may be helpful (15). Potentially, there is even an implementation team (16) or other entity that can guide change processes and function as a point of contact. Stakeholders' implementation experience is assessed with a focus on the barriers and facilitators that they have met at multiple levels of their service system. Preferably, this is done in workshops, focus groups or individual interviews and guided by an implementation determinants framework, such as the Consolidated Framework for Implementation Research (14).

(2) Assess intervention outcomes, implementation outcomes, and performance objectives:

The purpose of step 2 is to create clarity around the intended outcomes for an implementation process and the degree to which stakeholders have been able to achieve these. The evaluation team identifies and—if possible—assesses the intervention and implementation outcomes that stakeholders initially intended to pursue. Intervention outcomes are indicators for the effectiveness of the intervention and may have been formulated at the beginning of the existing implementation process. Implementation outcomes are indicators for the effectiveness of implementation strategies (17). Depending on the ongoing process, these may need to be made explicit in collaboration with stakeholders. Both types of outcomes are discussed with stakeholders to generate shared understanding about what has been accomplished so far and which barriers and facilitators influenced this accomplishment. It is also discussed whether the current range of intervention and implementation outcomes needs to be refined, considering the current state of the implementation process and the determinants that have been identified in step 1. Finally, it is crucial to define performance objectives, i.e., concrete tasks to be solved by implementers to achieve revised outcomes. This process is described in detail by Fernandez et al. (2).

(3) Assess (implicit) logic models and adapt implementation strategies:

The purpose of step 3 is to generate an overview of implementation strategies that are already in use and to understand the degree to which these could be adjusted to improve implementation. The evaluation team asks stakeholders, who have been involved in the existing process as implementation agents, to describe employed implementation strategies, i.e., “methods or techniques used to enhance the adoption, implementation, and sustainability of a clinical program or practice” (18). Here, reasons for choosing initial implementation strategies should be explored. For example, strategies may have been chosen due to available resources or opportunities, or they may be based on implicit or explicit theories of change. Most likely, implementers had implicit theories about how strategies would lead to certain outcomes. Making these theories explicit in logic models is helpful for prompting discussions about how employed strategies can lead to desired results. This necessitates the use of insights

gained through step (1) and (2) and allows for rating already employed strategies in terms of their fit with previously identified implementation determinants. For this purpose, both the CFIR-ERIC matching tool (19) and Haley et al.'s (20) description of methods for tracking modifications to employed implementation strategies can be helpful resources. As a result of these discussions, employed implementation strategies may be adapted, discontinued, expanded, or replaced by new strategies deemed to better support the achievement of intervention and implementation outcomes. Furthermore, the conditions that are required for respective strategies to be effective, i.e., their parameters for success, should be described (2).

(4) Co-design implementation protocol:

The purpose of step 4 is to clearly document and detail decisions made in previous steps to ensure that stakeholders can integrate these in everyday operations. The evaluation team co-designs an implementation protocol outlining the updated intervention and implementation outcomes, theories of change, and implementation strategies together with stakeholders who have been involved in steps 1–3. This should include a timeline specifying when to put implementation strategies in place and when to expect changes in intervention and implementation outcomes, facilitating the systematic continuation of the ongoing implementation process. The protocol can be complemented by additional materials that describe the planned implementation strategies and their target groups in more detail. When preparing the implementation protocol, the evaluation team should account for documents describing the existing implementation process that might already be in use.

(5) Co-design evaluation protocol:

The purpose of step 5 is to co-develop an evaluation protocol that stakeholders can use to systematically monitor their continued implementation based on the revised strategies and outcomes. An important goal of this process is to ensure that stakeholders gain full ownership of this approach and can self-evaluate implementation outcomes whenever feasible. For the development of the evaluation protocol, the evaluation team and stakeholders discuss indicators for the attainment of outcomes as well as data sources and measurement instruments to assess these indicators. Already available data sources, such as internal monitoring systems, as well as additional implementation outcome measures should be considered, with a focus on identifying pragmatic, user-friendly instruments that are appropriate to use in the respective context. The implementation outcome repository developed at the Centre for Implementation Science, King's College London, provides a helpful resource for selecting these measures (21). The evaluation team and stakeholders also select an evaluation design with feasible measurement points for self-evaluation and/or suitable time points for external monitoring. Furthermore, and similar to the logic of plan-do-study-act cycles (22), the evaluation protocol can describe iterations of the five steps of Implementation Mapping allowing for a continuous improvement of implementation strategies.

MAPPING THE IMPLEMENTATION OF SWISS COLORECTAL CANCER SCREENING PROGRAMS—A PRACTICE EXAMPLE

The above approach will be applied in an ongoing study aimed at understanding the strategies used to implement multiple organized colorectal cancer (CRC) screening programs in Switzerland. About half of all Swiss cantons have established or are in the process of establishing organized CRC screening programs. These programs aim to improve early detection of colorectal cancer by disseminating easily understandable information about CRC screening, providing low-threshold access and affordable procedures, and using a centralized system to invite and track program participants (23). Yet, little is known about how and why these programs work. By working closely with program leaders and other stakeholders, we will work to identify concrete avenues for improving the implementation of organized CRC screening programs in Switzerland, thereby improving program performance and reducing preventable colorectal cancer-related mortality.

The five steps of Implementation Mapping will be employed in the following way: (1) Across programs, we will map the key stakeholders involved at different levels of program implementation. These will be interviewed, individually and in focus groups, to illicit information about their experience with barriers to the implementation of organized CRC screening programs and their perceptions of what is needed to better navigate these barriers. (2) Interviews and focus groups together with a review of program documentation will also be used to identify intervention and implementation outcomes that have been defined for the different cantonal programs. Moreover, performance objectives for different stakeholder groups who are involved in the implementation will be defined. (3) In a third step, we will illicit information from stakeholders to identify the strategies that are currently used to integrate and maintain organized CRC screening programs in routine health services in Switzerland. This will help to understand the rationale that lies behind the choice of different strategies and to identify the implicit or explicit theories of change that underlie different programs. One output from this phase will be a generic theory of change for the existing implementation of Swiss CRC screening programs. We will then use the literature—based on a systematic integrative review—to assess the degree to which currently used implementation strategies are suited to address shared barriers that exist across programs. The goal of this assessment is to identify gaps in or needs for further modification of existing implementation and to provide suggestions for how to adapt, replace, or expand existing and/or design additional implementation strategies, as well as their parameters for success. An integral part of this work will be regular member checks to enhance the implementability and usability of suggestions made. (4) We will detail the adaptation processes and codify novel implementation strategies in designated CRC screening implementation protocols and provide concrete examples of how to apply these approaches in practice settings. The

aim is to support current and future program stakeholders in solving existing implementation problems and to better navigate common challenges in Swiss CRC screening program implementation. Program stakeholders will be invited to review and provide feedback on all protocols. (5) Protocols will also contain concrete suggestions for how to monitor and evaluate the use of implementation strategies together with their intended implementation outcomes.

DISCUSSION

When planning to refine the existing implementation of an empirically supported intervention, it is crucial to include stakeholders' experience and build on the knowledge and skills already gained through previous implementation efforts. The adapted Implementation Mapping framework presented here provides practical step-by-step guidance on how to evaluate existing implementation in a participatory, stakeholder-centered approach. At the core of this approach are the concrete—rather than hypothetical—barriers and facilitators that stakeholders experience when implementing interventions in specific settings. These settings often differ from the more ideal conditions of research projects in that financial or human resources may be more scarce, organizational climate less optimal, or stakeholder engagement more volatile. As such, Implementation Mapping of existing implementation represents a promising approach for building the knowledge base on real world implementation.

Applying the adapted Implementation Mapping approach is not without challenges. First, the approach may cause concerns among stakeholders about failed implementation efforts being exposed. For example, if a sub-optimal organizational climate is identified as a key barrier to implementation, pointing to implementation leadership building as a strategy, this may unsettle organizational leaders involved in the Implementation Mapping. It is therefore important to consider stakeholders' roles, responsibilities, and interests in the implementation process and to navigate these with great sensitivity (5). Second, it can be challenging to find a shared language that can be used by and with all stakeholders in an Implementation Mapping process. This is important for building a constructive work relationship (3), mutual understanding, and trust. Although collaboration and communication competences are seen as essential for leading successful implementation projects, these are rarely targeted by implementation science training (24) and more practical guidance is needed on how to create successful participatory implementation processes. Finally, both researchers and stakeholders may have limited resources for conducting retrospective Implementation Mapping. For researchers, it may be difficult to obtain funding for adapting implementation processes that are already in progress, and for stakeholders, who are invested in complex implementation efforts, it may

be challenging to find the time needed for an Implementation Mapping process. Finding a good balance between following the steps in detail and using economic ways to do so can include using available documentations, for example, to collect as much information as possible before conducting stakeholder workshops. Moreover, qualitative data collections can be designed efficiently with the goal of reaching high "information power," while working with small samples (25).

Nevertheless, employing Implementation Mapping to evaluate existing implementation offers several benefits. Merging stakeholders' setting expertise, especially regarding local change processes, with implementation science expertise can provide useful information for identifying and targeting implementation challenges. Implicit assumptions explaining choices of current implementation strategies can be made explicit and potential mechanisms of action of implementation strategies are documented. Assessing the current state of implementation outcomes can serve as a baseline for studying future changes in implementation outcomes resulting from refined implementation efforts, just as a retrospective overview of employed implementation strategies can serve as a helpful reference point for interpreting this baseline. In summary, evaluating existing implementation can generate valuable information for the improvement of ongoing implementation efforts, and an adapted Implementation Mapping methodology offers a tool to guide this process.

AUTHOR CONTRIBUTIONS

M-TS, BA, and LCI conceptualized the article. LCa and EN contributed to the theoretical discussion about stakeholder engagement and existing implementation with a literature review. M-TS wrote the first draft of the manuscript and BA included the practice example. BA, LCa, EN, and LCI provided feedback on the manuscript. LCI wrote the contribution to the field statement. All authors approve of the final version of the article.

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Theory-Informed Design of a Tailored Strategy for Implementing Household TB Contact Investigation in Uganda

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Since 2012, the World Health Organization has recommended household contact investigation as an evidence-based intervention to find and treat individuals with active tuberculosis (TB), the most common infectious cause of death worldwide after COVID-19. Unfortunately, uptake of this recommendation has been suboptimal in low- and middle-income countries, where the majority of affected individuals reside, and little is known about how to effectively deliver this service. Therefore, we undertook a systematic process to design a novel, theory-informed implementation strategy to promote uptake of contact investigation in Uganda, using the COM-B (Capability-Opportunity-Motivation-Behavior) model and the Behavior Change Wheel (BCW) framework. We systematically engaged national, clinic-, and community-based stakeholders and collectively re-examined the results of our own formative, parallel mixed-methods studies. We identified three core behaviors within contact investigation that we wished to change, and multiple antecedents (i.e., barriers and facilitators) of those behaviors. The BCW framework helped identify multiple intervention functions targeted to these antecedents, as well as several policies that could potentially enhance the effectiveness of those interventions. Finally, we identified multiple behavior change techniques and policies that we incorporated into a multi-component implementation strategy, which we compared to usual care in a household cluster-randomized trial. We introduced some components in both arms, including those designed to facilitate initial uptake of contact investigation, with improvement relative to historical controls. Other components that we introduced to facilitate completion of TB evaluation—home-based TB-HIV evaluation and follow-up text messaging—returned negative results due to implementation failures. In summary, the Behavior Change

Wheel framework provided a feasible and transparent approach to designing a theory-informed implementation strategy. Future studies should explore the use of experimental methods such as micro-randomized trials to identify the most active components of implementation strategies, as well as more creative and entrepreneurial methods such as human-centered design to better adapt the forms and fit of implementation strategies to end users.

Keywords: implementation strategies, implementation science, intervention design, tuberculosis, Uganda, low-and-middle-income countries, implementation mapping, contact investigation

INTRODUCTION

More than 10 million patients develop active tuberculosis annually, but over three million are never diagnosed because they cannot or do not access diagnostic evaluation and treatment services (1). The WHO End TB Strategy, endorsed by the World Health Assembly in 2015, has called for expanding beyond “passive” facility-based diagnostic strategies to include “active” community-based approaches to finding missing individuals with undiagnosed TB (2). The archetypal example of active case finding is household TB contact investigation, an evidence-based intervention in which TB symptom screening; clinical and laboratory-based TB diagnostic evaluation; treatment for active TB disease; and preventive treatment for latent TB infection are offered to household members of newly diagnosed TB patients. Household TB contact investigation has been endorsed by WHO for routine implementation in high TB-burden countries (3, 4) based on a few high-quality studies (5–7) and a comprehensive systematic review (8). However, implementation studies suggest that the yield of contact investigation is often limited by low rates of uptake and follow-up among community members (9). Although formative research has identified explanations for poor uptake and completion, including a lack of TB-specific knowledge, fear, social stigma, dissatisfaction with clinic services, and lack of money or time to travel to clinics for evaluation (10), little has been published about what might be done to overcome these barriers and improve uptake and delivery of TB contact investigation.

Implementation strategies are specific techniques used to promote adoption, uptake, implementation, and sustainability of innovations and evidence-based practices previously known or believed to improve individual or public health outcomes (11, 12). A variety of approaches to cataloging, developing, or selecting these strategies have been proposed, including employing evidence-based implementation strategies (13) and applying behavioral theory and stakeholder engagement to design strategies targeted to intervention barriers and facilitators (14). The latter approach has much in common with implementation mapping (15), a process to develop strategies to promote adoption and implementation outcomes that is the focus of this Special Issue. The main difference is that implementation mapping is nested within a broader approach to planning and delivering multi-level health promotion activities called intervention mapping (16, 17), which includes separate procedures for designing and adapting interventions.

In contrast, behavior-change theories consider client and implementer behaviors and behavior change objectives at the same time, allowing interventions and implementation strategies to be developed concurrently using the same process rather than sequentially. Given the variety of approaches, there is a critical need for case studies describing the feasibility and results of different methods for designing and selecting implementation strategies. This is especially true in low-income countries, where there is a large body of literature on effective implementation strategies targeting healthcare workers and healthcare recipients but little information about how to select among them (18).

Therefore, beginning in 2014, we undertook a series of formative and implementation studies in Uganda, a low-income country preparing to roll-out household TB contact investigation as a routine service. We first characterized factors that might prevent or enable uptake and completion of contact investigation (19) and then developed a multi-component implementation strategy to target these barriers and facilitators. We drew on published guidelines for developing complex interventions (20) and applied a systematic approach to implementation design based on a general theory of behavior change (21). Using this implementation strategy, we introduced the adapted contact investigation intervention in seven government-run primary health clinics and their surrounding communities in Kampala, Uganda, and evaluated its reach, effectiveness, fidelity/adaptation, and impact in a cluster-randomized, controlled trial (22). Here, we present a case study describing the collaborative, stakeholder-engaged process that we undertook to design and introduce our multi-component, theory-informed implementation strategy for household TB contact investigation, including the outcomes of implementation. We conclude by summarizing learnings from this experience and comparing our approach to alternative approaches including implementation mapping.

MATERIALS AND METHODS

Project Setting and Objectives

The World Health Organization has designated Uganda one of 30 high HIV-TB burden countries (23), with an estimated TB incidence of 201/100,000 people and an estimated adult HIV prevalence of 6.5% in 2016 (24, 25). The Uganda Ministry of Health provides diagnostic evaluation and treatment services for TB and for HIV free of charge in government-run primary health

centers located in every district of the country. Nevertheless, based on data provided by the Uganda National TB and Leprosy Programme, WHO has estimated that about one-third of all individuals with active TB disease in Uganda go undiagnosed and unreported to public health authorities each year (26). In 2014, this large gap in TB case notifications led Uganda to begin making plans to implement household TB contact investigation in the capital city of Kampala, the district with the country's highest TB burden.

The overall objective of this project was to adapt household TB contact investigation to the local context and design a theory-informed implementation strategy (27) to overcome barriers to delivery of this evidence-based intervention (28). Drawing on our previous formative research (19), we conceptualized contact investigation as a series of activities requiring specific behaviors involving household members and lay health workers. We sought to identify a package of components that could facilitate these activities, including (1) index patients agreeing to TB contact investigation; (2) eligible household contacts accepting screening during the home visit; and (3) household contacts with TB symptoms or predisposing factors completing TB evaluation and if diagnosed initiating TB treatment. In addition, we sought implementation components that could maximize the quality of TB contact investigation service outcomes, including safety, timeliness, effectiveness, efficiency, equity, and client-centeredness (29).

Rationale for Using a Theory-Informed Approach to Design the Implementation Strategy

The British Medical Research Council (MRC) defines complex interventions as ones that (1) include multiple, interacting components; (2) address multiple behavioral targets among those delivering and/or those receiving the intervention; (3) target multiple groups or organizational levels; (4) address multiple outcomes that may vary between groups and cluster at different levels of an organization; and (5) allow adaptation of the intervention to local circumstances (20). Complex interventions should be designed with a sound theoretical understanding of the mechanisms through which change can be effected, a process that requires formative research (30). Moreover, a growing literature suggests that implementation strategies designed using behavioral theory are more effective than those designed without the use of theory (31, 32). Of note, the MRC guidelines do not differentiate between components targeting implementers and those that target recipients.

Selection of an Implementation Framework

While a number of implementation frameworks are available to guide planning and introduction of this evidence-based intervention (33–35), we selected the Behavior Change Wheel (BCW) Framework for several reasons. First, it provides a taxonomy for characterizing barriers to and facilitators of evidence-based practices that is systematic and grounded in a unifying theory of behavior, the Capability, Opportunity, Motivation–Behavior (COM-B) model (21, 36). Both COM-B

and an earlier, more expansive version of the model called the Theoretical Domains Framework (TDF) (14, 37)—were developed through a structured process in which experts from diverse disciplines in the social sciences and in public health systematically reviewed 19 widely used frameworks for designing behavior change interventions to identify commonalities. Their goal was to develop a single, comprehensive, and internally coherent model for understanding human behavior. The final result was a simplified theoretical model (COM-B) comprising six fundamental and overarching determinants of behavior, with the 14 component domains of the TDF nested within (and listed here in parentheses). These were *psychological capability* (knowledge; cognitive and interpersonal skills; memory, attention, and decision processes; behavioral regulation) and *physical capability* (physical skills); *physical opportunity* (environmental context and resources) and *social opportunity* (social influences); and *automatic motivation* (emotion, reinforcement) and *reflective motivation* (beliefs about capabilities; beliefs about consequences; optimism; intentions; goals) (21, 37). A second reason that we chose the BCW Framework is that it includes a systematic and comprehensive approach to identifying components of an implementation strategy, involving “intervention functions” and “behavior change techniques” that map to COM-B (or TDF) determinants of behavior using published matrices (36). The process is structured to ensure functional integrity of implementation components—the intervention function of education is suitable for deficits of psychological capability but not for those of reflective motivation, while the intervention function of incentivization is suitable for barriers of reflective motivation but not for barriers of psychological capability. The BCW framework also offers flexibility to adapt to local context and stakeholder preferences, by offering different forms through which selected intervention functions can be achieved (38). For example, the Behavior Change Techniques Taxonomy offers 15 different practical applications for delivery of the education intervention function, as well as 27 practical applications associated with the incentivization intervention function (39). Our third and final reason for selecting the BCW framework is that the simple and practical, step-wise process model prescribed by BCW was familiar to our design team, a diverse group of physicians, epidemiologists, public health practitioners, and front-line care providers working in Uganda and, at the time of this project, new to implementation science.

Study Procedures

Like other approaches to selecting implementation strategies (13, 15, 16) and consistent with MRC guidelines on complex interventions, the BCW includes a process model to guide planning (20). Specifically, the BCW calls for implementers to follow several fundamental steps: (1) understand the behaviors by defining the implementation problem in behavioral terms, selecting at least one target behavior, specifying the core characteristics of that behavior, and identifying what needs to change; (2) identify possible implementation components by specifying the *intervention* functions (i.e., mechanisms) through which the target behaviors that need to change can be

modified and the policies that could support the intervention functions at the organizational and/or societal level; and (3) identify intervention content and implementation options by selecting specific behavior change techniques, policies, and modes of delivery (36). In the Results section below, we provide the details of how we approached each of these steps in a logical progression, although in practice we sometimes diverged from this temporal sequence for convenience, since the qualitative and quantitative formative analyses were carried out in parallel under the leadership of two different team members (IA, MAH). Finally, we used a logic model to conceptualize the process of designing an individual and organizational behavior-change intervention within the larger context of an implementation strategy. Specifically, we sought to summarize the many external human and material resources that the project drew on, the extensive planning activities that were undertaken with stakeholders, and the jointly prepared outputs that influenced implementation outcomes and impact assessment.

Human Subjects

The study protocol was approved by the Uganda National Council for Science and Technology, the Makerere University School of Medicine Research Ethics Committee, the Committee on Human Research at the University of California San Francisco, and the Yale University Human Investigation Committee.

RESULTS

Step 1: Understand the Behaviors

In October, 2013, members of the research team (AC, JLD, AK) including the Uganda National TB Programme Manager (FRM) attended an international workshop to review newly issued WHO guidelines on TB contact investigation (3) and to define the target behaviors. We identified and specified three key activities requiring specific individual behaviors of health

care workers (including lay health workers), index TB patients, and household TB contacts: (1) *index patients* agreeing to a home visit by lay health workers to identify household TB contacts; (2) *lay health workers* screening household contacts for TB, including referring contacts screening positive for possible active TB disease based on symptoms or predisposing factors to attend clinics for testing and evaluation; and (3) *contacts* screening positive attending clinics to complete TB evaluation and treatment by health care workers (Table 1). To better characterize these behaviors, including what might need to change, the likelihood of change, the expected spillover (i.e., indirect) effects of change, and the ease of measuring change (36), we carried out several formative assessments. The first was a qualitative study carried out between February and November 2014 in which we conducted focus group discussions with each of three of the key stakeholder groups (health care workers, lay health workers, household contacts of index TB patients) while the Uganda National TB and Leprosy Programme (NTLP) was introducing TB contact investigation in Kampala. We sought to understand their expectations about the delivery and processes of contact investigation, and to characterize barriers and facilitators of the most important behaviors using the COM-B model, as previously described (19).

Second, we reviewed existing national and international guidelines on TB contact investigation. Uganda National TB Program guidelines specified which index TB patients should be offered contact investigation but did not provide details about how the services should be delivered (40). International guidelines went further, identifying priority populations and procedures for investigating contacts, but did not reference any published evidence on implementation procedures (3). The following year, recommendations from international experts on adaptation and implementation of TB contact investigation guidelines to local setting were released, along with standardized evaluation metrics (41, 42), and we incorporated these into our evaluation plan.

TABLE 1 | Specification of the behaviors required for delivery of household TB contact investigation.

| Specification domain | Contact investigation behaviors | | |
|------------------------------------|---|--|--|
| | Agree to contact investigation | Screen contacts for TB | Complete TB evaluation |
| Who needs to perform the behavior? | Index TB patients | Lay health workers | Household contacts |
| With whom do they need to do it? | Health workers | Household TB contacts | With other household TB contacts who require TB evaluation or by themselves |
| What do they need to do? | Agree to contact investigation and schedule a home visit for TB screening of household contacts | Interview contacts about TB symptoms and predisposing factors for TB | Complete TB diagnostic evaluation and initiate treatment for TB if TB is confirmed |
| When do they need to do it? | As soon as possible after TB diagnosis | When one or more contacts are available | As soon as possible when the services are available |
| Where do they need to do it? | At the clinic or by phone | In the home or possibly by phone | At the clinic or wherever testing is offered |
| How often do they need to do it? | Once | Once | Regularly until TB diagnostic evaluation is complete |

TB, tuberculosis.

The table specifies the characteristics of each of the required behaviors in contact investigation.

Third, we carried out and analyzed focus group discussions with health care workers, focus group discussions with lay health workers (LHWs), and interviews and one focus group with household contacts. We used the COM-B model to categorize emergent themes to identify antecedents of the specified behaviors that we could target for change (19). A full list of factors preventing each of the three key contact investigation behaviors from occurring are provided in **Table 2**. The most prominent of these were a lack of knowledge about TB among index patients and contacts (psychological capability) and a lack of belief in the value of engaging in TB screening and evaluation (*reflective motivation*); a lack of time and space in clinics for LHWs and index patients to meet for counseling and high travel costs to and from households for LHWs and contacts (physical opportunity); a perceived need for permission from the head of household for index patients to consent to a home visit and for contacts to attend clinic visits (social opportunity); anticipated TB-related stigma reported by household contacts, lay health workers, and health care workers and a lack of trust between clinic-based health care workers and household members (*automatic motivation*), including both index patients and contacts. The most important enabling factors noted by

both clinic health workers and household contacts were the personalized and supportive services provided by LHWs.

Fourth, we carried out a quantitative evaluation of the three required behaviors of household TB contact investigation in routine practice, in order to localize bottlenecks in the delivery process, as previously described (28). We found that lay health workers succeeded in scheduling the initial household visit for only 61% of index patients, and visited just 31% of index patient households. Once at the household, lay health workers screened 89% of contacts, but only 20% of contacts who screened positive subsequently attended the recommended TB evaluation visit at the clinic. In total, the conditional probability of an undiagnosed TB patient being screened and diagnosed with active TB among household contacts and linked to care was only 5% (i.e., 20% of all contacts referred, out of 89% of all contacts screened, out of 31% of all households visited).

At the conclusion of Step 1, we summarized the perspectives and experiences of stakeholders and discussed them with implementing partners. Together, we agreed that all three component behaviors could be targets for improvement during implementation, because they shared common behavioral determinants (especially barriers related to

TABLE 2 | Behavioral determinants influencing adoption of three core behaviors of household TB contact investigation, and possible intervention functions specified by the behavior change wheel framework.

| COM-B determinants of behavior | Is change needed for the key behaviors to occur? | | |
|--------------------------------|--|---|---|
| | Agree to contact investigation (Index cases) | Screen contacts for TB (Lay health workers) | Complete TB evaluation (Contacts) |
| Physical capability | No, index patients know how to agree to contact investigation. | Yes, lay health workers lack skills to elicit TB symptoms from contacts during TB screening. | No, most contacts already have the strength and skills to do this. |
| Psychological capability | Yes, index patients lack knowledge about TB to understand the need for contact tracing. | No, lay health workers know how to carry out home visits for screening. | Yes, some contacts cannot remember to follow-up in clinic and do not understand the risk of TB. |
| Physical opportunity | Yes, clinics lack space for private conversations between index patients and household contacts. | Yes, lay health workers are not able to find every household contact in the home at the time of the visit(s). | Yes, some contacts lack the time and money to travel to clinic. |
| Social opportunity | Yes, some index patients feel that they lack authority to consent to contact investigation, especially if not the head of household. | No, clinic workers already trust and encourage lay health workers to perform many TB evaluation activities. | Yes, some contacts need permission from family members to go to clinic. |
| Reflective motivation | Yes, some index patients do not believe that it is necessary or beneficial to contacts undergo TB screening and evaluation. | No, lay health workers already believe they can and should play this role. | Yes, some contacts do not wish to follow-up in clinic because they do not believe that it is necessary or valuable. |
| Automatic motivation | Yes, some index patients fear stigma from the household or community if a health worker visits the home for contact investigation. | Yes, some lay health workers are afraid of contracting TB. | Yes, some contacts are afraid to go to the clinic and do not trust health workers. |
| Intervention functions | Education, Persuasion, Modeling, Environmental restructuring, Enablement. | Education, Training, Persuasion, Environmental restructuring, Enablement, Incentivization. | Education, Training, Persuasion, Environmental restructuring, Enablement, Incentivization. |

COM-B, Capability, Opportunity, and Motivation determinants of Behavior framework; TB, tuberculosis.

For each of the three required behaviors for TB contact investigation, the table presents answers to the question, "Is change needed for the key behaviors to occur?" We provided answers to this question considering each of the six theoretical determinants of behavior specified by the COM-B model, drawing on focus group discussions with and/or direct observation of the core participants in contact investigation, who include lay health workers, index patients, and contacts. Finally, the list of all intervention functions appropriate to the identified COM-B determinants are drawn from published matrixes that list all intervention functions that might fit the identified determinants (36).

psychological capability, social opportunity, and automatic motivation); because implementation components targeting these determinants could all be delivered by lay health workers; and because the close linkage between key screening and evaluation processes within the contact investigation cascade increases the possibility of positive spillover effects on other related behaviors.

Step 2: Identify Implementation Options

In August 2015, the implementation research team met to discuss and select the functional components of the implementation strategy using the Behavior Change Wheel framework (Table 2). To target the determinants of the first behavior, index patients agreeing to a home visit, we identified education, persuasion, and modeling as potential intervention functions best targeted to the identified behavioral determinants. Specifically, we chose education targeting psychological capability (e.g., lack of knowledge of TB and benefits of screening), and persuasion and modeling targeting social opportunity (e.g., lack of authority to agree to home visit), reflective motivation (e.g., beliefs about consequences of exposure to a TB patient), and automatic motivation (e.g., anticipated stigma). We also identified environmental restructuring (i.e., changing the location of screening) and enablement (i.e., social and material support from lay health workers) as intervention functions addressing the physical opportunity (e.g., lack of time and private space in clinics) and other automatic motivation (e.g., distrust of clinic-based health care workers) barriers.

To target the determinants of the second behavior, lay health workers screening household contacts for TB, we identified education, training, persuasion, environmental restructuring, enablement, and incentivization as possible intervention functions. Specifically, we found the most promising of these were education and training to address physical capability (e.g., lack of skills in screening for TB), environmental restructuring through re-timing of visits to weekends to address physical opportunity (e.g., difficulty finding every household contact at home), and persuasion to address automatic motivation (e.g., fear of contracting TB in the household).

To target the determinants of the third behavior, eligible contacts completing TB evaluation clinic, we identified the same set of intervention functions—education, training, persuasion, environmental restructuring, enablement, and incentivization. The most promising of these implementation components included education to address psychological capability (e.g., inability to remember follow-up appointments), environmental restructuring by initiating the TB testing process at home in order to address physical opportunity (e.g., lack time and money travel to clinic), enablement to address social opportunity (e.g., lack of authority to consent to home visit), and education and persuasion to address reflective motivation (e.g., belief of contacts that TB evaluation is not important).

Step 3: Identify Implementation Strategy Content and Delivery Options

Having identified possible intervention functions, we proceeded to select specific behavior change techniques from the Behavior Change Techniques Taxonomy (39), design setting-specific

content, and choose modes of delivery, as shown in Table 3. To convince index patients to agree to contact investigation, the first target activity, we identified multiple behavior change techniques, including (1) *providing information about health consequences of TB/HIV*; (2) ensuring that health information provided to index patients has been approved and validated by a *credible source*, the national TB program; (3) describing *anticipated regret* and possible social and environmental consequences in the form of blame by family members for not referring household contacts for evaluation; (4) providing *information about the social & environmental consequences* of not agreeing to a home visit, including putting household contacts at risk; and (5) eliciting *comparative imaginings of future outcomes* of doing and not doing the behavior. We also considered several other behavior change techniques but did not adopt them routinely because clinic-level stakeholders found them infeasible or inappropriate: (6) inviting a former index TB patient to share the difficult decision to agree to household contact investigation as a *demonstration of the behavior*; (7) *restructuring the social environment* by phoning the head of household to obtain permission for a household visit rather than asking an index patient who is not head of household to consent; and (8) *restructuring the physical environment* by screening the index patient by phone to allow greater privacy and convenience.

To change the second target behavior of lay health workers to enable them to screen more contacts for active TB, we identified multiple possible behavior change techniques, including (1) providing *instruction on performing the behavior* through lectures about how to carry out TB screening; (2) encouraging *behavioral practice/rehearsal* through role plays with one another; (3) *framing/reframing* the first priority of the home visit as supporting the index patient during treatment rather than as performing symptom screening; (5) providing electronic *prompts/cues* to lay health workers using decision support on electronic tablets to guide whom to refer to clinic for further evaluation; (6) *adding objects to the environment* by providing lay health workers with N95 respirators to reduce the risk and fear of contracting TB; and (7) *providing material incentives for the behavior* in the form of a modest financial allowance to lay health workers for transportation to the community and for meals. We also considered one other behavior change technique but did not select it routinely because it was not deemed feasible or acceptable to programmatic officials: (8) *restructuring the physical environment* by screening unavailable contacts by phone.

To change the third target behavior, getting household contacts to complete TB evaluation, we also identified multiple potential behavior change techniques. Several of these, including (1) *information about health consequences*, (2) *credible source*, (3) *anticipated regret*, (4) *information about social & environmental consequences*, and (5) *comparative imaginings of future outcomes* were selected with very similar content and modes of delivery as used for the first target behavior of encouraging index patients to agree to contact investigation. There were also several other possible behavior change techniques that we identified, including (6) *restructuring the physical environment* by collecting sputum and performing HIV counseling and testing at home, a more convenient and accessible location for testing than the clinic and by asking follow-up screening questions by SMS; (7) *restructuring*

TABLE 3 | Selected behavior change techniques, setting-specific intervention content, and modes of delivery for each of the target behaviors.

| Intervention function | Behavior change technique | Setting-specific intervention content | Mode of delivery | Implement? |
|---|---|---|-------------------|---------------------|
| Agree to contact investigation (index cases) | | | | |
| Education | Information about health consequences | See examples below under "Complete TB evaluation." | Lay health worker | Yes |
| Persuasion | Credible source | See examples below under "Complete TB evaluation." | Lay health worker | Yes |
| | Anticipated regret | See examples below under "Complete TB evaluation." | Lay health worker | Yes |
| | Information about social & environmental consequences | See examples below under "Complete TB evaluation." | Lay health worker | Yes |
| | Comparative imaginings of future outcomes | See examples below under "Complete TB evaluation." | Lay health worker | Yes |
| Modeling | Demonstration of the behavior | Invite former index TB patient to share the difficult decision to agree to household contact investigation. | Former TB patient | Worth considering |
| Enablement | Restructuring of the social environment | Seek permission for the home visit from the head of household by telephone instead of asking the index patients to consent. | Lay health worker | Yes, only as needed |
| Environmental restructuring | Restructuring of the physical environment | Screen the index patient by phone for greater privacy and convenience, if preferred. | Lay health worker | Yes, only as needed |
| Screen contacts for TB (lay health workers) | | | | |
| Education | Instruction on performing the behavior | Provide a lecture about how to carry out TB screening. | TB Program | Yes |
| Training | Behavioral practice/rehearsal | Perform TB counseling role plays with one another. | Lay health worker | Yes |
| Persuasion | Framing/reframing | Describe the first priority of the home visit as supporting the index patient during treatment rather than as performing symptom screening. | Lay health worker | Yes |
| Enablement | Prompts/cues | Provide decision support on which contacts to refer for TB diagnostic evaluation using answers to questions about TB symptoms and predisposing factors. | mHealth / eTablet | Yes |
| Environmental restructuring | Adding objects to the environment | Provide lay health workers with N95 particulate respirators to reduce the risk and fear of contracting TB during household visits. | TB Program | Yes |
| | Restructuring the physical environment | Screen unavailable household contacts by phone for greater privacy and convenience if contacts prefer. | Lay health worker | Yes, only as needed |
| Incentivization | Material incentive (behavior) | Receive a modest allowance for transportation to the community and for meals. | TB Program | Yes |
| Complete TB evaluation (contacts) | | | | |
| Education | Information about health consequences | Give positive/negative health information about health consequences of seeking/not seeking TB/HIV evaluation, treatment, and/or prevention. | Lay health worker | Yes |
| Persuasion | Credible source | Explain that index patient/contacts that TB health information has been approved by the leading TB authority in Uganda, the National TB Program. | Lay health worker | Yes |
| | Anticipated regret | Describe the regret that the index patient/contact could experience if screen-positive contacts do not receive evaluation & treatment. | Lay health worker | Yes |
| | Information about social & environmental consequences | Give positive/negative health information about social consequences of seeking/not seeking TB/HIV care, including putting other contacts at risk. | Lay health worker | Yes |
| | Comparative imaginings of future outcomes | Invite index patient/contacts to explicitly compare outcomes of screen-positive contacts receiving/not receiving TB/HIV evaluation/care. | Lay health worker | Yes |
| Environmental restructuring | Restructuring the physical environment | Collect sputum and provide HIV counseling and testing at home instead of in a clinic, using a safe and convenient place in or near the home. | Lay health worker | Yes, but randomize |
| | | Deliver automated survey about TB symptoms every 6 months for 2 years for those found not to have TB and not treated for latent TB infection. | SMS | Yes, but randomize |
| | Restructuring the social environment | Provide TB and HIV testing at home, a less threatening social environment than the clinic. | Lay health worker | Yes, but randomize |

(Continued)

TABLE 3 | Continued

| Intervention Function | Behavior change technique | Setting-specific intervention content | Mode of delivery | Implement? |
|-----------------------|--|---|-------------------------------------|--------------------|
| Training | Instruction on performing the behavior | Instruct screen-positive contacts on how to expectorate sputum for TB examination safely and effectively at home. | Lay health worker | Yes, but randomize |
| Enablement | Action planning | Ask screen-positive contacts to schedule a time to go to clinic for TB/HIV evaluation. | Lay health worker | Yes |
| | Commitment | Ask screen-positive contacts to formally commit to going to clinic for TB/HIV evaluation. | Lay health worker | Yes |
| | Social support—emotional | Encourage screen-positive contacts invited to return to clinic together to provide mutual emotional support. | Lay health worker | Yes |
| | Feedback on outcome of behavior | Deliver results of sputum examination to contacts and recommend next steps. | Lay health worker, or Automated SMS | Yes |
| Incentivization | Non-specific reward | Arrange for screen-positive contacts to bypass the clinic waiting area and go directly to the TB unit when presenting for TB diagnostic evaluation. | Lay health worker | Yes |
| | Incentive (outcome) | Provide a small electronic cash transfer if a screen-positive contact returns to clinic for TB diagnostic evaluation. | SMS | No, not feasible |

SMS, short messaging services; TB, tuberculosis.

The table shows an implementation mapping exercise using the Behavior Change Wheel Framework and Behavior Change Techniques Taxonomy for each of the three key target behaviors (and the individual targeted). The intervention functions identified in **Table 2** provide the starting point for **Table 3**, where candidate behavior change techniques are considered for each intervention function from a matrix listing all possibilities (36). The decision about whether to implement each of these behavior change techniques with their setting-specific content and mode of delivery was based on subjective ratings by implementers and stakeholders using the APEASE (Acceptability, Affordability, Practicality, Effectiveness/cost-effectiveness, Safety, and Equity) criteria, a subjectively assessed set of implementation and service outcomes.

the social environment, by initiating TB and HIV testing at home, a less threatening social environment than the clinic; (8) providing *instruction on how to perform a behavior*, specifically sputum expectoration for TB examination; (9) encouraging *action planning*, by asking contacts to schedule a time to complete TB evaluation in clinic, (10) seeking a *commitment* in the form of a promise to complete TB evaluation in clinic; (11) recommending *emotional social support* by encouraging contacts to travel to clinic together; (12) providing *feedback on the outcome of the target behavior* by delivering results and follow-up instructions via SMS; and (13) offering a *non-specific reward* by enabling contacts to bypass the clinic waiting area when they present for TB evaluation. We also identified (14) providing an *incentive for the outcome* in the form of a small electronic cash transfer upon returning to the clinic, but did not include it, as it was not deemed feasible or acceptable by programmatic stakeholders. All selected behavior change techniques were integrated into contact investigation training materials, procedures, and operating protocols, for easy reference during the trial.

Finally, we also identified three policy changes that could leverage the impact of the selected intervention functions as part of an integrated implementation strategy. The first was a service delivery innovation, shifting responsibility for contact investigation from already over-burdened clinic health care workers to lay health workers. The design team identified a large body of evidence supporting the feasibility, acceptability, and effectiveness of lay health workers in delivering community interventions for TB treatment and other disorders, when provided adequate training, supplies, and modest compensation (43). In addition, health care workers identified them as uniquely suited to this work. Second, a print and radio

advertising campaign to increase general awareness of TB in the community and specific awareness of the new household contact investigation services was proposed and launched by a non-governmental organization serving as implementing partners to the National TB program in Kampala. Finally, local guidelines on contact investigation were envisioned, and these were developed by the National TB Program with input from the study team and other local experts and released in 2019 (44). **Table 4** shows a logic model that summarizes the design of the implementation strategy to improve household TB contact investigation, highlighting the resources, activities, outputs, outcomes, and impact assessment plans (45).

Implementation and Evaluation

Between July 2016 and July 2017, we introduced and evaluated a multi-component implementation strategy to improve uptake and completion of contact investigation. Lay health workers had previously completed Ministry of Health approved trainings on TB contact investigation (5 days) and household HIV testing (4 weeks), training on electronic-tablet based data entry and decision-support by a regional information technology consultant (5 days), and completed a 9-month pre-trial pilot period delivering standard TB contact investigation. Prior to the launch of the trial, they completed a 5-day refresher training covering the specific behavior change techniques and intervention functions that emerged from the BCW design process. Specifically, lay health workers completed didactic and practice sessions with the components targeting uptake, including all of the client-centered education, persuasion, and enablement techniques laid out in **Table 3**, and were encouraged to tailor their use of specific techniques (e.g., weekend visits, language related to framing of invitations) to the preferences

TABLE 4 | Logic model for design of a novel implementation strategy to adapt and deliver household TB contact investigation.

| Resources | Activities | Outputs | Outcomes | Impact assessment |
|------------------------|------------------------------|----------------------------|------------------------------|------------------------------|
| Evidence & Guidelines | Reviewing evidence | Adapted evidence | Implementation protocol | Drafting evaluation protocol |
| WHO | Document review | New TB diagnostic policies | Ethical approvals | Trial registration |
| TB-CARE | Attending CI training | CI implementation guide | Regulatory approvals | Design of fidelity studies |
| NTLP | Inviting local expert input | NTRL diagnostic guidelines | | |
| Systematic reviews | Identifying gaps | New CI literature | | |
| Targeted reviews | Projecting uptake | Cascade of CI delivery | | |
| Frontline stakeholders | Engaging & soliciting input | Summaries of input | Prepared stakeholders | Metrics for M&E |
| Index TB patients | Direct observation | Key behaviors | Education & training | Feasibility measures |
| Household contacts | Focus group discussions | Key themes | Pilot testing | Acceptability measures |
| Clinic patients | Surveys | Behavioral determinants | Direct observation | Fidelity measures |
| Clinic workers | Process mapping | Targeted interventions | Data review | Outcome measures |
| Lay health workers | Skill assessments | Behavior change techniques | Protocol revision | |
| Implementers | Building collaborations | Dialogue with implementers | Coordinated implementation | Disseminating results/plans |
| Uganda MoH | Exchanging information | New TB diagnostic policies | Sharing preliminary results | Local presentations |
| Capital City Council | One-on-one meetings | Facility renovations | CI/adherence support bundle | Local reports |
| Research groups | Exchanging ideas | Kampala TB CI rollout | Troubleshooting technologies | Scientific publications |
| International NGOs | Coordinating roll-out | Staffing agreements | | |
| Community NGOs | Negotiating staff allocation | Mobile app prototype | | |
| ICT vendors | Bidding & specification | Uganda TB CI Guidelines | | |

CI, contact investigation; ICT, Information & Communications Technology; M&E, monitoring and evaluation; MoH, Ministry of Health; NGOs, non-governmental organizations; NTLP, National Tuberculosis and Leprosy Programme; NTRL, National TB Reference Lab; TB, tuberculosis, WHO, World Health Organization.

The table shows the progression, from left to right, of the intervention adaptation and implementation design process, which was characterized by multi-level engagement with stakeholders in order to adapt the WHO recommended household TB contact investigation intervention to the local context and plan for implementation. We began with a formative phase (Resources, Activities, Outputs columns) in which we (1) identified key contact investigation behaviors and activities in collaboration with stakeholders; (2) employed mixed-methods data collection to explore key questions of interest; (3) applied an established theory of behavior change to identify barriers and facilitators of key contact investigation behaviors; and (4) tailored behavior change techniques into implementation strategies targeted to overcome barriers and enhance facilitators. We subsequently moved to a summative phase (Outcomes, Impact Assessment columns) where first piloted then adapted and evaluated the delivery of TB contact investigation, comparing a client-centered, mHealth-facilitated implementation strategy with a standard approach.

of participants. Lay health workers also completed training on implementation components targeting health-workers, and were similarly instructed to apply all of the environmental restructuring, incentivization, and enablement techniques in all households. The implementation effectiveness of these strategies was therefore evaluated in comparison to historical controls. These trainings were jointly delivered by National TB Program implementing partners and research staff, who also provided longitudinal supportive supervision and regular data audits; these were the only two implementation components not derived from BCW and they were implemented because high quality data was required to ensure the integrity of the evaluation. In the pre-post implementation evaluation, uptake of contact investigation (*i.e.*, the first key behavior) among index patients improved markedly from 31 to 79% after introduction of the implementation strategy, while uptake among contacts (*i.e.*, the second key behavior) improved from 89 to 99%, relative to the pilot period (28).

Finally, we evaluated the implementation strategy components that were targeting completion of TB contact investigation (*i.e.*, the third key behavior), including home-initiated HIV-TB testing and follow-up text messaging, in a household cluster-randomized, controlled implementation trial involving 471 eligible index TB patients and 919 household contacts (22). In the standard of care arm, eligible contacts

were referred to clinics for TB and HIV testing and clinical evaluation and did not receive automated text messages. By the end of the trial, we saw no improvement in the proportion of individuals who completed TB evaluation at 60 days (20 vs. 18%, difference 2.5%, 95% CI -6 to 11%, $p = 0.57$), and these proportions were similar to the proportion of 20% observed in the pilot study carried out prior to the implementation period. The negative trial results were primarily attributable to low fidelity delivery of the core implementation components. First, home sputum collection was successful in only 39% of eligible contacts; the reasons for failure included lay health workers not carrying enough sputum collection cups to the home visit, lay health workers being afraid of contracting TB while collecting or transporting sputum; and clients not understanding how to produce sputum and anticipating stigma if neighbors saw or overheard them in the act of expectorating (46). Second, automated text messages were sent out from the data server to only 58% of contacts because of a coding error. Furthermore, only 19% of eligible contacts ultimately received, opened, read, and remembered the messages, for a variety of reasons, including a reliance on shared phones, a lack of electricity to charge phones, weak cell-phone networks in some communities, and a preference for chat and social media applications over SMS (47). Finally, although home HIV testing was feasible and accurate

(48), rates of acceptance were low, primarily because of fear of positive results and anticipated stigma with testing (49).

DISCUSSION

The design of effective implementation strategies is a critical aspect of implementation science that merits greater empirical study to help foster testing and development of best practices (46), especially in low- and middle-income countries. It has been hypothesized that applying a structured approach to designing and selecting implementation strategies may facilitate delivery of evidence-based practices, enhance service and quality, and improve individual and population health outcomes (47). Several influential articles have laid out the theory and practice of designing implementation strategies (30, 48, 49), but there have been relatively few examples of how these approaches can be applied in low-income countries. In addition, it is still unknown how best to tailor interventions to promote implementation (17). Here we have provided a comprehensive overview of our use of a leading implementation planning framework, the Behavior Change Wheel framework. Use of this framework enabled us to develop a multi-component implementation strategy to improve delivery of TB contact investigation, an evidence-based practice that has not been widely or effectively adopted in low-income countries.

When our multi-component strategy was prospectively evaluated, it was extremely successful at increasing uptake of contact investigation among both cases and contacts, but unsuccessful at improving completion of TB evaluation among eligible contacts. While both lay health workers and clients found the implementation components resulting from the theory-informed design process to be feasible and acceptable (50), the delivery of the two key implementation components, home sputum collection (51) and SMS messages (52) lacked fidelity leading to implementation failure. Our results were similar to those from two recent negative randomized trials of BCW-informed interventions, one delivering thrombolytic therapy for stroke in Australia (53) and the other promoting physical activity among adults at risk for cardiovascular disease in the Netherlands (54). Similar to our experience, the authors of these studies found the BCW framework to be feasible and useful for rigorously selecting and specifying implementation components, as have other investigators planning trials of novel BCW-informed strategies to promote smoking cessation in China (55), encourage physical activity among adolescent girls in Ireland (56), and reduce sedentary behaviors at work in England (57). The two groups that observed implementation failures, the Australian thrombolytic therapy group and the Dutch physical activity group, identified challenges with implementation fidelity and a compressed implementation period as factors that limited engagement of the health care workers whom their implementation strategies targeted. These findings contrast with two prior studies that found BCW-informed strategies to be effective for reducing inclusion of unhealthy foods in school lunches in Australia (58) and for preventing melioidosis in Thailand (59). A search of PubMed and clinicaltrials.org

at the end of 2021 identified more than a dozen trials of BCW-informed implementation strategies that were planned, ongoing, or completed and awaiting publication, offering additional opportunities for evaluating the theory-informed design approach.

There were several strengths to our approach. First, we engaged stakeholders at multiple levels of the health system, from household contacts to the national TB program manager to international content experts in contact investigation. Second, we applied a systematic approach to identifying barriers to and facilitators of change, in which we defined the target behaviors of interest and collected extensive amounts of quantitative data to localize practice gaps and qualitative data about emergent themes that might help explain or mitigate these gaps. Finally, we applied a unifying theory of behavior change to develop a behavioral diagnosis for the practice gaps and a prescription for components of an implementation strategy targeted to overcome these gaps. Notably, we found the BCW approach to be equally applicable to both implementers and clients, demonstrating the flexibility of planned behavior change strategies across multiple levels of implementation.

There were also a few limitations to our approach. First, we only considered three general behaviors, a simplification that did not permit us to design for the micro-behaviors of sputum collection and text messaging that gave rise to the key implementation failures. Second, we did not include index patients in our initial qualitative studies, although we did directly observe their participation, survey them on their reasons for non-participation, and elicit information on their perspectives from household contacts and lay health workers (19, 28). Third, our approach, while comprehensive, produced a large number of potential behavior change techniques, too many for us to systematically evaluate for potential effectiveness. Preliminary evaluation of the individual implementation components might have allowed additional opportunities for iterative adaptation to improve the fidelity and fit of the strategy to the local setting (60, 61). Finally, we did not systematically assess organizational readiness (62), to identify individual and health system factors that might have facilitated adaptation at an earlier stage, although we did partner closely with programmatic leaders and implementing partners.

Beyond challenges with implementation fidelity that may or may not be attributable to the design process, we hypothesize that theory-informed design using the Behavior Change Wheel may have other limitations. First and most importantly, the Behavior Change Techniques Taxonomy includes only individual behavior change strategies, and the BCW framework does not offer specific methods for enacting change at the organization level, beyond a few general policies. In contrast, implementation mapping and the Expert Recommendations for Implementing Change (ERIC) approach offer methods for organizational change (16). Second, selecting appropriate intervention functions and behavior change techniques for producing strategies well-targeted to the underlying behavioral determinants, there may still be a need for additional tailoring of these implementation components to the local context. In this regard, showing that a strategy is acceptable may provide sufficient justification for

a TB program to supply that service but may not actually increase demand for that service in a world where clients face choices and tradeoffs about if, when, and how to engage with implementers. While theory-informed design excels at identifying functions (referred to as “methods” in intervention mapping parlance), there is a need for greater attention to developing the forms of the implementation strategy (what intervention mapping calls “practical applications”) (38). Better forms may help ensure that the resulting implementation strategy truly suits the needs of end-users, and one way of achieving this is through iterative refinement prior to or during implementation. Future studies should therefore explore experimental and adaptive approaches to selecting and tailoring implementation components, including the multiphase optimization strategy (MOST) (63), and experiential and empirical methods like human-centered design (64). The ultimate goal should be to ensure that the most active implementation components can be refined to improve their feasibility, acceptability, and fit to the target setting and context.

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

All studies involving human participants were reviewed and approved by the Uganda National Council for Science and Technology, the Makerere University School of Medicine Research Ethics Committee, the Committee on Human Research at the University of California San Francisco, and the Yale

University Human Investigation Committee. Participants and/or their legal guardians/next of kin provided written informed consent and/or assent for contact investigation study activities. In addition, health workers provided either written or verbal consent for participation in qualitative studies.

AUTHOR CONTRIBUTIONS

Material preparation, data collection, and analysis were performed by JLD, IA, AJG, MA-H, JG, EO, DB, and PT. The first draft of the manuscript was written by JLD. All authors commented on previous versions of the manuscript, read and approved the final manuscript, and contributed to the study conception and design.

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Applying Implementation Mapping to Expand a Care Coordination Program at a Federally Qualified Health Center

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Background: A large and growing percentage of medically underserved groups receive care at federally qualified health centers (FQHCs). Care coordination is an evidence-based approach to address disparities in healthcare services. A partnered FQHC established a care coordination model to improve receipt and quality of healthcare for patients most at risk for poor health outcomes. This care coordination model emphasizes identification and support of behavioral health needs (e.g., depression, anxiety) and two evidence-based behavioral health programs needs were selected for implementation within the context of this care coordination model. Implementation Mapping is a systematic process for specifying the implementation strategies and outcomes. The current case study describes the application of Implementation Mapping to inform the selection and testing of implementation strategies to improve implementation of two behavioral health programs in a Care Coordination Program at a partnered FQHC.

Methods: We applied Implementation Mapping to inform the development, selection and testing of implementation strategies to improve the implementation of two evidence-based behavioral health programs within a care coordination program at a partnered FQHC.

Results: Results are presented by Implementation Mapping task, from Task 1 through Task 5. We also describe the integration of additional implementation frameworks (The Consolidated Framework for Implementation Research, Health Equity Implementation Framework) within the Implementation Mapping process to inform determinant identification, performance and change objectives development, design and tailoring of implementation strategies and protocols, and resulting evaluation of implementation outcomes.

Conclusions: The current project is an example of real-world application of Implementation Mapping methodology to improve care outcomes for a high priority

population that is generalizable to other settings utilizing similar care models and health equity endeavors. Such case studies are critical to advance our understanding and application of innovative implementation science methods such as Implementation Mapping.

Keywords: Implementation Mapping, care coordination, federally qualified health center, evidence-based practice, implementation strategy

INTRODUCTION

Profound disparities in accessing and receiving quality healthcare exist for Hispanic or Latino/a individuals, likely contributing to the unequal rates of health issues spanning multiple health areas (e.g., health status, acute and chronic diseases, behavioral health) (1–4). Among these are higher rates of behavioral health conditions and unmet mental health needs when compared to White individuals, conferring vulnerability to further medical and behavioral health problems, preventable morbidity, and societal cost (1, 5). These care disparities have immense public health implications given that the Hispanic or Latino/a population represents the largest and most rapidly growing minority population in California and the United States (6). Efforts to promote equitable and effective care are critical to improve the health of this increasing population and diminish the associated public health impact. Given both the prevalence of behavioral health conditions and substantial public health impact, behavioral health represents a key target within healthcare and health equity efforts.

Federally qualified health centers (FQHCs) play a significant role in the care provision of largely underserved populations, especially Hispanic or Latino/a individuals. FQHCs are funded to provide health care, including primary care and related services, in underserved areas to offset multiple barriers (e.g., geographic, cultural) in care access and utilization. Data suggest that traditionally marginalized individuals, including lower income, racial and ethnic minority or uninsured individuals, comprise a large and increasing portion of those served by FQHCs (7). Further, Hispanic or Latino/a individuals comprise as much as 38% of those served by FQHCs (8, 9), making FQHCs uniquely positioned to promote health and healthcare equity for this population. Importantly, the prevalence of behavioral health conditions among patients are higher in FQHCs compared to other settings (10), with data suggesting that behavioral health conditions such as depression or anxiety were the third most frequent condition seen in FQHCs in 2020 (11). These higher rates of behavioral conditions further underscore the importance of ensuring FQHCs are equipped to address the behavioral health needs of patients served as part of the broader care provision model.

Care coordination is an evidence-based care model that is increasingly implemented to improve care equity, including in FQHCs (12–14). Defined as a person-centered, interdisciplinary approach to integrating healthcare, care coordination models involve case managers to integrate and support patient

care, including services from primary care and other care specialists, patient education and treatment management, adjustment, and follow-up (12–14). Care Coordinators identify the specific needs of patients and the services they are receiving to ensure communication across the multiple service providers and to provide patient education and support surrounding treatment goals and recommendations (15–19). Such models can help bridge key care gaps to improve health equity and are increasingly recommended given their effectiveness for patients with co-occurring medical and behavioral health conditions (19, 20). Indeed, a focus on behavioral health needs is a key qualification area for care coordination accreditation models (21). Further, data support the effectiveness of collaborative care models in treating depression among low-income and minority communities, including Hispanic or Latino/a individuals (19, 22).

In 2017, a partnered FQHC implemented a care coordination model to support health promotion among most at-risk patients. Given the location along the US-Mexico border, most patients served are Hispanic or Latino/a, living at or below 200% of the federal poverty line, and/or largely uninsured. Consistent with broader accreditation standards, behavioral health conditions are a qualifying condition for the care coordination program as well as a prioritized health target of the broader organization. Training in evidence-based behavioral health programs is provided as part of this program, including training in two well recognized and federally and locally prioritized evidence-based practices (EBPs), Mental Health First Aid (23–25) and the Adverse Childhood Experiences Screener (26). Mental Health First Aid is an educational program to increase mental health literacy, reduce stigma, and support mental health service navigation. Through didactic training, implementers are provided with a broad knowledge of behavioral health conditions and basic skills in recognizing, approaching and providing initial support for behavioral health problems (23). The Adverse Childhood Experiences Screener is a short questionnaire used to rapidly identify and assess patients that may be at risk for poor health outcomes due to childhood trauma (26). To optimize implementation and effectiveness of these programs and improve both implementation and patient health outcomes, we applied Implementation Mapping to support an effort to expand and support implementation of behavioral health EBPs within the context of this Care Coordination program serving patients with chronic health condition (e.g., Diabetes, hypertension) at the partnered FQHC.

Implementation Mapping

Informed by the Intervention Mapping process and implementation science, Implementation Mapping provides step-by-step guidance for selecting and designing implementation strategies to guide implementation efforts (27). Implementation Mapping details five sequential tasks: (1) conduct a needs assessment; (2) identify implementation outcomes and performance objectives, identify determinants, and create matrices of change objectives; (3) identify and select theoretical methods implementation strategies; (4) create implementation protocols and materials; and (5) evaluate implementation. Consistent with the Intervention Mapping process on which it was based, Implementation Mapping facilitates implementation strategy development and selection that appropriately consider and address contextual needs and determinants, thereby optimizing implementation outcomes (27). In the current case study, Implementation Mapping in conjunction with broader implementation frameworks, including those specifying key health equity domains, will allow for identification of organizational and provider specific strategies to support EBP implementation and consider key implementation and care equity barriers (e.g., stigma, limited awareness) common to implementing behavioral health programs in settings like the partnered FQHC (28–30).

The purpose of this manuscript is to present a case study featuring the application of Implementation Mapping as part of a study that aims to examine the implementation and expansion of an existing, community-initiated health equity effort within a FQHC located along the US-Mexico border. In combination with relevant health equity and determinant implementation frameworks, we utilized the Implementation Mapping process to inform the development, selection and testing of different strategies to expand and enhance the implementation of evidence-based behavioral health programs within the Care Coordination program at a partnered FQHC.

METHODS

This study is supported as part of the NIMHD-funded San Diego State HealthLINK Center for Transdisciplinary Health Disparities Research (U54MD012397; PIs: Ayala, Wells) aiming to enhance community capacity and improve infrastructure to advance minority health and health disparities. This project focuses on adapting and developing behavioral health evidence-based practice components and corresponding implementation strategies to expand and facilitate delivery of existing evidence-based behavioral health programs implemented within an existing care coordination model at a FQHC. This study was conducted in collaboration with key stakeholders at the FQHC, particularly those involved with the Care Coordination program, and investigators who have extensive experience working with Hispanic or Latino/a communities (E.A.). These individuals provided input and guidance for the design and selection of implementation strategies. This study was approved from the Institutional Review Board (IRB) at the academic institution as

well as the *ad-hoc* IRB at partnered FQHC. Informed consent was obtained from all participants in the current project.

Guiding Implementation Frameworks

In addition to the Implementation Mapping Process, we applied the Consolidated Framework for Implementation Research [CFIR; (31)] to guide the current study. We selected CFIR given the interest in examining organizational level determinants, specification of key implementation determinants, and utility in prior programs conducted in FQHCs applying the Implementation Mapping process [e.g., (32)]. Given the specific emphasis on health equity in the current project, we also applied the Health Equity Implementation Framework [HEIF; (33, 34)] to enable examination of key implementation determinants that may explain the social determinants of health. Specifically, we integrated the three health equity domains detailed within this framework into our application of CFIR.

RESULTS FOR THE APPLICATION OF IMPLEMENTATION MAPPING

Implementation Mapping Task 1: Conduct a Needs Assessment

The first aim of this study consisted of a sequential mixed-methods (quan-QUAL) needs assessment to identify care coordinator perspectives regarding: (1) client service and Care Coordinator training needs related to behavioral health; (2) implementation determinants for selected evidence-based behavioral health programs; and (3) necessary modifications or enhancements to selected evidence-based behavioral health programs. We also assessed perceptions regarding existing and potentially relevant implementation strategies via our initial quantitative survey. The selected implementation frameworks (CFIR, HEIF) guided data collection, analyses, and interpretation, including application to iteratively develop and refine a qualitative focus group guide and codebook applied to conduct and analyze focus groups through in-depth coding. Consistent with the HEIF, for example, we included an explicit emphasis on culturally relevant factors and determinants through specific focus group questions, probes, and codebook. We also included questions pertaining to the CFIR constructs of behavioral health knowledge and beliefs and compatibility of existing evidence-based behavioral health programs such as “Given your experience with these programs, how well do these programs fit with or are appropriate for [the needs of your patients, your role as a care coordinator, the realities of your organization]?” We then included an additional probe assessing for the HEIF health equity domain of cultural relevance, including the fit or acceptability of these practices with the culture, beliefs, preferences and/or language of the largely Hispanic or Latino/a patients served.

Participants included Care Coordinators ($n = 8$ or 50% of the broader population of Care Coordinators at the FQHC) who participated in the initial web-based survey and subsequent virtual focus group; the pilot project lead (K.D.) with experience in mixed-methods needs assessment and qualitative methods led

the focus groups. Each focus group lasted approximately 45 min and were conducted in English *via* secure videoconferencing software (i.e., HIPAA-compliant Zoom). The majority of participants were female (75%), with a Bachelor's (63%) or Associate's (38%) Degree. All identified as Mexican or of Mexican descent and reported delivering care coordination services in English and Spanish. The pilot project lead (K.D.) also conducted two informational interviews with FQHC leaders to gather necessary information regarding evidence-based practice decision making and identification of relevant processes and resources. Qualitative data were initially analyzed using rapid assessment process (35, 36), with findings categorized following each focus group in alignment with focus group guide domains specified by CFIR and HEIF. We (K.D. and T.H.) conducted subsequent in-depth consensus coding, applying an iteratively developed codebook informed by *a priori* and emergent themes and the guiding frameworks. The codebook contained definitions of the codes and guidelines for use. We integrated both quantitative and qualitative types to examine complementarity and expansion (37).

Results from our needs assessment indicated multilevel determinants spanning the organizational, implementer and end recipient or patient levels, including perceived client service and Care Coordinator training needs, for consideration. This suggested a need for multilevel performance objectives to best address these needs and achieve outcomes (see Task 2). Findings indicated limited behavioral health knowledge among both patients and Care Coordinators as well as Care Coordinator limited self-efficacy addressing or assessing behavioral health concerns and implementing behavioral health EBPs. Importantly and consistent with HEIF, our results also indicated several culturally relevant factors or determinants that were raised several times throughout both focus groups. This included the cultural stigma commonly associated with behavioral health and behavioral health treatments within the Mexican culture. A poor match between care practices or recommendations and cultural values was also described. For example, several participants described preferences or beliefs regarding alternative or traditional treatments among their patients frequently limit or impeded adherence to additional treatment recommendations. At the organizational level, limited collaboration between Care Coordinators and behavioral health providers as well as challenges related to the availability of behavioral health services emerged as barriers to EBP implementation. Results also indicated several relevant strategies to address these determinants, including ongoing, dynamic behavioral health trainings, additional culturally relevant and tailored behavioral health educational materials for both patients and Care Coordinators and increased collaboration between Care Coordination and behavioral health. Following analyses, we shared our results with our FQHC partners to aid further contextualization and interpretation and used them to inform identification of relevant outcomes, performance objectives and change objectives (Task 2) as well as selection and design of implementation strategies (Task 3).

In collaboration with our FQHC partners, our needs assessment also informed and confirmed those involved

in the implementation of the evidence-based program and those required to support execution of the corresponding implementation plan. We confirmed that Care Coordinators would be the primary program implementers given the alignment between the evidence-based program target of behavioral health and workload responsibilities and expectations surrounding behavioral health for Care Coordinators. Care Coordination and organizational leaders would facilitate execution of the implementation strategies identified in Task 2. While the initial evidence-based behavioral health trainings would be facilitated by the research team, trainings were designed to be sustainable such that Care Coordination leaders can continue to facilitate and conduct these trainings following the completion of the study.

Implementation Mapping Task 2: Identify and State Adoption and Implementation Outcomes, Performance Objectives, Determinants, and Change Objectives

As mentioned, Task 1 findings aided the identification of relevant implementation outcomes, performance objectives corresponding to each identified implementation outcome, determinants of each performance objective, and change objectives mapped onto identified performance objectives and determinants. In collaboration with FQHC partners, we identified relevant implementation outcomes as well as necessary performance objectives to achieve these outcomes. The project lead and coordinator then reviewed the preliminary needs assessment findings to identify multilevel determinants relative to these performance objectives. Importantly, our Task 1 needs assessments identified several determinants, especially those pertaining to broader outer context or community-level, that while relevant, were deemed not directly relevant to our stated performance objectives and outside the scope of the current project. Thus, these were not included among our final determinants. This included barriers not directly related to behavioral health needs such as social service offerings (e.g., food distributions) or cultural food preferences that were incompatible with broader medical care or medically-related Care Coordination goals (e.g., limiting high carb such as those common in non-perishable foods).

Determinants were also informed by broader CFIR and HEIF health equity domains to ensure alignment with our guiding implementation theories. For example, our needs assessment findings suggested limited knowledge and efficacy surrounding behavioral health. Consistent with the CFIR inner context domains Knowledge and Beliefs and Personal Attributes, this contributed to our specification of behavioral health knowledge and efficacy determinants. Additionally, and consistent with the HEIF health equity domain of culturally relevant factors, we identified knowledge and self-efficacy related to culturally relevant resources and practices as important determinants of stated performance objectives. Finally, we identified change objectives tied to each performance objective and determinant selected. See **Table 1** for summary of implementation outcomes, performance objectives and relevant determinants.

TABLE 1 | Implementation outcomes with corresponding performance and determinants.

| Implementation outcomes | Performance objectives | Determinants (mapped onto CFIR and HEIF domains in parentheses) | | |
|--|---|--|---|---|
| | | Knowledge (CFIR-knowledge and beliefs; HEIF-cultural relevance) | Skills and self-efficacy (CFIR-personal attributes) | Outcome expectations (CFIR-compatibility; personal attributes; relative priority) |
| Care coordinators | | | | |
| Implementation: <ul style="list-style-type: none">• Care coordinators implement behavioral health EBP strategies• Care coordinators will follow identified EBP implementation workflows and procedures (e.g., screen for behavioral health) Sustainability: <ul style="list-style-type: none">• Care coordinators continue using behavioral health EBPs with patients | PO.1: Utilize behavioral health EBP strategies, including culturally relevant strategies, to support recognition of signs or symptoms of behavioral health concerns PO.2: Utilize behavioral health EBP strategies to initiate discussion of behavioral health concerns and refer to behavioral health services (if applicable) PO.3: Follow identified EBP workflow and procedures | K.1: Awareness of behavioral health EBP strategies K.2: Awareness of culturally relevant behavioral health resources and practices K.3: Knowledge of caregiver-directed strategies K.4: Awareness of organizational EBP implementation procedures and workflows | SSE.1: Demonstrate ability to deliver and maintain use of behavioral health EBP strategies to address patient behavioral health needs SSE.2: Express confidence in ability to identify and use culturally relevant behavioral health strategies SSE.3: Express confidence using caregiver-directed strategies to increase care engagement SSE.4: Demonstrate ability to navigate and adhere to EBP workflow procedures | OE.1: Expect that EBP training, delivery, and maintenance will better meet patient behavioral health needs and improve care effectiveness OE.2: Expect that culturally relevant resources and practices will improve match between patient cultural values and care OE.3: Expect that caregiver-directed strategy use will improve patient engagement OE.4: Expect that workflows and procedures will aid EBP implementation |
| Organization and leaders | | | | |
| Adoption: <ul style="list-style-type: none">• Provide behavioral health EBP materials Feasibility: <ul style="list-style-type: none">• Identify, adapt, and execute necessary EBP implementation procedures and workflows Implementation: <ul style="list-style-type: none">• Facilitate ongoing behavioral health EBP trainings and resources• Maintain EBP implementation and workflow procedures Sustainability: <ul style="list-style-type: none">• Maintain EBP implementation and workflow procedures | PO.1: Communicate with staff about practice change PO.2: Facilitate EBP materials and ongoing trainings PO.3: Assure procedures in place for EBP implementation PO.4: Assure sustained EBP implementation and corresponding workflow procedures | K.1: Describe process for communicating practice changes K.2: Describe processes for ongoing EBP training K.3: Describe process for ensuring EBP implementation procedures K.4: Describe steps to assure sustained EBP implementation workflow and procedures | SSE.1: Demonstrate administrative ability to communicate planned practice changes SSE.2: Demonstrate administrative ability to facilitate ongoing program EBP trainings SSE.3: Demonstrate administrative ability to maintain EBP implementation procedures SSE.4: Demonstrate administrative ability to maintain ongoing program EBP implementation | OE.1: Expect that practice change communication will improve care coordinator readiness OE.2: Expect that EBP training will improve implementation OE.3: Expect that workflow procedures will improve staff engagement and completion of EBP trainings OE.4: Expect that sustained workflow procedures will improve sustained EBP implementation |

Implementation Mapping Task 3: Change Method and Implementation Strategy Selection and Design

To complete this task, we first developed and selected theoretical change methods expected to target the determinants and change objectives identified in Task 2. This informed the subsequent, iterative selection of implementation strategies that appropriately operationalized our change methods. As in prior Tasks, this process was done in collaboration with our FQHC partners. We began by considering the implementation determinants and change objectives identified in Task 2 and referred to specific Task 1 quantitative results regarding Care Coordinators perspectives of relevant implementation strategies. This led to the development of specific theoretical change methods, informed by our guiding CFIR and HEIF implementation frameworks as well as literature regarding causal theories in implementation science [e.g., (38)]. For example, given the identified role of knowledge and knowledge change in promoting successful

adoption and implementation, this was hypothesized as a key change method. To operationalize these change methods, we then developed and selected a list of possible implementation strategies. Informed by CFIR, we then prioritized those methods and strategies that would address implementation determinants toward achieving outcomes across multiple inner context levels, including providing information via training and educational materials targeting behavioral health knowledge and efficacy. We iteratively refined our implementation strategies following feedback from our community partner, including feedback regarding fit and feasibility within their organization (Table 2).

During our design, selection, and refinement of implementation strategies, we were mindful of the specific implementation context and parameters within the partnered FQHC. For example, we considered but ultimately did not include the specific strategies of identifying implementation champions and/or quality monitoring to operationalize our change methods of Skill-building, Guided Practice, and Capacity

TABLE 2 | Sample change objectives with corresponding implementation determinants, methods and implementation strategies.

| Change objective | Determinant | Theoretical change methods | Implementation strategies/practical application |
|---|---|---|---|
| Care Coordinators | | | |
| SSE.1: Demonstrate ability to deliver and maintain use of behavioral health EBP strategies to address patient behavioral health needs | <ul style="list-style-type: none"> Skills/self-efficacy Outcome Expectation | <ul style="list-style-type: none"> Provide Information Skill-building and Guided Practice | <ul style="list-style-type: none"> Conduct brief face-to-face training incorporated into existing monthly Care Coordinator meetings |
| K.2: Awareness of culturally relevant behavioral health resources and practices | <ul style="list-style-type: none"> Knowledge and Awareness | <ul style="list-style-type: none"> Improved knowledge Provide Information | <ul style="list-style-type: none"> Develop and distribute additional culturally relevant, tailored behavioral health materials |
| Organization and leaders | | | |
| SSE.2: Demonstrate administrative ability to facilitate ongoing program EBP trainings | <ul style="list-style-type: none"> Skills and Self-Efficacy | <ul style="list-style-type: none"> Organizational Planning Technical assistance/Capacity building | <ul style="list-style-type: none"> Brief face-to-face behavioral health trainings incorporated into existing monthly Care Coordination meetings |
| K.4: Describe steps to assure sustained EBP implementation workflow and procedures | <ul style="list-style-type: none"> Knowledge and Awareness | <ul style="list-style-type: none"> Communication Organizational Planning | <ul style="list-style-type: none"> Meetings to discuss maintaining trainings and EBP implementation workflow maintenance Facilitate discussion regarding linkage and collaboration with behavioral health |

Building but did not select these as they did not optimally fit with the specific structure and roles of the care coordination program, including Care Coordinator workload expectations and responsibilities. Additionally, we developed and tailored strategies to ensure complementarity with existing strategies utilized. For instance, the partnered FQHC conducted trainings for the selected behavioral health EBP materials with Care Coordinators as well as distributed behavioral health educational materials. To complement these strategies, we designed additional behavioral health educational materials targeting improved behavioral health knowledge and efficacy. Given the health equity focus within this project and consistent with the HEIF, strategies were designed or tailored to address or include culturally relevant factors such as patient beliefs, preferences, and treatment or care expectations. For example, educational materials developed aimed to destigmatize behavioral health and detail what the patient could expect from behavioral health services. To expand on existing EBP trainings, we designed ongoing, dynamic and adaptable trainings that were tailored to the specific needs (e.g., health care needs, cultural) of patients served. Trainings will be supplemented with ongoing implementation support and consultation as needed. **Table 3** details the specific implementation strategies selected.

Implementation Mapping Task 4: Implementation Protocol and Materials

We finalized the process of identifying and developing implementation strategies (Task 3) to create an implementation protocol. It details the implementation strategies and practical applications, or those more detailed aspects of the implementation strategies, we designed to create change in the implementation determinants and change objectives identified in Task 2. We expect these implementation determinants and change objectives to drive achievement of the performance

objectives and influence the specified implementation outcomes. Development of the protocol, activities and materials occurred in collaboration with our community partners to enhance the contextual fit within the organization as well as improve identified implementation strategies. To optimize feasibility and sustainability for example, we designed our ongoing trainings to be brief and pragmatic to permit incorporation into existing Care Coordinator team meetings (vs. requiring identification of additional training time). Psychoeducational and training topics were selected and/or developed to address patient and Care Coordinator behavioral health needs as well as normalize and destigmatize behavioral health. Sample topics included what to expect from behavior health services for patients, evidence-based stress management, coping strategies and patient engagement strategies, psychoeducation for setting behavioral health-oriented treatment goals, and psychoeducation for addressing and preventing secondary trauma. Further, we annotated all materials to enable ongoing delivery by partnered Care Coordinator leaders and/or staff as needed.

Implementation Mapping Task 5: Evaluate Implementation Outcomes

Implementation evaluation is planned as part of an ongoing preliminary pilot test of the selected EBP components and implementation protocol within the context of the partnered Care Coordinator program. Evaluation of identified strategies and associated impact on determinants and implementation outcomes is planned using a mixed-methods (quan->QUAL) approach. Initial quantitative measures will assess feasibility, acceptability, and appropriateness, as well as Care Coordinator knowledge and efficacy surrounding behavioral health using existing measures [e.g., Feasibility of Intervention Measure, Acceptability of Intervention Measure and Intervention

TABLE 3 | Final implementation protocol.

| Implementation stage | Determinants/change methods | Theoretical change methods | Implementation strategies (E = Existing; A = Added) | Practical application |
|----------------------|---|--|---|--|
| Adoption | <ul style="list-style-type: none"> • Knowledge and Awareness • Skills and Self-Efficacy • Outcome Expectations | <ul style="list-style-type: none"> • Organizational Consultation/Planning • Information • Persuasion | <ul style="list-style-type: none"> • Capture and share local knowledge (E) • Develop academic partnership (A) • Conduct local needs assessment (A) • Identify implementation determinants (A) | <ul style="list-style-type: none"> • Informational interview with care coordinator and organizational leaders • Complete implementation readiness checklist • Review of existing behavioral health educational materials and EBPs • Review of existing behavioral health workflows and procedures • Ongoing meetings to support iterative and collaborative development of additional behavioral health EBP materials, workflows, and implementation supports • Needs assessment findings and training plans shared with care coordinators |
| Implementation | <ul style="list-style-type: none"> • Knowledge and Awareness • Skills and Self-Efficacy • Outcome Expectations | <ul style="list-style-type: none"> • Information • Improved Knowledge • Persuasion • Skill building and Guided Practice • Improved Collaboration • Improved Efficacy | <ul style="list-style-type: none"> • Develop and distribute educational materials (E/A) • Make training dynamic and promote adaptability (A) • Conduct ongoing educational meetings and training (E/A) • Develop and implement tools and procedures for quality monitoring (E/A) • Promote network weaving (A) | <ul style="list-style-type: none"> • Development and distribute additional culturally relevant, tailored behavioral health materials • Develop tailored, pragmatic behavioral health EBP strategies and training • Brief face to face behavioral health trainings incorporated into existing monthly Care Coordinator • Establish procedures for increased collaboration between Care Coordinator and behavioral health • Establish behavioral health EBP implementation workflows and procedures |
| Sustainability | <ul style="list-style-type: none"> • Knowledge and Awareness • Skills and Self-Efficacy | <ul style="list-style-type: none"> • Information • Organizational Planning • Communication • Technical Assistance/Capacity Building | <ul style="list-style-type: none"> • Provide ongoing consultation and technical assistance (A) | <ul style="list-style-type: none"> • Meetings to discuss maintaining trainings and EBP implementation workflow maintenance • Training annotated to support delivery by care coordination leaders and staff • Research team provide ongoing technical assistance and implementation support and available as needed |

Appropriateness measure (39); adapted evidence-based practice knowledge and confidence measure (40)] tailored for the current study. Qualitative interviews will expand on quantitative data regarding implementation outcomes as well as explore participating Care Coordinator perspectives' regarding programmatic impact on patient-level determinants and outcomes. Again, data collection and analyses will be guided by CFIR and the HEIR. Similar to our Task 1 needs assessments, questions will assess the compatibility of the developed evidence-based behavioral health practices and strategies as well as implementation strategies, including questions such as "You mentioned in the survey that you found the specific strategy of [insert strategy identified in quantitative survey here] as helpful. Can you tell us how you found this helpful?" with the specific probes regarding the cultural relevance and/or fit of this strategy with patients. We anticipate analyzing data using similar methods as in our Task 1 mixed-methods needs assessment.

DISCUSSION

Implementation Mapping has the potential to respond to the need for enhanced methods to design, tailor, test, and evaluate implementation strategies in service of improving effective care delivery and outcomes in community settings (41). Indeed, prior work as well as the work included within this special issue highlight its utility in applying this approach to develop and test implementation strategies to improve the translation of effective care practices (27, 32). The current work presented a case study of ongoing work to apply Implementation Mapping to inform implementation strategy development to expand an existing community-initiated health equity initiative at a partnered FQHC.

A particular strength of the Implementation Mapping approach is the systematic approach to developing and tailoring implementation strategies and materials that begins with articulating desired outcomes and works in a stepwise,

linked fashion toward describing behaviors and behavioral determinants associated with those outcomes. This allowed for facile application of this process as part of community-identified implementation effort where outcomes, especially service outcomes, were already selected and prioritized. In the current project, that included improving the health outcomes, especially behavioral health outcomes, of patients served in the Care Coordination program. An additional strength of this approach is the ease of incorporation of additional implementation science frameworks within the Implementation Mapping process. Given the explicit focus on health equity and organizational implementation determinants in the current study, for example, the application of CFIR and health equity domains from the HEIF was necessary for the current project. Finally, the current project demonstrates the immense utility of applying the Implementation Mapping to advance health equity implementation efforts given the strong emphasis on identifying and addressing implementation determinants, including those contributing to ongoing healthcare inequities, throughout each stepwise task.

This case study also underscored the importance of incorporating strong community partnerships as part of the Implementation Mapping process. The continued input and feedback obtained from our partners and leaders at the FQHC was invaluable to our application of Implementation Mapping, particularly during the selection and design of implementation strategies and methods (Task 3) to assure the feasibility and appropriateness within their organizational context and existing implementation strategies. The value added of involving community stakeholders is consistent with its role as an integral component of implementation and consideration as best practice for implementation research (42, 43). Community engagement adds additional value as part of implementation science methodologies such as Implementation Mapping through by assuring that the continued development and application of these methodologies align with community originated implementation initiatives such as the care coordination program of interest in the current study.

We noted some limitations to Implementation Mapping process, namely the time intensive nature of this process. As noted, the application of this process spanned multiple months, which is consistent with similar work noting a similar timeline as well as large number of individuals involved (32, 44). While these limitations certainly do not outweigh the immense benefits resulting from this process, the time and resources necessary may preclude its use in projects that may otherwise greatly benefit but lack these resources, including community-initiated implementation projects. Future directions include additional application of Implementation Mapping, especially within the context of rapid implementation projects or those applying more

rapid implementation methods to better understand its use and utility in such projects.

CONCLUSIONS

There is a need for more systematic selection, design, specification, and testing of implementation strategies, including methods and tools to support doing so, to maximize the successful translation of EBPs. Implementation Mapping represents a practical method that has the potential to advance our use and understanding of implementation strategies. The current study provides a case study of the application of Implementation Mapping to an applied, community-partnered project aiming to examine the implementation and expansion of an existing, community-initiated health equity effort within a FQHC. It may provide useful insights for future work aiming to apply the Implementation Mapping process to support further health equity implementation efforts.

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 San Diego State University. The patients/participants provided their written informed consent to participate in this study.

AUTHOR CONTRIBUTIONS

KD and TH wrote sections of the manuscript. KD and EA participated in the development of implementation mapping process. All authors reviewed and edited the manuscript.

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Use of Implementation Mapping With Community-Based Participatory Research: Development of Implementation Strategies of a New Goal Setting and Goal Management Intervention System

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Aims: This study aims to identify implementation determinants, mechanisms of action, implementation strategies, and implementation outcome evaluation plans for a new theory-based rehabilitation goal setting and goal management intervention system, called MyGoals, using Implementation Mapping with community-based participatory research principles.

Methods: We completed Implementation Mapping tasks 1 to 4 as a planning team consisting of MyGoals target implementers (occupational therapists (OTs), MyGoals intervention target clients (adults with chronic conditions), and the research team. We are currently conducting mapping task 5. These processes were guided by the Consolidated Framework for Implementation Research, social cognitive theory, the taxonomy of behavior change methods, and Proctor's implementation research framework.

Results: We identified intervention-level determinants (*MyGoals' evidence strength & quality, relative advantages*) and OT-level determinants (*knowledge, awareness, skills, self-efficacy, outcome expectancy*). We selected the MyGoals implementation outcome (*OTs will deliver MyGoals completely and competently*), outcome variables (*acceptability, appropriateness, feasibility, fidelity*), and process outcomes. We also determined three performance objectives (e.g., *OTs will deliver all MyGoals intervention components*) and 15 change objectives (e.g., *OTs will demonstrate skills for delivering all MyGoals intervention components*). Based on the identified outcomes, objectives, and determinants, we specified the mechanisms of change (e.g., *active learning*). To address these determinants and achieve the implementation outcomes, we produced two tailored MyGoals implementation strategies: *MyGoals Clinician Education* and *MyGoals Clinician Audit & Feedback*. We developed evaluation plans to explore and evaluate how these two MyGoals implementation strategies perform using a mixed-methods study of OT-client dyads.

Conclusion: We produced tailored implementation strategies for a rehabilitation goal setting and goal management intervention by using Implementation Mapping with community-based participatory research principles. The MyGoals implementation strategies may help OTs implement high-quality goal setting and goal management practice and thus contribute to bridging current research-practice gaps. Our findings can provide insight on how to apply implementation science in rehabilitation to improve the development and translation of evidence-based interventions to enhance health in adults with chronic conditions.

Keywords: goals, action planning, implementation science, implementation mapping, community-based participatory research, rehabilitation, chronic condition, patient-centered care

INTRODUCTION

Goal setting and goal management is a core routine rehabilitation practice that can determine overall care planning, quality of care, and health outcomes (1–5). Evidence indicates that the implementation of theory-based, client-engaging goal setting and goal management can help clinicians build a better understanding of clients' goals, daily life performance, environment, etc., so they can provide quality person-centered rehabilitation to enhance clients' health (6, 7). Despite such evidence, theory-based, client-engaging goal setting and goal management is not well-implemented in current community-based rehabilitation (8).

Two major research-practice gaps in current goal setting and goal management include limited use of theory-based intervention components and poor client engagement throughout the intervention (8). Current practice often focuses on intervention components related to making goals and plans and does not sufficiently address the monitoring and adjustment of goals and plans (8). In addition, clients are often passive recipients of their rehabilitation goals, and clinicians express difficulties facilitating active client engagement during goal setting and goal management (9, 10). To address these research-practice gaps, it has been suggested that the development of a new practical and effective system that guides clinicians through the process of theory-based, client-engaging goal setting and goal management is needed (8, 10, 11).

To address this need, we developed a new system, called MyGoals, to guide occupational therapists (OTs) to implement comprehensive theory-based, client-engaging goal setting and goal management for adults with chronic conditions in community-based rehabilitation. We developed MyGoals using Intervention Mapping combined with community-based participatory research (CBPR) (12–15). MyGoals ultimately aims to enable clients to achieve personally meaningful rehabilitation goals by supporting OTs in providing a high-quality and person-centered goal setting and goal management intervention. To do so, MyGoals provides OTs with instructions, scripts, and materials for a sequence of six structured goal setting and goal management activities (*Education, Reflection, Find My Goals, Make My Goals, Make My Plans, and My Progress*) that they can directly apply in their practice without considerable

modifications. To facilitate active client engagement, MyGoals guides OTs to use an empowerment-based approach that involves supporting clients to make self-determined decisions and actions (16). These two MyGoals approaches can help OTs deliver a theory-based, client-engaging goal setting and goal management intervention completely and competently.

Complex interventions like MyGoals require tailored and effective strategies to enhance their implementation (17, 18). If MyGoals cannot be implemented by OTs in practice as intended, it will not be efficacious nor effective in a real-life context. Therefore, it is recommended to explore and develop implementation strategies as a part of intervention development (17). This process can be rigorously navigated using an implementation science approach. Although it is not yet widely adopted in occupational therapy and rehabilitation, the use of implementation science has been identified by scholars in those fields as critical in facilitating the translation of evidence-based interventions into practice (12, 18, 19).

Implementation Mapping is an innovative implementation science approach that provides a set of systematic iterative tasks to guide implementation strategy development and evaluation (12). Implementation Mapping emphasizes the importance of using CBPR principles throughout the overall tasks (12). CBPR principles involve engaging and collaborating with community partners such as clients, clinicians, researchers, organizational representatives, policymakers, etc. to better understand the complex intervention context and facilitate the integration of real-world and academic knowledge, thus enhancing the likely effectiveness of interventions and their implementation strategies (14, 15). Implementation Mapping with CBPR principles or collaboration with community partners has shown benefits in other fields, but it has yet to be widely adopted in developing implementation strategies for rehabilitation interventions (12, 20, 21). Given its promising effects, Implementation Mapping may inform the development of effective MyGoals implementation strategies.

The purpose of this study was to use Implementation Mapping to identify MyGoals implementation determinants, mechanisms of action, implementation strategies, and outcome evaluation plans. The results from this study will provide insight into factors that influence the implementation of quality goal setting and goal management in community-based rehabilitation with adults with

chronic conditions and how to address these factors to enhance its implementation. This study will also inform future efforts to apply implementation science and collaborate with community partners to develop and optimize rehabilitation interventions.

MATERIALS AND METHODS

Overall Study Design

This is a mixed-methods study involving five Implementation Mapping tasks as a part of the MyGoals implementation strategy development and optimization process.

Research Context and Planning Team

Members

This paper reports the Implementation Mapping tasks that were completed as a part of the larger MyGoals development project. In the larger MyGoals development project, we established a planning team consisting of two OTs, two adults with chronic conditions, and the research team to develop MyGoals using Intervention Mapping (13) and to develop the MyGoals implementation strategy using Implementation Mapping (12).

We conducted a total of 10 virtual meetings using video-conference calls and in-person meetings at a research-based university in the Midwest, United States. The planning team members were asked to join the meetings when the mapping tasks and meeting agenda were directly applicable to them. The OT planning team members participated in all Intervention Mapping and Implementation Mapping tasks. The client members joined in all Intervention Mapping and Implementation Mapping tasks 4–5. Because our study first aimed to create and optimize MyGoals and its implementation strategy for community-based rehabilitation generally before targeting a specific site, we did not address the adoption and maintenance of MyGoals. The MyGoals Intervention Mapping process will be published elsewhere.

Planning Team Eligibility and Recruitment

Occupational Therapists

Two OTs who met the following inclusion criteria participated as planning team members: (1) aged > 18 years old, (2) English speakers, (3) licensed OTs, (4) experience working in community-based rehabilitation settings with adult clients, (4) at least 1-year professional clinical experience relevant to goal setting and goal management with adults with chronic conditions. The exclusion criteria were (1) no access to the REDCap survey, e-mail, or internet and (2) <1 year of professional clinical experience relevant to goal setting and goal management with adults with chronic conditions to prevent a lack of clinical experience interfering with MyGoals' feasibility evaluation. The OTs were recruited by word of mouth.

Clients

Two clients who met the following inclusion criteria participated as planning team members: (1) aged > 18 years old, (2) English speakers, (3) have one or more chronic conditions. The exclusion criteria were (1) severe cognitive impairment or dementia defined as a total Montreal Cognitive Assessment (22)

score < 21 and (2) any other condition that may interfere with research participation (e.g., blindness). Client participants were recruited using a research participant registry and word of mouth.

Theories, Models, and Frameworks for MyGoals Implementation Strategies

In implementation science, theories, models, and frameworks can be used to guide (1) the implementation process, (2) implementation determinant identification and strategy development, and (3) implementation outcome evaluation (23). In this study, we used Implementation Mapping (12), Consolidated Framework For Implementation Research (CFIR) (24), social cognitive theory (25), the taxonomy of behavior change methods suggested by Intervention Mapping (26), and Proctor's implementation research framework (27).

We used Implementation Mapping (12) to guide the overall process of identifying and optimizing implementation determinants, mechanisms of action, implementation strategies, and implementation outcome evaluation plans for MyGoals. Implementation Mapping provides five iterative tasks including (1) conducting the implementation needs assessment, (2) identifying implementation outcomes and the matrices of change, (3) selecting implementation strategies, (4) making implementation materials, and (5) evaluating implementation outcomes (12).

We used the CFIR (24) to identify MyGoals implementation determinants and guide implementation strategy development. The use of CFIR allowed us to explore and identify influential implementation contextual factors across domains. The CFIR includes intervention, individuals involved, inner setting, outer setting, and process domains (24). As mentioned above, because this study targeted community-based rehabilitation generally, not a specific site, we did not evaluate inner setting determinants. In addition, we used the CFIR-Expert Recommendations for Implementing Change (ERIC) Matching tool (28). The CFIR-ERIC Matching tool provides a list of recommended implementation strategies to address each CFIR-based determinant (28). Thus, the CFIR-ERIC matching tool provided us with potential sets of strategies to start with. To develop implementation change objectives and mechanisms of action, we used social cognitive theory (25) and the taxonomy of behavior change methods (26).

Lastly, we used Proctor's implementation research framework (27) to determine the MyGoals implementation outcomes. In this study, we evaluated the appropriateness, acceptability, and feasibility of MyGoals and MyGoals implementation strategies (27). We also evaluated the fidelity of MyGoals.

Implementation Mapping Tasks

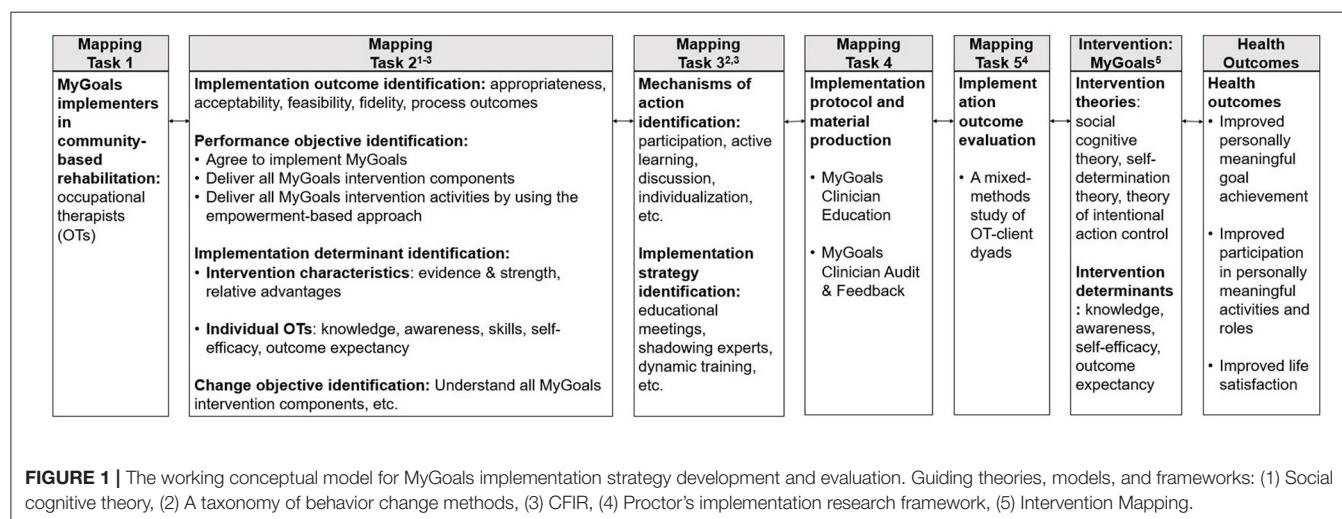
All Implementation Mapping tasks were completed through the planning team meetings. Throughout the meetings, we had a different agenda for each mapping task but used the same principles to maximize client and OT team members' participation in the tasks. Before the meetings, the research

team prepared easy-to-understand and eye-catching meeting readings, presentations, drafts, etc. to facilitate all team members' understandings of topics and brainstorming. During the meetings, the research team reflected, summarized, and facilitated interactive discussions. The research team ensured that all members participated in discussions by explicitly asking individual members' opinions to reach a consensus for each task. After meetings, if the research team found any inconsistent content, they brought these points back and double-checked with planning team members to reach a consensus. **Figure 1** describes the working conceptual model for MyGoals implementation strategy development and evaluation.

In the first task, we conducted a needs assessment through informal discussions to identify who implements MyGoals (i.e., implementers) using the following question: "Who will implement MyGoals in community-based rehabilitation settings?" In the second task, we determined implementation outcomes, performance objectives (what specific step or action MyGoals implementers need to perform to achieve the implementation outcomes), change objectives (what and how determinant needs to be changed to achieve the performance objectives), and implementation determinants. We choose all applicable implementation outcomes from Proctor's implementation research framework (27). To identify the performance objectives, we used the following question: "What do the MyGoals implementers need to do to deliver MyGoals completely and competently?" The implementation determinants were identified using the CFIR (24) and social cognitive theory (25). We used the CFIR Interview Guide Tool to determine MyGoals implementation determinants for each performance objective (29). We used all questions from the CFIR Interview Guide Tool that are designed to explore intervention, individuals involved, and process domains (29). For the outer setting domain, we only explored one determinant, *Patient Needs & Resources*, because other constructs such as *External Policies & Incentives* can vary considerably across OT inner work settings. Based on the identified determinants, we developed the change objectives and the matrices of change.

In the third task, we selected mechanisms of action and implementation strategies that are deemed applicable and effective in targeting the MyGoals implementation determinants to achieve the change and performance objectives. To choose theory- and evidence-based mechanisms of action, we first reviewed all the taxonomy of behavior change methods that are suggested effective in targeting the identified determinants and then identified ones that are applicable with the chosen implementation strategies (26). To determine the MyGoals implementation strategy, we first chose potential strategies that have shown at least 20% of experts' endorsement from the Expert Recommendations for Implementing Change (ERIC) (28) to address the MyGoals implementation determinants. We then selected and optimized final strategies that are most applicable in the current stage of MyGoals and community-based rehabilitation generally. We took into consideration the parameters for effectiveness suggested by the taxonomy of behavior change methods to translate the chosen implementation strategies more effectively and practically (26). It is important to note that the processes of identifying change methods and implementation strategies and designing these strategies based on the parameters for effectiveness were completed iteratively. As we completed these series of iterative steps to reinforce the connections among determinants, change and performance objectives, implementation strategies, and the parameters of effectiveness, we were able to design the MyGoals implementation strategies to align with the chosen determinants, the objectives, and the parameters.

In the fourth task, we produced *MyGoals Clinician Education* and *MyGoals Clinician Audit & Feedback*. We first drafted the *MyGoals Clinician Education* content. Then we optimized the *MyGoals Clinician Education* content and delivery based on the developed matrices of action and chosen implementation strategies. After the initial development of *MyGoals Clinician Education*, we conducted pilot-testing with a new OT-client dyad (identified using the same eligibility criteria and methods described above for planning team members) to optimize *MyGoals Clinician Education*. The OT completed the following



tasks in order: (1) two virtual *MyGoals Clinician Education* sessions, (2) deliver *MyGoals* activities 1–5 to a client, (3) *MyGoals Clinician Audit & Feedback*, (4) deliver *MyGoals* activity 6 to the client, and (5) implementation outcome evaluations. Based on the findings from this pilot-testing, we refined *MyGoals Clinician Education*, *MyGoals Clinician Audit & Feedback*, and *MyGoals*.

In the fifth task, we specified the process evaluation question items, outcome indicators and measures, and the study design to evaluate *MyGoals* implementation outcomes. We are currently conducting the *MyGoals* implementation strategy evaluation using a mixed-methods study of OT-client dyads.

RESULTS

Mapping task 1: We identified that the *MyGoals* implementers are OTs.

Mapping task 2: We determined the *MyGoals* implementation outcome, OTs will deliver *MyGoals* completely and competently, and outcome variables including acceptability, appropriateness, and feasibility of *MyGoals* implementation strategies and acceptability, appropriateness, feasibility, and fidelity of *MyGoals*. Due to the early nature of our research, other implementation outcomes suggested by Proctor's implementation research framework (27) such as penetration, sustainability, uptake, and costs of implementation strategies were not explored in this research. We also identified three performance objectives: (1) Agree to implement *MyGoals*, (2) Deliver all *MyGoals* intervention components, and (3) Deliver all *MyGoals* intervention activities by using the empowerment-based approach.

We then explored *MyGoals* implementation determinants using all CFIR domains except the inner setting and found that intervention- and individual-level determinants are key determinants. The identified intervention-level determinants are *MyGoals*' evidence & strength and relative advantages. This is because *MyGoals* is new, so OTs are not yet aware of its evidence and benefits over other existing systems. Thus, to facilitate *MyGoals* implementation, it will be crucial that OTs understand its evidence and its advantages over other existing systems. The OT-level determinants are their knowledge, awareness, skills, self-efficacy, and outcome expectancy. To target these OT-level determinants, we specified change objectives for each chosen determinant. **Table 1** shows the matrices of change which illustrates determinant, change objectives, and performance objectives. No outer setting- and process-level determinants were found to be critical in this research.

Mapping task 3: Based on the identified change objectives, we selected the mechanisms of change using the taxonomy of behavior change methods (26). All selected mechanisms of change are outlined in **Table 1**. For a detailed description of each mechanism and parameters for effectiveness, refer to Kok et al. (26).

To develop *MyGoals* implementation strategies, we first selected 27 potential ERIC-recommended strategies that can address the *MyGoals* implementation determinants. Then we selected nine ERIC-recommended implementation strategies

that can inform the development of *MyGoals* implementation strategies. Based on these nine strategies, we developed two *MyGoals* implementation strategies: *MyGoals Clinician Education* and *MyGoals Clinician Audit & Feedback*. These strategies were further enhanced by incorporating the parameters for effectiveness suggested by the taxonomy of behavior change methods (26). For instance, one of the common mechanisms of change used in this project included individualization. According to the taxonomy of behavior change methods, providing personal communication tailored to a person's needs is an essential parameter to activate the individualization change method (26). Thus, we incorporated personal communication in developing *MyGoals* implementation strategies by being more intentional and explicit to ask and respond to the individual OT's needs to improve the likely effectiveness of *MyGoals* implementation strategies. **Figure 2** describes the *MyGoals* implementation strategy selection and optimization process.

We developed *MyGoals Clinician Education* based on the following six ERIC-recommended strategies: conducting educational meetings, developing educational materials, distributing educational materials, making training dynamic, promoting adaptability, and shadowing other experts (28). The remaining three strategies, auditing and providing feedback, facilitation, and providing ongoing consultation, were used to inform *MyGoals Clinician Audit & Feedback* (28). We described two *MyGoals* implementation strategies based on the reporting guideline for implementation strategies by Proctor et al. (30) in **Table 2**.

Mapping task 4: Based on the identified strategies and matrices of action, we drafted the *MyGoals Clinician Education* and *MyGoals Clinician Audit & Feedback* and completed pilot-testing. The results from the pilot-testing indicated that most of the developed implementation strategies seem feasible. We made minor revisions to scripts, wording, and sequence of presentation contents to streamline *MyGoals Clinician Education*. We edited the audio recordings of the experienced OT's *MyGoals* sessions provided as a part of *MyGoals Clinician Education* to more efficiently deliver key messages from the case examples. After the pilot-testing, we also added options for OTs to choose when and how they want to complete the *MyGoals Clinician Audit & Feedback*. In the pilot-testing, we delivered an in-person *MyGoals Clinician Audit & Feedback* right before the OT sees the client for their second visit. We found that it can be more beneficial to provide individual OTs with options for when (e.g., right after their 1st client session, between sessions, etc.) and how (e.g., virtual or in-person) they want to complete the *MyGoals Clinician Audit & Feedback*. This revision allowed us to tailor the *MyGoals Clinician Audit & Feedback* to the individual OT's learning style and preferences. We also extended *MyGoals Clinician Audit & Feedback* from 15-min to 30-min to provide enough time for OTs to discuss their feedback, concerns, questions, etc.

Table 2 describes the details of the *MyGoals Clinician Education* and *MyGoals Clinician Audit & Feedback*. The first education session aims to educate on overall goal setting and goal management concepts, practice, and application and evidence of *MyGoals*. The second education session

TABLE 1 | MyGoals matrices of change.

| Performance objectives (OTs will...) | | Change objectives (OTs will...) | | | | |
|---|--|--|--|---|---|--|
| | | Knowledge | Awareness | Skills | Outcome expectancy | Self-efficacy |
| 1. Agree to implement MyGoals as intended | | 1.1. Understand goal setting and goal management practice concepts and its importance 1.2. Understand evidence of MyGoals | 1.3. Acknowledge that current goal setting and goal management practice is not optimal 1.4. Acknowledge that MyGoals is acceptable 1.5. Acknowledge that MyGoals is appropriate 1.6. Acknowledge that MyGoals is feasible | NA | 1.7. Expect delivering MyGoals will improve personally meaningful goal achievement in clients | NA |
| Mechanisms of action | | Participation, active learning, individualization, advance organizers, discussion, elaboration | Participation, active learning, individualization, consciousness raising, self-evaluation | NA | Participation, active learning, individualization, self-reevaluation, shifting perspective, elaboration | NA |
| 2. Deliver all MyGoals intervention components | | 2.1. Understand all MyGoals intervention components | NA | 2.2. Demonstrate skills for delivering all MyGoals intervention components completely | 2.3. Expect delivering all MyGoals intervention components will improve personally meaningful goal achievement in clients 2.4. Express confidence in one's ability to deliver all MyGoals intervention components | |
| Mechanisms of action | | Participation, active learning, individualization, advance organizers, discussion, elaboration | NA | Participation, active learning, individualization, guided practice | Participation, active learning, individualization, self-reevaluation, shifting perspective, elaboration | Participation, active learning, individualization, guided practice |
| 3. Deliver all MyGoals intervention activities by using the empowerment-based approach | | 3.1. Understand 4 MyGoals communication strategies | NA | 3.2. Demonstrate skills for delivering all activities by using 4 MyGoals communication strategies | 3.3. Expect using 4 MyGoals communication strategies will improve personally meaningful goal achievement in clients 3.4. Express confidence in one's ability to deliver all activities by using 4 MyGoals communication strategies | |
| Mechanisms of action | | Participation, active learning, individualization, advance organizers, discussion, elaboration | NA | Participation, active learning, individualization, guided practice | Participation, active learning, individualization, self-reevaluation, shifting perspective, elaboration | Participation, active learning, individualization, guided practice |

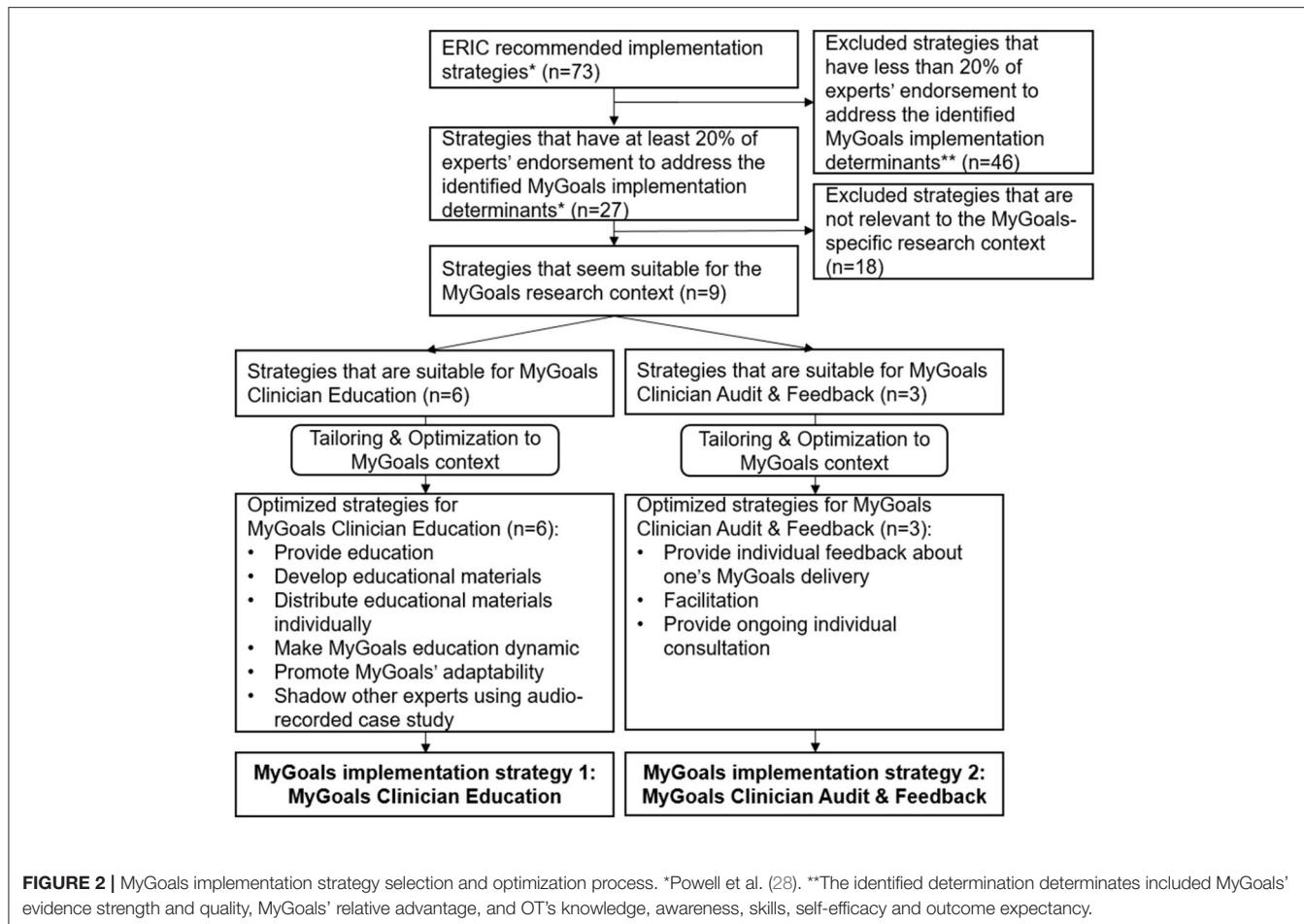


FIGURE 2 | MyGoals implementation strategy selection and optimization process. *Powell et al. (28). **The identified determination determinants included MyGoals' evidence strength and quality, MyGoals' relative advantage, and OT's knowledge, awareness, skills, self-efficacy and outcome expectancy.

aims to equip OTs to administer MyGoals with a client through role-playing with the research team member. The *MyGoals Clinician Audit & Feedback* aims to provide OTs with individualized feedback and consultation to enhance their MyGoals implementation.

Mapping task 5: We identified measures, respondents, and time points to evaluate the selected implementation outcomes described in **Table 3**. We confirmed that all selected measures worked well from the pilot testing. We will explore the preliminary effects of the MyGoals implementation strategies using quantitative measures and explore OTs' perspectives of how it may be optimized using a qualitative interview (e.g., How can we make *MyGoals Clinician Education* more feasible?).

We also developed quantitative measures to explore how successfully the *MyGoals Clinician Education* and *MyGoals Clinician Audit & Feedback* help OTs achieve each change objective and qualitative questions to explore how to improve them. The self-report quantitative question items were developed based on the change objectives outlined in **Table 1** and will be answered by using an 11-point Likert scale (0: strongly disagree –10: strongly agree). For instance, to evaluate the change objective 1.2, OTs will be asked to rate their agreement with the following item: *I understand the evidence of MyGoals*. Qualitative interview questions will be used to explore OT's

perspectives on the change objectives (e.g., How can we better help you understand the evidence of MyGoals?). We are currently undergoing implementation outcome evaluation using a mixed-methods study of OT-client dyads to explore and optimize MyGoals implementation strategies in preparation for a future larger study.

DISCUSSION

This study aimed to develop effective strategies to ensure high-quality implementation of a goal setting and goal management intervention called MyGoals in community-based rehabilitation with adults with chronic conditions. To do so, we used Implementation Mapping with CBPR principles to determine MyGoals implementation determinants, mechanisms of action, implementation strategies, and evaluation plans. To our knowledge, this is the first study to use Implementation Mapping with CBPR principles to develop implementation strategies for a community-based rehabilitation goal setting and goal management system. We found that Implementation Mapping can guide the development and optimization of theory- and evidence-based MyGoals implementation strategies and their evaluation plans. In turn, the developed MyGoals implementation strategies may support OTs in providing

TABLE 2 | MyGoals implementation strategies specification.

| | MyGoals Clinician Education | MyGoals Clinician Audit & Feedback |
|--|--|--|
| Actors | The research team | The research team |
| Actions | <ul style="list-style-type: none"> Provide MyGoals clinician education to introduce concepts, importance, and current limitations of goal setting and goal management, and MyGoals Develop easy-to-use MyGoals instructions, script, and materials to enhance the quality of MyGoals and facilitate learning Develop eye-catching PowerPoint for MyGoals Clinician Education to facilitate learning Distribute MyGoals by email to provide the opportunity to thoroughly review MyGoals evidence during the self-study session Role-play with the clinician trainee to boost confidence and perceive the potential benefits of using MyGoals Promote MyGoals' flexible activity steps that can be tailored to each client Provide audit and active discussion on the audio-recording of the experienced OT's MyGoals sessions to learn ideal MyGoals practice and boost one's confidence to deliver MyGoals | <ul style="list-style-type: none"> Provide feedback about OT's MyGoals delivery based on direct observation of the MyGoals session to boost one's confidence for the next MyGoals delivery Facilitate OT's reflection on areas that they performed well and areas that can be improved to reinforce the perceived benefits of using MyGoals and to support better MyGoals delivery Provide ongoing consultation about OT's MyGoals delivery based on direct observation of the session to boost one's confidence about MyGoals delivery |
| Action target | Newly trained OT's knowledge, self-awareness, skills, outcome expectancy, and self-efficacy | Newly trained OT's knowledge, self-awareness, skills, outcome expectancy, and self-efficacy |
| Temporality | Two education sessions will be provided before any client visit | Audit & Feedback will be provided before the second visit with each client |
| Dose | 2 sessions (2 hours each) | 1 session for each client (0.5 hours) |
| Implementation outcomes affected | Appropriateness, acceptability, feasibility, process outcomes | Appropriateness, acceptability, feasibility, process outcomes |
| Justification | The six integrated ERIC recommended implementation strategies are deemed promising to address the MyGoals determinants | <ul style="list-style-type: none"> The three integrated ERIC recommended implementation strategies are deemed promising to address the MyGoals determinants Providing post-training to clinicians shows promise for enhancing the quality of intervention implementation (31) Provide individual feedback about one's MyGoals delivery (OT's self-efficacy) Facilitate (Intervention's relative advantage, OT's knowledge) Provide ongoing individual consultation (OT's self-efficacy) |
| Incorporated ERIC recommended implementation strategies (Target determinants*) | <ul style="list-style-type: none"> Provide education (Intervention's evidence strength & quality, intervention's relative advantage, OT's knowledge) Develop educational materials (Evidence strength & quality, OT's knowledge) Distribute educational materials individually (Intervention's evidence strength & quality) Make MyGoals education dynamic (OT's self-efficacy) Promote MyGoals' adaptability (Intervention's relative advantage) Shadow other experts using an audio-recorded case study (OT's self-efficacy) | |

*We listed MyGoals determinants that have shown at least 20 percent of experts' endorsement from the ERIC study (28).

better goal setting and goal management in community-based rehabilitation with adults with chronic conditions. These findings can inform future research on how to use implementation science to develop and optimize rehabilitation interventions and their implementation strategies, and thus help bridge research-practice gaps to improve health in adults with chronic conditions.

In our study, we enhanced the theoretical rigor and ecological validity of our research findings by using theories, models, and frameworks combined with CBPR principles. The collaboration and co-learning process with MyGoals implementers and MyGoals intervention target clients helped us (the research team) better understand the complex MyGoals implementation context from the end-users' perspective. If we did not actively collaborate with OT members throughout this research but

merely interviewed them as research subjects, we may have been able to identify key determinants but then developed implementation strategies deemed feasible and effective from the researchers' but not clinicians' perspectives. At the same time, as much as the use of CBPR principles is important, it is critical to develop implementation strategies with theoretical rigor. To do so, we used theories, models, and frameworks as guidance to synergize the real-world and academic knowledge for developing effective MyGoals implementation strategies.

We took a holistic approach to identify determinants that will play important roles in implementing MyGoals in community-based rehabilitation. We found that having the buy-in of individual OTs can be key to facilitating MyGoals implementation. Previous literature suggests that OTs'

TABLE 3 | Selected outcome variables, measures, respondent, and measurement time point.

| Outcome variables | Measures* |
|---|--|
| MyGoals clinician education & MyGoals clinician audit & feedback | |
| Acceptability | Acceptability of intervention measure (33), qualitative interview |
| Appropriateness | Intervention appropriateness measure (33), qualitative interview |
| Feasibility | Feasibility of intervention measure (33), qualitative interview |
| Process outcomes (Change objectives) | Quantitative questions, qualitative interview |
| MyGoals | |
| Acceptability | Acceptability of intervention measure (33), qualitative interview |
| Appropriateness | Intervention appropriateness measure (33), qualitative interview |
| Feasibility | Feasibility of intervention measure (33), qualitative interview |
| Fidelity – competence, adherence | Fidelity survey – competence and adherence scales, qualitative interview |

*All measures except fidelity will be completed by an OT after the completion of the last MyGoals session. Fidelity will be measured by both OT and observer (the research team) right after the completion of each MyGoals session.

self-awareness about their interaction with clients can promote quality goal setting practice (9). Our findings expand on this by identifying additional implementation determinants. These include OTs' skill, knowledge, self-efficacy, outcome expectancy, and MyGoals' evidence and relative advantages in the context of community-based rehabilitation. Future studies should examine if and how these determinants impact goal setting and goal management in different settings.

We identified MyGoals implementation outcome variables that can contribute to enhancing the quality of MyGoals intervention. We chose *Enabling OTs to deliver MyGoals completely and competently* as the implementation outcome. This outcome was chosen because achieving high levels of MyGoals' completeness and competency can facilitate the comprehensive use of theory-based intervention components and active client engagement. As a result, it can address the abovementioned two major research-practice gaps in community-based goal setting and goal management rehabilitation. In addition, we chose to evaluate MyGoals' and MyGoals implementation strategies' appropriateness, acceptability, feasibility, and fidelity of MyGoals. Good appropriateness, acceptability, feasibility, and fidelity are known prerequisites for high-quality intervention delivery to improve clients' health (27). Thus, we hypothesized that targeting these selected implementation outcomes will enhance MyGoals intervention quality.

We identified theory- and evidence-based mechanisms of action to facilitate MyGoals implementation and then used them to guide the MyGoals implementation strategy development. The specification of mechanisms of action is essential to understand why and how implementation strategies can enhance the implementation of interventions (32). In this study, we used social cognitive theory (25) and the taxonomy of behavior change methods (26) to clarify the mechanisms of action deemed applicable and effective for targeting the MyGoals determinants and facilitating MyGoals implementation. To produce effective implementation strategies, it is important to develop tailored strategies with clear targeted determinants and mechanisms of action (31, 32). MyGoals implementation strategies are tailored to the identified determinants and

developed based on the theory- and evidence-based mechanisms of actions and the parameters of effectiveness. Given that tailored implementation strategies are known to be more effective than the non-tailored ones (31, 32), we hypothesized that MyGoals implementation strategies would be effective in achieving good appropriateness, acceptability, feasibility, fidelity, and process outcomes. Because we clearly and carefully mapped the mechanisms of action and implementation strategies, this study will advance our understanding of why and how MyGoals implementation strategies work and what aspects of these strategies require improvement to further enhance the implementation of MyGoals.

Despite existing implementation strategy reporting guidelines, many intervention studies have limited descriptions of their implementation strategies, which can hinder reliable interpretation of research findings and replication in future work (30, 32). We demonstrated that it is feasible to report implementation strategies for a rehabilitation intervention according to the guideline (30, 32). As recommended by the guideline (30), we labeled MyGoals implementation strategies consistent with the implementation science literature and defined the actors, actions, action targets, temporality, dose, target implementation outcomes, and justifications. This work will allow replication of high-quality MyGoals implementation in future studies as well as inform implementation strategies for other potential goal setting and goal management interventions. Furthermore, it may stimulate better reporting practices, and thus better synthesis and replication of future rehabilitation research in general.

Overall, we demonstrated that it is feasible to develop both MyGoals implementation strategies and MyGoals concurrently. Implementation science literature has recommended taking more active consideration of implementation strategies, ideally from the earliest stages of intervention development, to facilitate intervention translation (12). However, implementation strategies are not regularly addressed in the developmental phase of interventions in general and even more rarely in rehabilitation fields (12, 18). Our collaborative and systematic approach enabled us to develop tailored implementation strategies and

enhance the adaptability of MyGoals without compromising its essential intervention components. We are currently testing MyGoals implementation strategies using a mixed-methods study of OT-client dyads based on the developed implementation outcome evaluation plans. The findings from these outcome and process evaluations will allow us to further optimize MyGoals implementation strategies and inform other works.

LIMITATION

We had a comparatively small planning team. The client and OT members only had limited time to commit to this research. Both OT planning team members worked at the same university community-based clinic, so they do not represent all community-based OTs. If we could have worked with a larger number of people from different settings, from more diverse demographic and socioeconomic backgrounds, and with more protected time to work on this research throughout the study design, analysis, and manuscript writing, we could have further enhanced the overall Implementation Mapping process and produced more equitable and generalizable findings. However, to address these limitations, we incorporated multiple approaches to enable all members to actively participate in the current research study so that we were able to complete the collaborative Implementation Mapping tasks.

We endeavored to develop MyGoals implementation strategies that are deemed feasible and effective for general community-based settings, so extensive adaptation work may not be required. However, future studies may still benefit from adapting MyGoals to facilitate its implementation in specific contexts. Organizational and systematic support to allow diverse stakeholders' active and sustainable participation in research can enhance our efforts to incorporate community-engaged research in implementation science.

CONCLUSION

We demonstrated that it is feasible and beneficial to develop implementation strategies using Implementation Mapping with the CBPR principles in conjunction with the development of the rehabilitation intervention itself. We identified MyGoals implementation determinants, strategies, and evaluation

plans. The MyGoals implementation strategies, which are currently being evaluated using the developed evaluation plans, should enable OTs to implement high-quality goal setting and goal management intervention. These efforts to address implementation strategies early and systematically may help bridge the current research-practice gaps in community-based rehabilitation and enhance health in adults with chronic conditions.

DATA AVAILABILITY STATEMENT

The datasets presented in this article are not readily available because for privacy protection, we do not plan to share the original data. Requests to access the datasets should be directed to EK, eunyoung@wustl.edu.

ETHICS STATEMENT

The studies involving human participants were reviewed and approved by Human Research Protection Office Washington University in St. Louis. The participants provided their consent to participate in this study.

AUTHOR CONTRIBUTIONS

EK wrote the manuscript. EF reviewed and edited the manuscript. Both authors contributed to the article and approved the submitted version.

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Using Implementation Mapping to Build Organizational Readiness

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Organizational readiness is essential for high-quality implementation of innovations (programs, policies, practices, or processes). The $R = MC^2$ heuristic describes three readiness components necessary for implementation—the general functioning of the organization (general capacities), the ability to deliver a particular innovation (innovation-specific capacities), and the motivation to implement the innovation. In this article, we describe how we used the *Readiness Building System (RBS)* for assessing, prioritizing, and improving readiness and *Implementation Mapping (IM)*, a systematic process for planning implementation strategies, to build organizational readiness for implementation of sexual assault prevention evidence-based interventions (EBIs). While RBS provides an overarching approach for assessing and prioritizing readiness constructs (according to the $R = MC^2$ heuristic; *Readiness* = *Motivation* \times *general Capacity* \times *innovation specific Capacity*), it does not provide specific guidance on the development and/or selection and tailoring of strategies to improve readiness. We used the five IM tasks to identify and prioritize specific readiness goals and develop readiness-building strategies to improve subcomponents described in the $R = MC^2$ heuristic. This article illustrates how IM can be used synergistically with the RBS in applied contexts to plan implementation strategies that will improve organizational readiness and implementation outcomes. Specifically, we provide an example of using these two frameworks as part of the process of building organizational readiness for implementation of sexual assault prevention EBIs.

Keywords: implementation science, organizational readiness, implementation strategies, implementation mapping, change management

USING IMPLEMENTATION MAPPING TO BUILD ORGANIZATIONAL READINESS

Organizational readiness is important for effective implementation of any program, policy, practice, or process (1–4). An understanding of *how ready* an organization is can be helpful for organizations as they prepare to implement new interventions and throughout the process of implementation (4). However, the link between determining readiness and the actions needed to improve readiness has not been systematically described and there is scant literature to support specific evidence-based strategies for building readiness. A systematic approach linking readiness needs to actionable implementation strategies that are designed to build readiness can address this gap. In this article,

we describe how we used Implementation Mapping (IM; see list of all abbreviations used in **Table 1**) to develop actionable readiness building strategies in an applied project to prevent sexual assault (5).

Compilations of implementation strategies, such as the Expert Recommendations for Implementing Change [ERIC; (6)], are readily available to organizations and planners. What is limited, however, is specific guidance about which strategies to use (7). Additionally, even after strategies are selected, the content and details of those strategies (e.g., technical assistance, training) must still be developed. Researchers and implementers have had little guidance on how to improve critical implementation factors, such as organizational readiness, to achieve more effective implementation. They often select inappropriate strategies and/or struggle with the content of implementation strategies to improve readiness and implementation outcomes (7, 8).

IM is a systematic approach for developing or selecting and tailoring implementation strategies to accelerate evidence-based intervention (EBI) uptake and use and increase the likelihood of sustainability. It includes a five-step process that incorporates implementation and behavioral science theories and frameworks, empirical evidence, and community and stakeholder input. IM clearly articulates implementation outcomes, actions (implementation behaviors), determinants, and expected outcomes, and it describes a process for developing targeted implementation strategies. By identifying and linking these elements, the IM process articulates the mechanism through which implementation strategies are intended to work. Recent studies have described its application to improve the implementation of EBIs in clinics, communities, and schools (9–11). The five steps are listed and discussed in detail in both **Figure 1** and the Methods section (5).

Readiness and the Readiness Building System

According to Nilsen (12) categorization, implementation science “determinants frameworks,” such as the Interactive Systems Framework (ISF) for Dissemination and Implementation can help identify the barriers and facilitators to implementing EBIs in new settings (13). According to the ISF and other frameworks, organizational readiness is a critical aspect (determinant) of successful implementation (14). The $R = MC^2$ heuristic (Readiness = Motivation \times Innovation-Specific Capacity \times General Capacity), derived from the ISF, expands our understanding of organizational readiness and posits that each component is critical for successful implementation (4).

Motivation refers to the degree to which an organization wants and is committed to the implementation of the EBI. *General capacity* refers to the overall ability of an organization to function successfully on a day-to-day basis. *Innovation-specific capacities* are the abilities necessary to implement a specific intervention (program, policy, practice, or process) with quality. Each component has multiple subcomponents that are described in **Table 2**. A premise of the $R = MC^2$ heuristic is that organizations must have sufficient capacities and motivation for successful

TABLE 1 | List of abbreviations.

| List of Abbreviations | |
|-----------------------|---|
| CMOR | Change management of organizational readiness |
| EBI | Evidence-based intervention |
| IM | Implementation mapping |
| ISF | Interactive systems framework |
| MSSAP | Multi-Site Sexual Assault Prevention Initiative |
| $R = MC^2$ | Readiness, motivation \times innovation-specific capacity \times general capacity |
| RBS | Readiness building system |
| RDS | Readiness diagnostic scale |
| TA | Technical assistance |

implementation. Therefore, when motivation or capacities are low, additional efforts to build readiness are needed to ensure that an innovation (e.g., EBI) will be successfully implemented.

Although organizational readiness is a critical factor for success, there is relatively little guidance on how to build readiness to enhance implementation. The four phases of the Readiness Building System (RBS), include the following: (1) Engagement, (2) Readiness Assessment, (3) Feedback and Prioritization, and (4) Change Management of Organizational Readiness [CMOR; **Figure 2**; (15, 16)]. While the RBS provides a general process for building organizational readiness and includes tools to assess and prioritize readiness constructs, it has lacked a detailed protocol for developing or selecting strategies to improve readiness. Without such guidance, an opportunity is lost; organizations may not know the specific actions (e.g., strategies) they need to employ to build their readiness. Thus, there continues to be a need for a systematic approach to building readiness. IM, which is designed to be used in conjunction with other tools and frameworks, is one protocol that can address this gap. IM provides a structured approach that systematically links readiness building strategies to the desired outcomes they are designed to influence.

Using Implementation Mapping to Build Organizational Readiness for Sexual Assault Prevention

The Multi-Site Sexual Assault Prevention Initiative (MSSAP) is a large and long-term capacity building project taking place at eight sites across the U.S. with support from technical assistance (TA) providers. The purpose of the initiative is to increase adoption and implementation of EBIs at each site to prevent sexual assault, a serious public health problem affecting millions of men and women annually (17). To identify and adapt or develop readiness building strategies designed to improve organizational readiness, our team used RBS tools to measure and prioritize readiness subcomponents and used IM to develop and/or adapt strategies for readiness building.

Figure 3 illustrates the alignment between RBS and IM. Several of the steps in both frameworks overlap. For example, the needs and assets assessment phase of IM is analogous to the

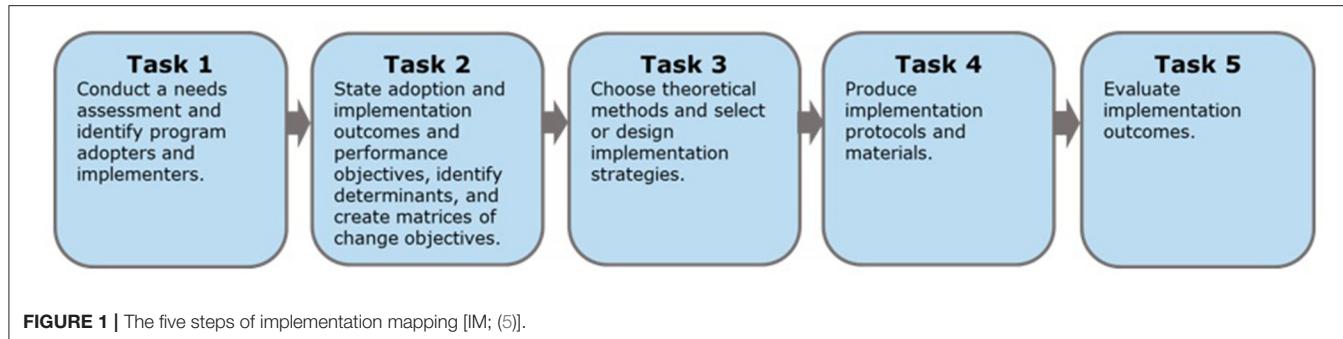


TABLE 2 | Readiness components and subcomponents.

| Subcomponent | Definition |
|--|--|
| Motivation | Degree to which the organization wants the new innovation to happen. |
| Relative advantage | The degree to which the innovation seems more useful than what has been done in the past. |
| Compatibility | The degree to which the innovation fits with how the site does things. |
| Simplicity | The innovation seems simple to use. |
| Ability to pilot | Degree to which the innovation can be tried out. |
| Observability | Ability to see that the innovation is producing outcomes. |
| Priority | Degree of importance of the innovation in relation to other things the site does. |
| Innovation-specific capacity | What we need to implement the innovation. |
| Innovation-specific knowledge & skills | Sufficient abilities to implement the innovation. |
| Program champion | A well-connected person who supports and models the use of the innovation. |
| Supportive climate | Necessary supports, processes, and resources to enable the use of the innovation. |
| Intra-organizational relationships | Relationships within the site that support the use of the innovation. |
| Inter-organizational relationships | Relationships between the site and other organizations that support the use of the innovation. |
| General capacity | The overall functioning of the organization. |
| Culture | Norms and values of how things are done at the site. |
| Climate | The feeling of being part of the site. |
| Innovativeness | Openness to change in general. |
| Resource utilization | Ability to acquire and allocate resources including time, money, effort, and technology. |
| Leadership | Effectiveness of leaders at multiple levels. |
| Structure | Effectiveness at communication and teamwork. |
| Staff Capacities | Having enough of the right people with the right knowledge/skills, to get things done. |

engagement and assessment of organizational readiness phases of RBS. IM steps 2–4 fall within the CMOR phase of RBS. IM Steps 5 and 6 relate to evaluation and feedback to earlier

phases as in RBS. In the MSSAP project, we used RBS tools for assessing and prioritizing readiness constructs to determine the most salient factors influencing implementation and IM to create the readiness building strategies. Below we describe the process we followed, highlighting examples from the MSSAP in each phase. At the time of writing this article, MSSAP was still ongoing with concurrent implementation and TA provided (specific site information is de-identified).

METHODS

As presented in **Figure 3**, we followed the five IM tasks with each site, which were broadly informed by the RBS: (1) conduct a needs assessment and identify program adopters and implementers; (2) state adoption and implementation outcomes and performance objectives, identify determinants, and create matrices of change objectives; (3) choose theoretical methods and select or design implementation strategies; (4) produce implementation protocols and materials; and (5) plan for evaluation of implementation outcomes (**Figure 1**). Across all sites, TA providers engaged partners throughout the process by conducting initial site visits, identifying stakeholders to serve as members of a worksite implementation team, participating in regularly scheduled phone calls, leading worksite implementation teams through the 5 IM tasks, and providing expertise and feedback when appropriate.

To conduct a readiness/needs assessment (Implementation Mapping Task 1), an adapted Readiness Diagnostic Scale (RDS) was administered during the *Readiness Assessment Phase* of the RBS. Grounded in the $R = MC^2$ framework, we measured organizational readiness using the RDS with response choices on a 7-point Likert scale (1 = Strongly Disagree, 7 = Strongly Agree). The scale has been used previously, and current studies are being conducted to further develop the scale and assess its psychometric properties (18, 19). Because the vast majority of sites had not selected the specific sexual assault prevention EBI to implement, the instrument was adapted to a 48-item survey that measured *general capacity* and *motivation* domains (and *not innovation-specific capacity*).

The RDS was administered electronically to implementation team members and other key informants selected by the site leadership. These respondents typically included leaders with decision-making power and those familiar with the potential

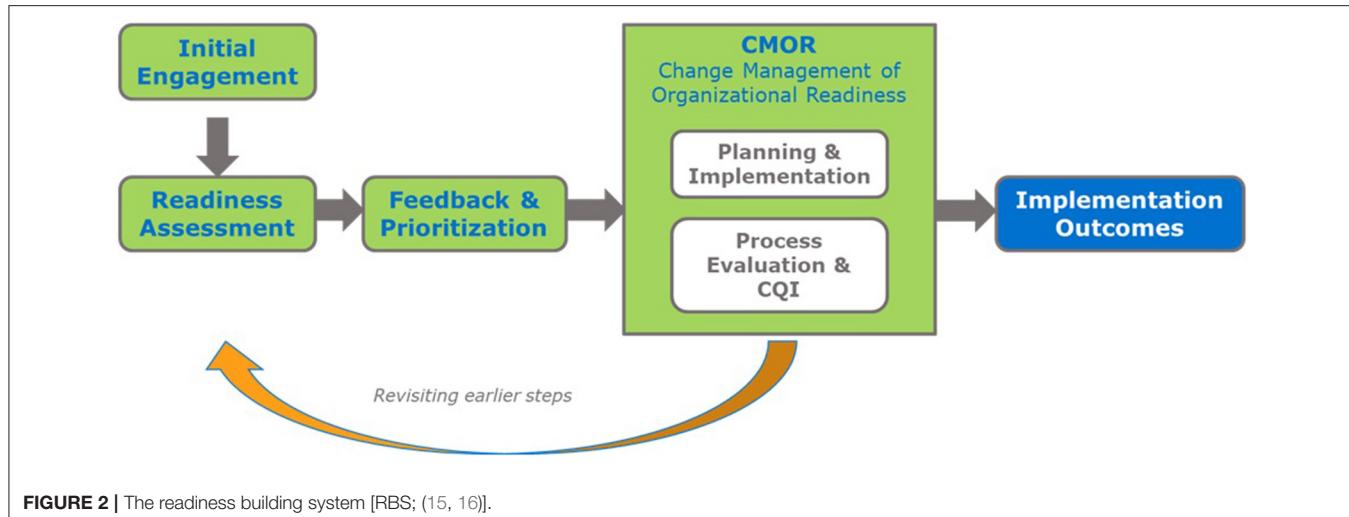


FIGURE 2 | The readiness building system [RBS; (15, 16)].

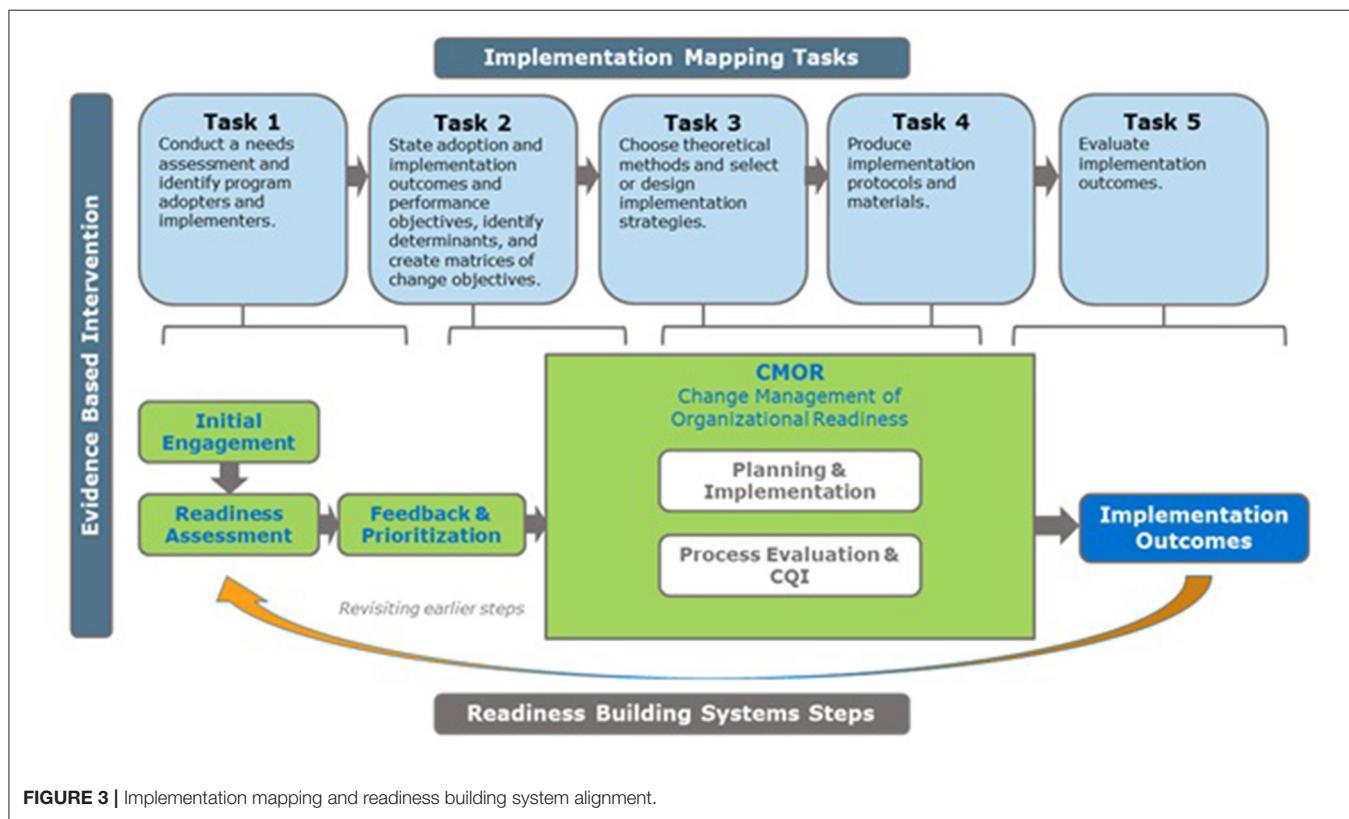


FIGURE 3 | Implementation mapping and readiness building system alignment.

barriers and facilitators to successfully implementing sexual assault prevention EBIs in their setting.

During regularly scheduled meetings via phone, worksite implementation teams and their TA providers (known together as the “implementation team”) met to discuss the results of their RDS and to work in collaboration to determine the subcomponent of readiness they wished to prioritize for readiness building efforts. The RBS provides detailed guidance on

how to determine the most salient subcomponent for readiness building using a Prioritization Tool.

Once the readiness subcomponents were prioritized, the implementation teams determined adoption and implementation outcomes, stated performance objectives, identified the underlying determinant, and **created matrices for change objectives (IM Task 2)**. Theoretical methods or change mechanisms were then operationalized to **select and/or design**



readiness building strategies (IM Task 3). Implementation protocols including action plans and other **relevant materials were produced (IM Task 4)**, and the readiness building strategies were implemented. Evaluation of the strategy's implementation was conducted **and implementation outcomes were measured (IM Task 5)**.

RESULTS

This section describes the results of using IM to identify and develop readiness building strategies, enhanced by the incorporation of the RBS. Below, we highlight each IM task using examples from the MSSAP.

Implementation Mapping, Task 1: Conduct a Needs Assessment and Identify Program Adopters and Implementers

IM Task 1 can be described (as shown in our alignment model; Figure 3) in three sub-tasks which correspond to three of the four RBS “phases” (Engagement, Readiness Assessment, Feedback and Prioritization).

Task 1a. Engagement

The TA provider engaged stakeholders who were involved in the adoption and implementation of sexual assault prevention programs at each site to participate in an implementation team. The team consisted of those in roles such as sexual assault prevention coordinators, prevention program facilitators, sexual assault victim advocates, peer support liaison personnel, equal opportunity managers, and organizational leaders. The implementation team identified areas of low readiness for implementing sexual assault prevention EBIs at the site which informed potential readiness building strategies. Additionally,

at least one member from the implementation team served as the point of contact for the site and would coordinate project activities with the TA provider. Examples of TA activities included ongoing engagement, joint planning, and specific guidance for moving forward with the readiness building process conducted mainly through virtual TA.

Task 1b. Readiness Assessment

The RDS was completed by 107 implementation team members across the eight sites with a customized Readiness Report provided to the implementation team. Data were analyzed at the organizational level and the average mean scores for each readiness subcomponent were calculated. The Readiness Reports facilitated the selection of the specific readiness components (motivation and general capacity) that were relatively stronger and weaker for each site. Figure 4 includes sample de-identified data contained in a Readiness Report. The chart displays mean organizational readiness scores for motivation subcomponents in green and general capacity subcomponents in blue. Supplemental information about the importance of the three highest and lowest readiness subcomponents was also provided in the report.

Task 1c. Feedback and Prioritization

As part of the needs assessment process (IM Task 1, which corresponds with the Feedback and Prioritization phase of the RBS), implementation teams identified three readiness subcomponents that they wanted to improve. The implementation teams used a Prioritization Tool to identify readiness subcomponents needing improvement based on the mean scores included in the report, the likelihood of having an impact on implementation outcomes, timeliness, priority for the change, and feasibility of the change (resources and staff are available, change is simple, etc.) (20). Because of the perceived

feasibility for change, the three lowest subcomponents were not always the ones prioritized. For example, resource utilization was a subcomponent that scored relatively low for most sites; however, there was a general understanding that very little could be done to improve this subcomponent given current funding levels. Therefore, this subcomponent was documented as important, but excluded from readiness building strategy planning efforts across sites. Across the participating sites, the most common subcomponents prioritized for change were leadership, complexity, priority, and observability.

Implementation Mapping, Task 2: State Adoption and Implementation Outcomes and Performance Objectives, Identify Determinants, and Create Change Matrices of Change Objectives

Task 2 (as shown in **Figure 3**), as well as Tasks 3 and 4, correspond to the CMOR phase section of the RBS framework. Using IM, implementation teams were able to identify factors influencing the various readiness subcomponents needing attention and develop approaches to address them.

The implementation teams progressed to Task 2 after identifying the prioritized subcomponents for change. The readiness building outcomes for each prioritized subcomponent were identified by answering the question: “What needs to change related to [subcomponent] to improve the site’s organizational readiness?” Examples of readiness building outcomes included: “The worksite will make sexual assault prevention a priority,” “The mid- and senior-level leaders will actively support sexual assault prevention programming,” and “Implementers will assess the short-term outcomes of the program to increase observability.” The performance objectives, which are sub-tasks needed to achieve the implementation outcomes, were determined by answering the question: “Who needs to do what in order to achieve the improvements in the readiness component, and, in turn, implementation outcome?” Examples of performance objectives included: “The prevention coordinators will communicate success stories from the pilot test with Leadership,” “The prevention coordinators will cultivate appropriate working relationships,” and “Leadership displays commitment and involvement in the implementation of sexual assault prevention programs.”

The implementation teams identified determinants of the readiness building outcomes by using dissemination, implementation, and behavioral health theories and frameworks, empirical evidence, and input from the implementation team at each site. Examples of determinants include attitudes toward sexual assault prevention, attitudes about and awareness of the specific sexual assault prevention EBI, the program specific knowledge, self-efficacy, and skills, the perception of risk associated with not performing implementation behaviors, and the outcome expectations of the sexual assault prevention EBI.

Matrices of change objectives were created by crossing each of the determinants with performance objectives and answering: “What needs to change in the determinant for the implementer to accomplish the performance objective?” Examples of change

objectives and the associated performance objectives are included in the partial sample matrix shown in **Table 3**. Matrices of change objectives were created for each subcomponent within general capacity and motivation ($N = 13$) and formed the blueprint for identifying and developing implementation strategies to improve readiness (Task 3).

Implementation Mapping, Task 3: Choose Theoretical Methods and Select or Design Implementation Strategies

To select, adapt, or develop the readiness building strategies that would achieve the readiness building outcome, implementation teams identified theoretical methods known to target the determinants identified (and associated with the specific change objectives within the matrices as outlined in Task 2). Theoretical methods are a key component of the mechanisms of action for influencing determinants, while practical applications of these methods, described here as readiness building strategies, operationalize them in a way that is consistent with the population and setting (10, 21). After methods to influence change in the determinants were identified, each implementation team developed specific strategies to operationalize these methods and ensured that the strategies developed were feasible to implement. To save time and resources, when possible, we leveraged and enhanced existing strategies that were being implemented at each site. For example, the performance objective “Leadership displays commitment and involvement in the implementation of sexual assault prevention programs” and its associated change objective “Leaders believe that displaying commitment and involvement for programs is a priority,” can be influenced by the change methods of arguments, persuasive communication, and repeated exposure. To operationalize these methods in one site, one site selected to distribute fact sheets that highlight the prevalence and organizational consequences (e.g., reduced productivity, mental health burden, etc.) of sexual assault. These fact sheets were regularly distributed to mid-level leaders prior to each time the sexual assault program was implemented.

Because each site (1) prioritized different readiness subcomponents, (2) implemented different sexual assault prevention EBIs, and (3) had varying levels of resources available for implementation, there was no standardized set of readiness building strategies that were used across all sites. Rather, each site identified specific strategies that targeted the readiness subcomponent they had prioritized for their site. Examples of readiness building strategies are included in **Table 4**. The change objectives are listed with corresponding theoretical change methods and specific strategies.

Implementation Mapping, Task 4: Produce Implementation Protocols and Materials

The implementation team adapted or developed the materials and protocols for the readiness building strategies in close collaboration with each site’s implementation team. In the example with the change objective, “Leaders believe that displaying commitment and involvement for programs is a

TABLE 3 | Partial matrix of change for observability (subcomponent of motivation).

| Performance objectives | Attitudes/awareness | Self-efficacy | Knowledge | Skills | Outcome expectations |
|---|---|--|---|---|--|
| A. Prevention coordinators will assess the short-term impact of the sexual assault prevention program among participants (<i>Observability</i>). AA1. Prevention Coordinators believe that assessing short-term impact of the sexual assault prevention program has advantages. AA2. Prevention Coordinators believe that assessing short-term impact of the sexual assault prevention program should be a priority. AA3. Prevention Coordinators believe that assessing short-term impact of the sexual assault prevention program is simplistic. AA4. Prevention Coordinators believe that the sexual assault prevention program fits the needs of the target population. | AA1. Prevention Coordinators believe that assessing short-term impact of the sexual assault prevention program has advantages. AA2. Prevention Coordinators believe that assessing short-term impact of the sexual assault prevention program should be a priority. AA3. Prevention Coordinators believe that assessing short-term impact of the sexual assault prevention program is simplistic. AA4. Prevention Coordinators believe that the sexual assault prevention program fits the needs of the target population. | ASE1. Prevention coordinators express confidence in their ability to assess the short-term impact of the sexual assault prevention program among participants. ASE2. Prevention coordinators express confidence in their ability to assess and analyze data. ASE3. Prevention Coordinators express confidence in their ability to reach short-term outcomes. | AK1. Prevention coordinators identify short-term outcome measures for the sexual assault prevention program. AK2. Prevention Coordinators list characteristics of the sexual assault prevention program. AK3. Prevention Coordinators describe the support needed to assess the short-term impact of the sexual assault prevention program. | AS1. Prevention coordinators demonstrate their evaluation plan for assessing the short-term impact of the sexual assault prevention program. AS2. Prevention coordinators demonstrate ability to implement metrics to measure short-term impacts of the sexual assault prevention program. | AOE1. Prevention coordinators believe that assessing short-term outcomes will help improve the success of the implementation of sexual assault prevention programs. AOE2. Prevention Coordinators believe that the sexual assault prevention program will lead to outcomes. AOE3. Prevention Coordinators believe that the sexual assault prevention program will help meet organizational priorities. AOE4. Prevention Coordinators believe that the assessment of outcomes from the sexual assault prevention program will be successfully sustained over time. |

TABLE 4 | Example change methods and readiness building strategies and their associated change objectives.

| Change objectives for worksite A | Determinants | Change methods | Parameters | Readiness building strategies |
|---|--|--|---|--|
| AA1. Prevention Coordinators believe that assessing short-term impact of the sexual assault prevention program has advantages. AA2. Prevention Coordinators believe that assessing short-term impact of the sexual assault prevention program should be a priority. ASE1. Prevention Coordinators express confidence in their ability to assess the short-term impact of the sexual assault prevention program among participants. AOE1. Prevention Coordinators believe that assessing short-term outcomes will help improve the success of the implementation of sexual assault prevention programs. | Attitudes, self-efficacy, and outcome expectations | A. Guided practice B. Discussion C. Feedback | A. Sub-skill demonstration, instruction, and enactment with individual feedback; requires supervision by an experienced person; some environmental changes cannot be rehearsed. B. Listening to the learner to ensure that the correct schemas are activated. C. Feedback needs to be individual, follow the behavior in time, and be specific. | A. Technical assistance provider lead discussion and assisted implementation team in develop an implementation plan for adoption and implementation of the sexual assault prevention program. B. At monthly meeting, TA providers discuss implementation plans and outcome and process evaluation instruments. C. At monthly meeting, TA providers give feedback on implementation plans and outcome and process evaluation instruments. |

priority," and the selected strategy of regularly distributing fact sheets, Task 4 includes the actual creation and/or editing of the fact sheets. Monthly meetings with each site were held to elicit feedback on the strategies; revisions were made accordingly. Detailed action plans were created for each readiness building strategy to outline associated tasks/materials needed, who was responsible for each, and deadlines for completion. Knowing who was responsible and when action items would be completed helped TA providers track readiness building strategy implementation across sites.

Implementation Mapping, Task 5: Evaluate Implementation Outcomes

Task 5 in IM is used to evaluate the implementation outcomes related to program implementation. Evaluation of program implementation is currently ongoing. However, to gain an understanding of the influence of the readiness building strategy on determinants and implementation performance objectives, participating implementation teams created evaluation plans aimed at evaluating the implementation of the readiness building strategy. This included an assessment of the reach, responsiveness, and fidelity of each readiness building strategy to be implemented. Reach was defined as the number of individuals who "received the strategy," responsiveness was defined as the degree of engagement from individuals who "received the strategy" (not engaged, semi-engaged, engaged), and fidelity was defined whether the strategy was implemented as it was planned (yes/no). To date, each site implemented between 3 and 11 readiness building-strategies with evaluation ongoing.

DISCUSSION

This article describes how IM and RBS were used together to develop readiness building strategies to improve organizational motivation and capacity to implement sexual assault prevention programs and therefore implementation outcomes. While the initial step of IM provides overall guidance about assessing needs and resources available for an implementation effort, RBS specifically focuses on the concept of organizational readiness (according to the $R = MC^2$ heuristic) and includes tools to help assess and prioritize subcomponents of organizational readiness. On the other hand, while RBS provides general guidance about addressing identified readiness building-needs through "change management," it provided relatively little guidance about how to choose and adapt or develop strategies once specific readiness needs were identified. IM addressed this gap. This article showcases how using RDS can improve the identification and prioritization of factors that need to be addressed to improve organizational readiness and, thus, implementation. IM provides guidance about what to do with this information through a step-by-step process for developing readiness building strategies to improve implementation of evidence-based interventions.

A strength of this study is that it addresses an ongoing challenge in implementation science: identifying and tailoring the most appropriate implementation strategies to address

identified barriers (7). Although several methods have been proposed to improve the systematic selection or development of implementation strategies, few provide a process that explicitly maps strategies to needs and simultaneously guides the development of concrete change objectives and content that enable that change. While IM has been used for the development of, or selection and tailoring of, implementation strategies for a variety of topics and settings, this is the first time it was used to build readiness for sexual assault prevention. Additionally, this is the first time it has been used to develop *readiness building strategies* specifically designed to increase organizational readiness. Researchers and practitioners agree that organizational readiness is important for successful implementation; systematic approaches guided by theory and evidence to inform the selection of methods and strategies that will impact specific determinants of implementation are needed (1–4, 7). Without approaches that use logic, evidence, theory, and systematic processes to incorporate these into decisions about strategy selection and tailoring, the use of strategies to build readiness will continue to be left to best guesses.

In the examples presented, we described the process of how the RBS and IM were used to develop strategies to improve readiness for the implementation of sexual assault prevention EBIs. Initially, we used RBS tools for assessing and prioritizing readiness subcomponents, we then used IM to identify performance objectives and determinants of readiness outcomes. IM then guided the selection of change techniques (methods) and specific site-appropriate strategies to build readiness (readiness-building strategies). This approach was used with eight different sites implementing programs to prevent sexual assault.

Community and stakeholder engagement in implementation science has received significant attention over the years and engagement of a broad array of stakeholders is needed to understand what is required for successful implementation (including what makes an organization ready to implement) and how to accelerate and improve the process (22). Both the RBS and IM underscore the importance of community and stakeholder engagement and provide explicit directions for how to engage the implementation team to develop implementation strategies during the needs and resources assessment phase and during the selection and tailoring of readiness building strategies. For the participating sites, the feedback and prioritization component continued in an iterative manner throughout the strategy development process. The RBS provided the tools for assessing and prioritizing readiness and the understanding that readiness building is an iterative process, and IM provided a structured way to engage with stakeholders by guiding teams through specific tasks. The IM tasks provide a natural structure to inform planning sessions with stakeholders while also allowing for iterative changes as the team learns what is needed to build and sustain readiness. However, the sites were not explicitly taught these processes. Rather, sites received TA to guide them through the process. TA providers used specific questions to identify readiness outcomes, performance objectives, and underlying determinants. In the future, additional user-friendly tools and a manual will likely need to be developed and distributed to

guide sites through this process without the presence of intensive TA supports.

LIMITATIONS

While the project and the process described has many strengths, there are a number of limitations. First, sites were at varying stages in the process of identifying a sexual assault prevention program to implement. There are few sexual assault EBIs for the specific population of focus that have been well-researched (23–26). Therefore, there was variability in their ability to define barriers and facilitators of implementation of “sexual assault prevention” generally rather than considering a specific program. As a result, several sites had not selected a program by the time that readiness building activities began. Therefore, it made little sense to assess and/or prioritize “innovation specific” readiness subcomponents. Thus, this important component of readiness was not assessed formally at the beginning of the project. Nevertheless, since general capacity and motivation are likely prerequisites to implement *any* sexual assault prevention program, addressing these subcomponents is likely to contribute to positive outcomes. To ensure readiness, as sites selected a program, they received TA to informally assess “innovation-specific readiness” and followed a similar approach to build innovation-specific capacity.

Another challenge was the ability to sustain the intensive efforts of planning and implementing a new program during the COVID-19 pandemic. The pandemic required significant modifications, including changing expectations and timelines. This often delayed and/or extended the TA being provided.

CONCLUSION

Organizational readiness is a critical factor for implementing EBIs, but there is little guidance on how to improve it. Using the RBS with IM is one approach to build an organization’s

readiness to adopt and implement EBIs. Using these frameworks synergistically provides a systematic process to further articulate the barriers to implementation, craft readiness goals and outcomes, identify determinants of readiness that can be addressed, and select and tailor readiness-building strategies. Future research should focus on the utility of using the RBS in conjunction with IM to develop readiness-building strategies, as well as evaluating the impact of these strategies on implementation outcomes.

DATA AVAILABILITY STATEMENT

The datasets presented in this article are not readily available due to protection of privacy. Requests for data can be directed to AWat, awatson@wandersmancenter.org.

ETHICS STATEMENT

The studies involving human participants were reviewed and approved by RAND IRB. Written informed consent for participation was not required for this study in accordance with the national legislation and the institutional requirements.

AUTHOR CONTRIBUTIONS

AWat, BH, JK-G, TW, and MF all wrote sections of the manuscript. All authors contributed to conception and design of study and contributed to manuscript revision, read, and approved the final submission.

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Leveraging Stakeholder Engagement and Virtual Environments to Develop a Strategy for Implementation of Adolescent Depression Services Integrated Within Primary Care Clinics of Mozambique

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Psychiatric disorders are the number one cause of disability in adolescents worldwide. Yet, in low- and middle-income countries (LMIC), where 90% of adolescents reside, mental health services are extremely limited, and the majority do not have access to treatment. Integration of mental health services within primary care of LMICs has been proposed as an efficient and sustainable way to close the adolescent mental health treatment gap. However, there is limited research on how to effectively implement integrated mental health care in LMIC. In the present study, we employed Implementation Mapping to develop a multilevel strategy for integrating adolescent depression services within primary care clinics of Maputo, Mozambique. Both in-person and virtual approaches for Implementation Mapping activities were used to support an international implementation planning partnership and promote the engagement of multilevel stakeholders. We identified determinants to implementation of mental health services for adolescents in LMIC across all levels of the Consolidated Framework for Implementation Research, of which 25% were unique to adolescent-specific services. Through a series of stakeholder workshops focused on implementation strategy selection, prioritization, and specification, we then developed an implementation plan comprising 33 unique strategies that target determinants at the intervention, patient, provider, policy, and community levels. The implementation plan developed in this study will be evaluated for delivering adolescent depression services in Mozambican primary care and may serve as a model for other low-resource settings.

Keywords: LMIC, mental health, depression, adolescent, implementation determinants, implementation strategies, community engagement

INTRODUCTION

Globally, psychiatric disorders are the largest contributor to burden of disease in adolescents (1). It is estimated that 90% of adolescents live in low- and middle-income countries (LMIC), and that 10–20% of these adolescents have one or more psychiatric disorders (2). Despite this, the majority of adolescents in LMIC do not have access to treatment (3, 4), and contextually appropriate strategies for delivering evidence-based adolescent mental health care are needed to expand services to these areas.

Integrating evidence-based practices for managing adolescent psychiatric disorders within primary care clinics (PCC) has been demonstrated effective in high-income countries (5) and proposed as an efficient and sustainable way to close the adolescent mental health treatment gap worldwide (4, 6). However, very limited data exist on how to effectively implement integrated mental health care in PCC settings of LMIC (4, 7). In particular, though common implementation determinants for integrated adult mental health care in LMIC have begun to emerge (8), little is known about implementation determinants for adolescent mental health care. Moreover, which implementation strategy or combination of strategies can most effectively address these determinants remains largely unstudied, especially with regard to youth mental health services (9).

Mozambique, a Lusophone country in southeastern Africa, has a population of almost 31 million, of whom nearly one-third are adolescents ages 10–24. Like other LMIC, Mozambique has an extreme shortage of mental health specialists—there are around 1.7 for every 100,000 Mozambicans, over 30 times less than in high income countries (10, 11)—and task-shared solutions are required to meet the need for mental health services. To address the adolescent mental health treatment gap, we (policymakers and mental health specialists at the Department of Mental Health of the Mozambican Ministry of Health and implementation science and mental health researchers from the United States) have formed a partnership to apply principles of implementation science to grow adolescent mental health services within the Mozambican National Health System.

Given that depression is estimated to be the leading cause of psychiatric disorder-associated disability in Mozambican youth, similar to other LMIC (1, 12), we chose to first focus on integrating screening and treatment for depression into PCC. We selected the Patient Health Questionnaire for Adolescents (PHQ-A) as the screening tool to be implemented, as it is a brief measure that can be administered by non-specialist providers and has been previously validated for identification of depression in adolescents as well as adults in Mozambique (13, 14). We selected Group Interpersonal Therapy for Adolescents (IPT-AG) (15) as the intervention to be implemented following a review of the evidence base and evaluation of the intervention fit relative to the context. Specifically, a recent meta-analysis of psychotherapies for depression in children and adolescents indicated that only IPT-A and Cognitive Behavioral Therapy (CBT) were more effective than control conditions (16), and IPT-AG has been shown effective for treatment of adolescent depression by non-specialist workers in sub-Saharan Africa (17, 18). Contextually, IPT-AG was determined to be the best fit owing to the cultural

relevance of therapy content (focus on interpersonal problems and collaborative solutions). We chose primary care clinics in Maputo City, the capital of Mozambique, as sites for pilot implementation because each clinic has a mental health specialist on site that would be able to manage adverse events in this initial research phase with a highly vulnerable population. While not representative of all cultures and contexts across the country, we believed that this population would allow for determination of a core set of strategies to comprise an implementation plan that could be adapted for scale-up across diverse regions of the country.

Implementation Mapping is a five step, systematic process for developing strategies that promote the adoption, implementation, and sustainability of evidence-based interventions (19). Here, we describe the use of Implementation Mapping to design a multilevel strategy for implementing screening, referral, and treatment for depression in adolescents integrated within PCC of Maputo Mozambique. Specifically, we used virtual and in-person approaches to identify adopters and implementers, conduct a qualitative investigation of implementation determinants, and engage stakeholders to select and specify implementation strategies that comprise the finalized implementation plan.

MATERIALS AND METHODS

All study activities (Supplementary Figure 1) were conducted in Maputo, the capital city of Mozambique. The Mozambican National Health System is led by the Ministry of Health and is where the vast majority of Mozambicans receive health care. The system is organized into community-level PCC, district-level hospitals, and province-level tertiary care hospitals as well as two specialized (quaternary care) psychiatric hospitals in the Maputo and Nampula provinces. The Department of Mental Health at the Mozambican Ministry of Health is the responsible for coordinating mental health services at all levels across the country through the National Mental Health Program. Current mental health specialists include 24 psychiatrists located in tertiary and quaternary care of four provinces and around 500 psychologists (e.g., clinical, educational, organizational), 30 occupational therapists, and 550 Psychiatric Technicians spread across primary through quaternary services throughout the country (20).

All study materials and procedures were approved by the New York State Psychiatric Institute Institutional Review Board and the Eduardo Mondlane University Institutional Health Bioethics Council.

Implementation Needs and Assets Assessment

The implementation planners comprised the authors of this article, who are implementation science and mental researchers from Columbia University as well as policymakers and mental health specialists at the Department of Mental Health of the Mozambican Ministry of Health. We represent junior, mid-level, and senior professionals in our fields, all with previous experience

in mixed-methods implementation science and mental health research. We are approximately half Mozambican ($n = 6$) and half non-Mozambican ($n = 5$); all but one implementation planner is fluent in Portuguese. Our educational backgrounds range from licensed mental health professionals to doctoral level researchers and practitioners. All but two implementation planners are also mental health practitioners.

Through a series of four virtual meetings among implementation planners, we identified adopters responsible for adolescent and mental health programming at both the national level (Ministry of Health Departments of Mental Health, School and Youth Health, and Primary Health Care) and local level (Maputo City Municipal Administration Offices of Mental Health and School and Youth Health). To identify implementers, we held two in-person workshops with 14 Mozambican stakeholders to map adolescent care pathways within PCC. Selected stakeholders included mental health specialists as well as municipal, provincial, and national coordinators of mental health services across primary through quaternary levels and coordinators of PCC-level adolescent friendly health services. With the mapped care pathways, we determined all potential points of entry, referral processes, and services provided for adolescents across primary care departments and provider-types (e.g., general medicine technician, maternal and child health nurse, physician, etc.). We then used these pathways to identify potential implementers of screening (i.e., providers that serve as points of entry for primary care services) and treatment (i.e., select providers who would be trained to deliver IPT- AG).

Identification of Implementation Outcomes and Determinants

Over an additional series of virtual meetings among planners, we selected implementation outcomes guided by Proctor's Implementation Outcomes Framework (21) and identified project-specific performance objectives for each of these based on Ministry of Health goals. We then conducted a qualitative assessment of implementation determinants with our identified adopters and implementers: key informant interviews with national and local health officials involved in adolescent ($N = 4$) and mental health programming ($N = 4$) as well as focus groups with mental health specialists ($N = 9$) and primary care providers ($n = 3$ general medicine technicians, $n = 3$ sexual and reproductive health counselors, $n = 5$ nurses, $n = 1$ physician) from four PCC. The four PCC included two urban clinics and two peri-urban clinics, the former characterized by providing a wider variety of services, serving a higher patient volume, and having a larger staff than the latter. Mozambican members of the implementation planners conducted four focus groups, one at each PCC. Trained research assistants (not affiliated with the Ministry of Health or primary care system) conducted key informant interviews. The first five interviews were conducted in a private room at the Ministry of Health; owing to COVID-19 related restrictions on in-person activities that occurred during data collection, the remaining three interviews were conducted over Zoom. Each interview lasted ~ 1 h and each focus group ~ 90 min. Interviews and focus groups were digitally audio

recorded and written notes were taken to summarize responses, record non-verbal communication, and note any disturbances or abnormalities during the session.

Interview and focus group guides explored implementation determinants based on the Consolidated Framework for Implementation Research (CFIR) domains (22). Mozambican implementation planners transcribed all interviews and focus groups in pairs, including one person who conducted the interview and one person who was not present. Transcripts were uploaded to Dedoose for coding. Mozambican implementation planners coded all transcripts in pairs, including one person who conducted the interview/focus group and one person who was not present. All transcripts were double coded by two pairs and discrepancies resolved via consensus with the Principal Investigator and the coding pairs. Initially, qualitative data was analyzed using the best fit framework approach (8, 23), in which transcripts were coded using the CFIR constructs as a priori codes and additional emergent codes created for concepts not in the CFIR. However, following attempted coding of two focus groups and two interviews using this method, the team chose to revisit the strategy because CFIR constructs were not well fit to the data. Specifically, the existing constructs did not capture many of the contextual determinants identified in the data. Therefore, the decision was made to instead use an open-coding approach, in which transcripts were coded in full and iteratively relabeled/subcoded as needed. Each code was then summarized and examined for patterns, triangulating results based on different participant (e.g., mental health specialists vs. non-specialist, provider vs. policymaker) perspectives and data type (interviews vs. focus groups), which yielded themes related to implementation determinants. Over a series of virtual meetings among implementation planners, themes were then organized within the five CFIR domains via consensus using Miro, an online visualization and collaboration platform. Peer debriefing was used to promote validity of both methodology and interpretation; prior to data analysis, methodology was presented to and discussed with experienced implementation scientists and global mental health researchers ($N = 6$) not involved in the present study and, following data analysis, methods and findings were presented to and discussed with implementation scientists with ($N = 6$) and without ($N = 4$) specialization in global mental health. We conducted member checking of results with stakeholders across a series of workshops (detailed below in Selection of Implementation Strategies).

Selection of Implementation Strategies

We held three, day-long workshops with stakeholders to review previously identified service mapping and implementation determinant data and to select, prioritize, and specify implementation strategies. Prior to workshops, the implementation planners created simplified implementation research logic models (24) for (1) the implementation process, (2) depression screening, (3) referral for depressed adolescents, and (4) treatment with IPT-AG (Supplementary Figure 2). We selected potential implementation strategies to include in logic models by first reviewing the Expert Recommendations for Implementing Change (ERIC) (25) and then tailoring

strategies to the setting and program objectives or identifying new strategies for determinants not able to be targeted by existing ERIC strategies. Logic models were developed in Miro during virtual meetings among implementation planners.

Workshop participants ($n = 15$) included policymakers (from the Ministry of Health Departments of Mental Health, School and Youth Health, and Primary Health Care, the Ministry of Education and the Office of the State Secretary for Youth), providers (mental health specialists and primary care providers for adolescents from two PCC not included in previous qualitative investigation of implementation determinants), and four local, non-governmental organizations (NGOs) with experience implementing adolescent health services in PCC. The first workshop focused on the implementation process and depression screening, the second on referral and treatment, and the third on strategy specification and finalization of the implementation plan. All workshops included a mix of presentation by the implementation planners and small group interactive discussions with participants and implementation planners. Presentations by implementation planners were used to describe objectives of the project, goals of the workshops, logic models, and implementation strategy specification. Small group discussions were used to (1) elicit feedback on implementation determinants identified and strategies proposed by the implementation planners; (2) identify additional implementation strategies not initially suggested by implementation planners; (3) prioritize strategies by importance and feasibility, by placing post-its of each strategy on a 2x2 table (**Supplementary Figure 3**); and (4) specify strategies selected for inclusion in the final implementation plan according to Proctor's implementation strategy specification recommendations (26). Across workshops, each small group included at least one implementation planner to guide discussion, one policymaker, two PCC providers (one mental health specialist, one primary care), and one NGO representative. Temporality of implementation strategies was specified using the EPIS framework (27).

Production of Implementation Protocols and Materials and Evaluation of Implementation Outcomes

Beginning in 2022, we will conduct a cluster randomized trial at PCC in Maputo, Mozambique. We will use mixed methods to compare the implementation outcomes selected in Task 2 (acceptability, appropriateness, penetration, retention, fidelity, sustainability) as well as patient outcomes (change in depression symptoms) in PCC implementing depression screening and IPT-AG compared to clinics continuing with care as usual. Additionally, because data around effective implementation strategies are so limited for LMIC (9), and data on mechanisms of implementation strategy effectiveness are limited in all contexts (28), we will use qualitative evaluation with policymakers, providers, adolescents, and their caregivers to explore mechanisms of implementation strategy action and effectiveness.

RESULTS

Definition of Potential Implementers

Through service mapping activities, we identified potential primary care providers to screen, refer, and treat adolescents with depression. While most PCC in Mozambique have adolescent-friendly health services, they are sometimes a separate department and sometimes integrated across multiple departments (i.e., providers in various departments trained in adolescent-friendly care). Additionally, even in clinics where there is a distinct adolescent-friendly health service department, adolescents can access care through multiple entry points at PCC. Moreover, some adolescents go directly to the mental health department when seeking specialist services. Therefore, we determined all general health and mental health providers at PCC should be considered as potential implementers of adolescent depression screening. Existing referral processes varied by provider, department, and PCC. In some cases, a mental health specialist was called to the department where an adolescent was identified in need of mental health services. In others, the adolescent was given a paper referral sheet to schedule a visit with mental health services or the adolescent was verbally informed they could seek mental health services in another area of the clinic but not given a paper referral. Therefore, we determined that all PCC providers who delivered screening should be implementers of a standardized referral protocol for depressed adolescents. Finally, some, but not all, PCC in Mozambique have a co-located mental health specialist, and these co-located mental health specialists already serve a large patient population. Thus, it was determined that we should consider mental health specialists as well as non-specialists as potential implementers of IPT-AG.

Identification of Implementation Outcomes and Determinants

Table 1 outlines the implementation outcomes and performance objectives developed by implementation planners. All outcomes but two are measured using routinely collected, quantitative clinical data. Fidelity to IPT-AG is evaluated using a checklist completed by IPT-AG supervisors during group observation. We chose to evaluate acceptability outcomes using qualitative methods so that an in-depth understanding of the factors influencing acceptability at the provider, patient, and caregiver level could be explored and applied to strategy improvement in future implementation efforts.

Analysis of qualitative data from policymakers and providers revealed barriers and facilitators to desired implementation outcomes across all CFIR domains (**Table 2**). Regarding intervention characteristics, we found that providers and policymakers highly valued evidence-based interventions and preferred the group format, as it allows for treatment of multiple adolescents at once and provides an opportunity for adolescents to share experiences with peers. However, there was concern that the content of IPT-AG would not be relevant to local adolescents and the need for adaptation to the context was emphasized. In IPT-AG, three sessions take place outside the group with just the provider, caregiver, and adolescent (one prior, one in the middle, and one at the end of group sessions). While involvement of

TABLE 1 | Implementation outcomes and performance objectives for integrated adolescent depression services in Mozambican primary care.

| Outcome | Measure | Performance objective |
|----------------|---|--|
| Acceptability | Qualitative interviews | Acceptable to providers, caregivers, & adolescents |
| Adoption | % PCC providers screening, referring, & delivering IPT-AG | 100% screening, referral, treatment |
| Fidelity | % correctly completed screens; % correctly completed referrals; IPT-AG fidelity checklist score | 90%, 90%, 90% |
| Penetration | % adolescents at PCC screened, % referred adolescents entering treatment | 90%, 90% |
| Retention | % IPT-AG sessions completed | 80% |
| Sustainability | Post-trial penetration & retention | 90% penetration, 90% retention |

PCC, Primary Care Clinic; IPT-AG, Group Interpersonal Therapy for Adolescents.

TABLE 2 | Implementation determinants for integrated adolescent depression services in Mozambican primary care.

| CFIR Domain | Implementation barriers [-] and facilitators (+) |
|------------------------------|---|
| Intervention characteristics | <ul style="list-style-type: none"> + High valuation of evidence-based interventions + Group intervention preferred ± Involvement of caregivers considered important but challenging to realize - Concern around contextual relevance of a non-locally developed intervention - Need for multiple, lengthy sessions |
| Outer setting | <ul style="list-style-type: none"> + Strong, intersectoral political will - Lack of existing policy and financial resources - Low MH literacy and high stigma at the community-level |
| Inner setting | <ul style="list-style-type: none"> ± Specialized health services for adolescents, but with limited personnel/space/privacy - Lack of incentive to prioritize MH - Lack of communication between PCC departments about services available - Lack of coordination between PCC services and poor referral systems - Frequent provider turnover |
| Individual characteristics | <p>Patients</p> <ul style="list-style-type: none"> + Depression recognized as common problems among adolescents + Caregivers motivated to seek help when MH interferes with school and home life - Adolescents have difficulty identifying or describing their own mental health problems - Caregivers more likely to seek help for an externalizing disorder/substance use than internalizing disorder - Caregivers often don't accompany adolescent at PCC <p>Providers</p> <ul style="list-style-type: none"> + Motivated to improve MH - Limited confidence in being able to deliver MH services - Lack of MH knowledge and MH stigma |
| Process | <p>Preparation phase</p> <ul style="list-style-type: none"> + Engagement with administrators & all PCC services + Engagement between MH and other departments at the Ministry of Health + Elaboration of a clearly structured implementation plan - Lack of engagement between implementation planners and community stakeholders <p>Implementation phase</p> <ul style="list-style-type: none"> + Ongoing supervision, monitoring, and technical support after training - Lack of ongoing engagement between implementation planners and local stakeholders |

⁺Implementation Facilitator; ⁻Implementation Barrier; MH, Mental Health; PCC, Primary Care Clinic.

caregivers in IPT-AG was considered helpful for adolescents' symptom improvement and treatment engagement, it was also viewed as a barrier because caregivers were likely to lack the funds, time, and interest to participate in therapy sessions. Moreover, a lack of support or negative relationship with the caregiver was considered common in adolescents with mental health problems thus creating a challenge in identifying an appropriate person to participate in IPT-AG sessions. Finally, the length and number of IPT-AG sessions was perceived to be a barrier, as the cost of travel to the PCC and time commitment was

considered challenging for adolescents, caregivers, and providers alike who are accustomed to brief, objective interventions (e.g., medication for infectious diseases).

At the level of the outer setting, adolescent mental health was considered a policy priority across multiple health sectors. However, extant funding and policy for adolescent mental health was extremely limited. Moreover, participants described community mental health literacy as low and stigma as high, citing a common cultural belief that mental health problems are a moral failing, spiritual deficit, or a normal part of adolescence

and not a medical condition that, in turn, contributes to limited care-seeking and adherence. At the level of the inner setting, participants highlighted the existence of adolescent-friendly health services at PCCs as an implementation facilitator, but indicated that these services have limited personnel, space, and privacy. Additional barriers of the inner setting included a lack of incentive to prioritize mental health among other health needs, limited communication between PCC departments and a corresponding lack of awareness of services offered at each, a lack of coordination between PCC services and poor referral systems that result in long wait times and loss of patients, and frequent provider turnover at the PCC.

Implementation determinants at the level of the individual were grouped into those regarding providers and those regarding patients, including both adolescents and their caregivers. PCC providers were highly motivated to address adolescent mental health, though non-specialists felt they had limited mental health knowledge and were unsure they would be capable of providing mental health services. Despite community-level stigma regarding mental health and a general lack of knowledge around treatment of mental health problems, participants shared that depression and anxiety were perceived as common, and therefore less stigmatized, problems among adolescents themselves. Still, there was concern that adolescents have difficulty identifying or describing their own mental health problems. Additionally, participants described caregivers as motivated to seek treatment when their adolescent was having problems at home or in school, whether or not they were able to name the source as a mental health problem. However, caregivers were also described as having limited involvement in or knowledge of their adolescent's emotional wellbeing and described as less likely to seek help for an internalizing disorder, such as depression or anxiety, than for an externalizing disorder or substance use. Moreover, adolescents most often are not accompanied by a caregiver at their PCC visits.

Finally, at the implementation process-level, participants used their experiences with previous health program implementation efforts to reflect on potential determinants of implementing adolescent depression services in PCC. Engagement between implementation planners and PCC administrators as well as all PCC services and engagement between the Mental Health Department and other departments at the Ministry of Health were considered major facilitators for implementation preparation, as was clear elaboration of program objectives, roles, activities, timelines, budget and expected outcomes. Lack of engagement between implementation planners and community stakeholders was cited as a critical barrier to preparation. In the implementation phase, lack of ongoing engagement between implementation planners and stakeholders at the local political, PCC, and community levels was perceived to be a barrier, whereas ongoing supervision of providers, monitoring of implementation, and technical support was a facilitator.

Implementation Strategy Selection

We developed 42 potential strategies to target implementation determinants (Table 3). We then created simplified logic

models to present and discuss with workshop participants (Supplementary Figure 2).

Among the additional implementation strategies suggested by workshop participants, all were captured in the existing strategies proposed by the implementation planners (i.e., a more detailed strategy encompassed within a proposed strategy or a broader strategy that encompassed multiple proposed strategies). Therefore, just the initial 42 potential strategies were ranked by importance and feasibility. We quantified prioritization numerically where 1 = important and feasible, 2 = important but not feasible, 3 = feasible but not important, and 4 = not important nor feasible (Table 3).

All but eight (19.0%) strategies were determined to be both important and feasible. Conducting depression screening in the waiting room prior to the consultation was considered important, as it would minimize burden on the provider, but was thought to be unfeasible owing to the lack of privacy in the waiting room and available personnel who would be capable of administering the screen. Having the adolescent self-complete the screen in the waiting room was considered important, again because of minimization of provider burden, but unfeasible owing to adolescents limited literacy, mental health awareness, and previous experience indicating adolescents are less likely to respond to screens accurately without a provider's assistance. Having administrative personnel assist the adolescent in screen completion was considered both unimportant and unfeasible, as participants did not feel these personal would have the time nor the capability to help adolescents complete screens more accurately. Finally, use of a digitized screen by providers was considered important as its auto-calculation of scores reduces administration time, promotes fidelity, and allows for remote quality assurance, but was thought to be unfeasible because providers do not use electronic systems for any other services and thus may encounter challenges maintaining a device solely for screening purposes (e.g., inconsistent access to a power source at the PCC to charge the clinic, competition or resentment from providers who do not screen and thus are not given a mobile device).

Regarding referral, the strategy of providing the first IPT-AG session on the day of positive screen was considered important, as it would promote adolescents' entry into mental health care, but also unfeasible, because it is unlikely that treatment providers would have time without advanced notice and, more significantly, because the first IPT-AG session is meant to occur with the adolescent and their caregiver, but adolescents are commonly unaccompanied by a caregiver at primary care visits. Regarding treatment, weekly sessions were considered important and feasible while biweekly sessions were considered important but not feasible; biweekly sessions were not thought to increase the likelihood an adolescent would be able to attend and would also make the length of treatment twice as long, which participants indicated would hinder adherence over time. Moreover, offering morning and afternoon groups was ranked as important, because some Mozambican adolescents attend school in the morning and some in the afternoon, but infeasible, as it would be difficult for a single treatment provider to fit groups at both times in their patient load. Finally, having the IPT-AG

TABLE 3 | Implementation strategies and their prioritization for integrated adolescent depression services in Mozambican primary care.

| Strategy type | Strategy | Priority |
|------------------------|----------------|--|
| Implementation process | How to prepare | 1 1 1 1 1 1 1 1 1 1 |
| | How to monitor | 1 1 1 1 1 1 1 1 1 1 |
| | Who/when/where | 2 2 4 1 1 1 1 1 1 1 |
| | How to deliver | 1 1 1 2 1 1 1 1 1 1 |
| | How to deliver | 1 1 1 1 2 1 1 1 1 1 |
| | Who/when/where | 1 1 2 1 1 1 1 1 1 1 |
| | How to deliver | 1 2 1 1 1 1 1 1 1 1 |
| | Who/when/where | 1 1 2 1 1 1 1 1 1 1 |
| | How to deliver | 1 2 1 1 1 1 1 1 1 1 |
| | How to deliver | 1 1 1 1 1 1 1 1 1 1 |

PCC, Primary Care Clinic, IPT-AG, Group Interpersonal Therapy for Adolescents, MH, Mental Health.

provider guided by a tablet during treatment facilitation was considered important, as it would increase fidelity and allow remote quality monitoring, though participants believed this to be unfeasible for the same reasons as having a digitized screen.

Of the eight strategies not considered both important and feasible, seven were not included in the final implementation plan and one was collapsed within another strategy. Since morning

and afternoon groups as well as Saturday groups were considered important to offer, but multiple group times was considered infeasible for providers, we combined them into one strategy “Creation of morning, afternoon, and Saturday groups” based on the availability of both adolescents and providers. Additionally, we initially proposed 1) all PCC providers and 2) all adolescent-friendly service providers as two different strategies for screening

TABLE 4 | Implementation strategy specification for integrated adolescent depression services in Mozambican primary care.

| ERIC match | Adapted strategy definition | Actor | Action | Target | Temp. | Dose | Outcomes affected | Justification* |
|--|--|-------|--|--------|-----------|---------|---|---|
| Implementation process strategies | | | | | | | | |
| Develop formal implementation blueprint | Create detailed implementation plan | IP | Develop document of project objectives, roles, activities, timeline, budget, and expected outcomes | I, A | Prep | Once | Adoption, sustainability | Elaboration of a clearly structured implementation plan; Lack of engagement between implementation planners and community stakeholders |
| Involve executive boards | Share implementation plan with national and local policymakers | IP | Present and deliver physical copy of implementation plan to Ministry of Health, Ministry of Education, National/Provincial/District Health Departments | A | Prep | Once | Adoption, sustainability | Engagement between MH and other departments at the Ministry of Health; Lack of engagement between implementation planners and community stakeholders |
| Obtain formal commitments | Obtain approval and commitment from PCC directors | IP | Present and request formal (signed) authorization of implementation plan to PCC administration | A | Prep | Once | Adoption, sustainability | Engagement with administrators & all PCC; Lack of engagement between implementation planners and community stakeholders |
| Organize clinical implementation team meetings | Create intervention team including implementers and adopters at PCCs | IP | Form intervention team at each PCC including all screening and treatment providers | I | Prep | Once | Acceptability, adoption, sustainability | Lack of coordination between PCC services and poor referral systems |
| | Collaborate with intervention team to create intervention flowchart | IP, I | Hold workshop to elaborate PCC-specific logistical details of screening (e.g., location), referrals (e.g., who completes warm hand-off to MH department), and treatment (e.g., who makes pre-session reminder calls) | I | Prep | Once | Acceptability, adoption, fidelity | Lack of coordination between PCC services and poor referral systems |
| Identify and prepare champions | Identify person at PCC to serve as intervention team lead | IP, A | Work with PCC administration to select one implementer with characteristics of leadership, flexibility, and self-motivation | I | Prep | Once | Adoption, fidelity | Lack of coordination between PCC services and poor referral systems |
| Increase demand | Conduct community awareness activities with Ministries of Health and Education | IP | Develop materials (e.g., presentations, flyers) for MH literacy, stigma reduction, and program promotion to be delivered in schools and by community health workers | C | Prep | Cont. | Acceptability, penetration | Low MH literacy and high stigma at the community-level; Lack of engagement between implementation planners and community stakeholders |
| Conduct educational meetings/ Audit and feedback | Conduct awareness presentations at PCC | IP, I | Intervention lead presents on MH literacy, stigma reduction, and project activities/updates at each PCC's monthly staffwide meeting | A, I | Prep/ Imp | 2x/year | Acceptability, adoption, fidelity, sustainability | Lack of communication between PCC departments about services available; Lack of MH knowledge and MH stigma; Lack of incentive to prioritize MH; Lack of engagement between implementation planners and community stakeholders |

(Continued)

TABLE 4 | Continued

| ERIC match | Adapted strategy definition | Actor | Action | Target | Temp. | Dose | Outcomes affected | Justification* |
|---|--|-------|---|--------|-------|-----------------|-----------------------------------|---|
| Develop educational materials | Base training in real cases | IP | Demonstrate evidence base of IPT-AG and include locally relevant examples of depressed adolescents and treatment in IPT-AG didactic | I | Prep | Once | Acceptability, adoption, fidelity | High valuation of evidence-based interventions; Concern around contextual relevance of a non-locally developed intervention |
| Provide clinical supervision | Supervise IPT-AG providers | IP | Following didactic training, supervision of 2 IPT-A groups by IPT-AG expert trainer and local IPT-AG expert | I | Prep | Once | Fidelity | Limited confidence in being able to deliver MH services |
| Change record systems | Create a screening record | IP | Develop paper form for each screener including # adolescents screened and # referred for IPT-AG, collected and reviewed by intervention team lead each week | I | Prep | Once, Cont. Use | Fidelity | Lack of coordination between PCC services and poor referral systems |
| Develop and organize quality monitoring systems | Meetings between intervention team lead and implementation planners | IP | Intervention team lead reports PCC screening and referral numbers to implementation planners | I | Imp | Weekly | Adoption, fidelity | Lack of coordination between PCC services and poor referral systems |
| | Continuous communication between implementation planners and team lead | IP | Open communication between implementation planners and intervention team lead to resolve time-sensitive issues | I | Imp | Cont. | Fidelity, penetration, retention | Lack of coordination between PCC services and poor referral systems |
| | Meetings with implementation planners and intervention team | IP, I | Intervention team lead reports on program fidelity, penetration, and retention and holds open discussion on feedback from adolescents/caregivers and resolving emerging implementation barriers | I | Imp | Monthly | Fidelity, penetration, retention | Lack of coordination between PCC services and poor referral systems |
| Conduct ongoing training | Conduct refreshment training for screening and IPT-AG providers | IP | Revision of cases and open discussion with providers, IPT-AG expert trainer and local IPT-AG expert | I | Imp | 2x/year | Fidelity | Ongoing supervision, monitoring, and technical support after training |
| Screening strategies | | | | | | | | |
| Revise professional roles | Screening by all PCC providers | IP | Screening by general providers (nurses, medicine technicians, counselors) in all departments attending to adolescents | I | Imp | Cont. | Penetration | Specialized health services for adolescents, but with limited personnel, space, privacy |
| Develop educational materials | Distribute support materials for screening | IP | Post visual materials with screen instructions and scoring algorithm in PCC | I | Imp | Once | Fidelity, penetration | Limited confidence in being able to deliver MH services |
| - | Use non-stigmatizing language to introduce screen to adolescents | I | Providers use clear, simple, age-appropriate language to describe screen | P | Imp | Cont. | Acceptability, penetration | Low MH literacy and high stigma at the community-level |

(Continued)

TABLE 4 | Continued

| ERIC match | Adapted strategy definition | Actor | Action | Target | Temp. | Dose | Outcomes affected | Justification* |
|--|---|-------|--|--------|-------|-------|---|---|
| Change physical structure and equipment | Identify adequate space for screening | I | Intervention team finds or creates quiet, private space | P | Imp | Cont. | Fidelity, penetration | Specialized health services for adolescents, but with limited personnel, space, privacy |
| Referral strategies | | | | | | | | |
| – | Use non-stigmatizing language to give feedback on screen results | I | Providers use simple terms (e.g., sadness) and normalize depression | P | Imp | Cont. | Acceptability, penetration | Low MH literacy and high stigma at the community-level |
| Intervene with patients to promote uptake and adherence | | | | | | | | |
| Revise professional roles | Provide psychoeducation following positive screen | I | Providers describe the importance of treatment and gives overview of IPT-AG | I, P | Imp | Cont. | Penetration | Low MH literacy and high stigma at the community-level |
| | Bring adolescent with positive screen directly to MH department | I | Providers deliver adolescents along with paper screen in MH providers | I, P | Imp | Cont. | Fidelity, penetration | Lack of coordination between PCC services and poor referral systems |
| Intervene with patients to promote uptake and adherence | Identify caregiver to participate in IPT-AG sessions with adolescent | I | Providers explain the role of caregivers in IPT-AG and decide with adolescent who is the appropriate person to involve | P | Imp | Cont. | Acceptability, penetration, retention | Involvement of caregivers considered important but challenging to realize |
| | Call adolescent and/or caregiver on day prior to initial IPT-AG session | I | Provider contacts adolescent and/or caregiver to remind them of upcoming session | P | Imp | Cont. | Penetration | Low MH literacy and high stigma at the community-level; Involvement of caregivers considered important but challenging to realize |
| Treatment strategies | | | | | | | | |
| Revise professional roles | Training of at least 3 providers in each PCC | IP | Inclusion of a MH specialist and 2 non-specialists as IPT-AG providers. | I | Imp. | Cont. | Acceptability, fidelity, sustainability | Frequent provider turnover; Limited confidence in being able to deliver MH services |
| | MH specialist and general provider deliver groups together | IP | Groups led by MH specialist and a non-specialist together for first 6 months. | I | Imp. | 6 mo. | Acceptability, fidelity, sustainability | Frequent provider turnover; Limited confidence in being able to deliver MH services |
| Intervene to promote uptake and adherence | Morning, afternoon, and Saturday groups offered | I | Work with adolescents and providers to identify best time for them to participate in sessions | P | Imp. | Cont. | Acceptability, retention | Need for multiple, lengthy sessions |
| Promote adaptability | Weekly group sessions | I | Hold IPT-AG sessions weekly | P | Imp. | Cont. | Acceptability, fidelity, retention | **Determined feasible and preferable in workshops |
| Change physical structure and equipment | Identify adequate space for sessions | I | Intervention team finds or creates quiet, private, open space | P | Imp. | Cont. | Acceptability, retention | Specialized health services for adolescents, but with limited personnel, space, privacy |
| Promote adaptability | Age-appropriate age composition | I | Composition of groups with adolescents 12–14 and 15–19 | P | Imp. | Cont. | Acceptability, retention | **Determined as appropriate age groups in workshops |

(Continued)

TABLE 4 | Continued

| ERIC match | Adapted strategy definition | Actor | Action | Target | Temp. | Dose | Outcomes affected | Justification* |
|---|---|-------|--|--------|-------|-------|--------------------------|---|
| Intervene to promote uptake and adherence | Educate adolescent about IPT-AG | I | Educate adolescent on IPT-AG treatment objectives, duration, content | P | Imp. | Cont. | Retention | Need for multiple, lengthy sessions |
| | Call adolescent and/or caregiver on day prior to each session | I | Provider contacts adolescent and/or caregiver to remind them of upcoming session | P | Imp. | Cont. | Retention | Need for multiple, lengthy sessions |
| | Include caregivers remotely when they are unable to join session at PCC | I | Use phone or online platforms to include caregivers in sessions | P | Imp. | Cont. | Acceptability, retention | Involvement of caregivers considered important but challenging to realize |

Temp, Temporality; IP, Implementation Planners; A, Adopters; I, Implementers; C, Community; P, Patient; Prep, Preparation Phase; Imp, Implementation Phase; Cont, continuous; PCC, Primary Care Clinic; IPT-AG, Group Interpersonal Therapy for Adolescents; MH, Mental Health; * Justification based on corresponding implementation determinant targeted by strategy; ** Justification based on stakeholder workshops and not qualitative formative assessment.

implementers. Since both strategies were deemed feasible and important, and adolescent friendly-service providers are a type of PCC provider, we combined the two strategies and used the inclusive terminology, all PCC providers, to name the strategy in the final plan. Therefore, in the final implementation plan, we included a total of 33 distinct implementation strategies.

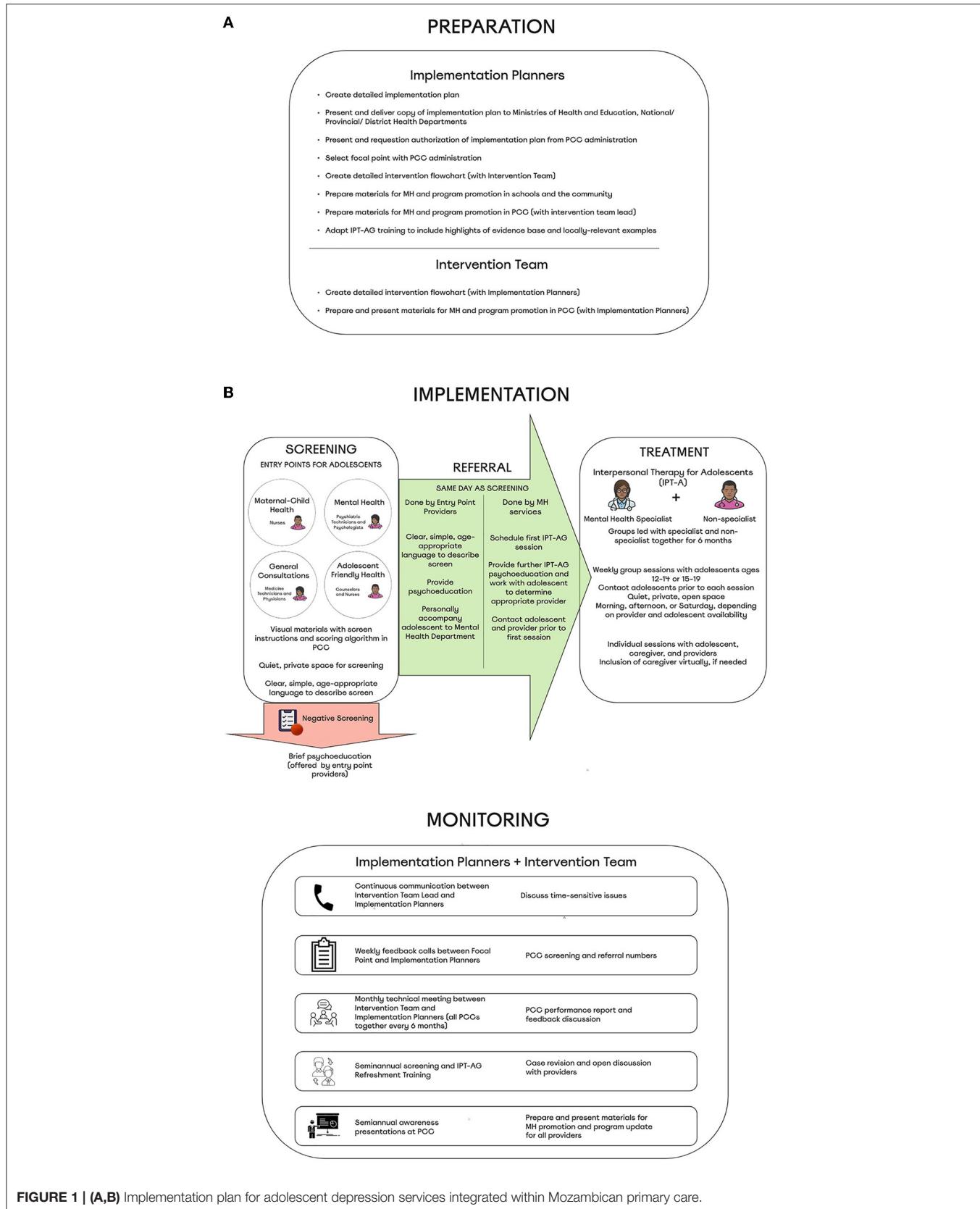
In the final workshop, participants worked with implementation planners to specify all 33 strategies, including the actor, action, target, temporality, and dose. We then completed the strategy specification by adding in the ERIC strategy match, the strategy outcomes targeted, and the justification for inclusion of the strategy (Table 4). Our implementation strategies spanned 20 distinct ERIC strategies, with the most common being “revise professional roles” ($n = 5$ selected strategies) and “intervene to promote uptake and adherence” ($n = 4$ selected strategies). Two of the 33 strategies, “use non-stigmatizing language to introduce the screen” and “use non-stigmatizing language to discuss screen results” were not derived from ERIC strategies and we were unable to identify an appropriate corresponding ERIC strategy in *post-hoc* comparison.

Implementation Materials and Evaluation of Implementation Outcomes

We will examine the patient and implementation outcomes associated with our finalized implementation plan (Figure 1) in a hybrid type II cluster randomized trial in PCC of Maputo, Mozambique. Protocols and materials for preparation and implementation of the trial are guided by strategies included in the final implementation plan. Specifically, we are currently developing a more detailed implementation plan that includes objectives, roles, activities, timeline, budget, and expected outcomes of the project. We are also working with the Ministries of Health and Education to develop materials (e.g., presentations, flyers) for a mental health awareness campaign to be delivered in schools and communities. Moreover, we will work with intervention implementers to create a presentation to promote general mental health awareness as well as project-specific activities in each of the participating PCC. We will also work with intervention implementers to design the detailed intervention flowchart for each PCC. Finally, we are adapting IPT-AG training materials to highlight the evidence base, include guidance on choosing an appropriate caregiver with the adolescent, and incorporate locally-relevant examples; creating a screening record to be used for quality control; and developing visual guides for conducting and scoring screening measures that will be posted in all PCC departments. Results of this pilot trial will be used to inform any modifications needed to the present implementation plan, for example additional strategies needed to promote treatment fidelity or to manage and promote retention among adolescents between initial screening and IPT-A groups.

DISCUSSION

Despite the enormous mental health treatment gap, there is still very limited data on effective strategies for implementing mental services in LMIC, especially with



regard to adolescent mental health services. The systematic selection of implementation strategies is critical to the success of a program as well as our understanding of the effectiveness of different implementation strategies across programs (29). We present here, to our knowledge, the first application of Implementation Mapping to develop an implementation plan for LMIC settings. We demonstrate that using a blend of in-person and virtual approaches for Implementation Mapping activities can facilitate international implementation planning partnerships and the engagement of multilevel stakeholders. Additionally, we identify a number of unique implementation determinants and strategies important for adolescent mental health care integration in PCC that have not previously been noted for implementation of adult mental health care in LMIC. In the coming years, the implementation plan developed here will be evaluated for delivering adolescent depression services in Mozambican primary care and may serve as a model for other low-resource settings.

The use of Implementation Mapping provided a systematic process employing theory, evidence, and stakeholder engagement to develop our implementation plan (19). Incorporating both virtual and in-person approaches provided the flexibility necessary for international work while maintaining fidelity to this structured process. One of the main ways that virtual tools were employed was for implementation planner activities (e.g., remote meetings, online qualitative data analysis with Dedoose, logic models built in Miro). While adjustment to use of these tools required additional time, they permitted the consistent involvement of local partners, which was critical to the veracity and contextual relevance of data. For example, all qualitative data was analyzed in Portuguese, rather than translating to English for analysis then back-translating for presentation at workshops, limiting data loss across activities. Virtual tools were also used to rapidly adapt during COVID-19 related restrictions on in-person activities (e.g., qualitative interviews over Zoom), highlighting their importance in an agile research process. Still, while virtual tools supported engagement that would otherwise not be possible, in-person activities continued to be invaluable to the process. Specifically, in-person workshops promoted communication and engagement between stakeholders ranging from junior PCC providers to high-ranking Ministry officials, which, in turn, resulted in the selection and specification of strategies informed by diverse perspectives, an integral component to effective implementation as well as future scale-up and sustainability of the program (27).

A recent systematic review of determinants to implementing adult mental health services in LMIC primary care found a number of common barriers and facilitators (8). Across CFIR levels, our findings were consistent with those previously demonstrated. For example, research from multiple other LMIC have similarly demonstrated the need for lengthy visits (30, 31), low mental health literacy and high levels of stigma in communities (30, 32–36), and poor communication and referral systems in PCC (37–39) as barriers as well as provider perception that mental health care integration is important as a facilitator (31, 40–42) to mental health service integration. Unique in

our study, however, are determinants which may serve as important targets of implementation strategies for interventions addressing adolescent mental health in this and other settings. For example, involvement of caregivers was considered very important but challenging to realize. We therefore included strategies to promote the inclusion of a caregiver in a way that is acceptable to both the adolescent (e.g., providers working with adolescents to select the appropriate caregiver) and the caregiver themselves (e.g., reminding caregivers of the session the day before and creating options for joining remotely if caregivers are unable to travel to the PCC). As a 2020 systematic review on implementation of depression interventions in LMIC did not identify a single study focused on implementation strategies for youth (child or adolescent) populations (9), further research on adolescent-specific implementation determinants and effective implementation strategies to target these determinants is urgently needed.

To further ground our study in implementation science, in addition to using Implementation Mapping to guide our process, we employed specific implementation frameworks in our selection of implementation outcomes (i.e., Proctor's Implementation Outcome Framework) (21), investigation of implementation determinants (i.e., CFIR) (22), selection of potential strategies (i.e. ERIC) (25), and project synthesis (i.e., Implementation Logic Models) (24). While use of these frameworks promoted the rigor and specification of our process, we encountered a number of challenges in their application. For one, while the CFIR domains were relevant to the present study, the specific constructs within each were not as obvious in their application to the context and project, causing us to shift from using a best-fit framework approach to an open-coding approach for qualitative analysis. Our experience is consistent with a systematic review that demonstrated a number of CFIR constructs to be considered incompatible or irrelevant by investigators using them in LMIC settings and suggested adaptations to the CFIR be made for use in these contexts (43). Moreover, while the potential strategies we selected were generated by reviewing the ERIC strategies and adapting them to the context, when mapping our finalized strategies back onto the ERIC during strategy specification, we found that individuals strategies at times appeared to fit into several different ERIC strategies. For example, we matched our strategy "Create a screening record" as the ERIC strategy *change record systems*, but it also could have mapped to *develop and implement tools for quality monitoring*. We therefore chose to select ERIC strategy matches by which we felt best captured our strategy's objective (i.e., the justification and implementation outcome targeted). Our experience supports a recent call to increase focus on the mechanisms of implementation strategies (29) rather than the strategies themselves, which are less readily compared across studies. Finally, in preparing the logic models for workshops, we determined that simplifying the models, like changing the names of CFIR domains to project-specific counterpart (e.g., PCC instead of inner setting), would allow stakeholders to more easily understand and interact with them. We share these experiences not to undercut the importance of using implementation frameworks in LMIC settings, but rather to

highlight the need to adapt to the context and prioritize program goals in their application.

The results presented here should be considered in light of the following limitations. For one, qualitative implementation determinant data collection and implementation strategy selection workshops occurred in one province. While we included PCC providers from urban and periurban regions as well as policymakers and NGO representatives that serve multiple provinces, adaptations may be needed to the implementation plan to meet the needs and assets of other Mozambican provinces where care-seeking and cultural norms, such as gender roles, may differ and which have more limited PCC staff and mental health providers. Additionally, owing to the COVID-19 related restrictions on in-person activities, we were unable to include community members (e.g., adolescents, caregivers, traditional healers) in our exploration of implementation determinants. Future research with community members should be explored to understand additional determinants (e.g., stigma, health beliefs) and strategies to further improve contextual relevance of the implementation plan. Finally, the vast majority of implementation strategies proposed were ranked as high priority (both feasible and important). In this project, we were able to include all high priority strategies in the implementation plan; however, for other projects in which it is not possible to include a large number of strategies within the implementation plan, it may be necessary to use a different prioritization methodology. We grouped participant feedback from the 2×2 table into four categories because, when we asked workshop participants to rank strategies within each quadrant, they informed us that they generally believed the strategies within each quadrant to be equally important/feasible, unless they had clearly placed the strategy toward the middle axes. In other projects, it may be necessary to better familiarize participants with this type of ranking system and/or require participants to rank strategies so that none are given equal priority.

Despite these limitations, we believe this study provides important contributions to the literature. To our knowledge, this is one of the first studies to systematically develop a strategy for implementation of adolescent mental health services and the first to apply Implementation Mapping in LMIC. Findings from this study will inform future scale-up of integrated adolescent mental health services in Mozambique and may serve as a model for efforts in other LMIC. Additionally, the use of virtual tools to facilitate an international research-policy

partnership and implementation activities demonstrates a flexible application of Implementation Mapping that can promote diverse stakeholder engagement.

DATA AVAILABILITY STATEMENT

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

ETHICS STATEMENT

All study materials and procedures were approved by the New York State Psychiatric Institute Institutional Review Board and the National Committee for Bioethics in Health of Mozambique. The patients/participants provided their written informed consent to participate in this study.

AUTHOR CONTRIBUTIONS

KL conceived of and designed the study with support from PS, CD, RB, and MW. PS, SA, CB, MF, BK, TR, and AJ managed data collection. KL, SA, CB, MF, BK, TR, and AJ contributed to data analysis. KL wrote the initial draft of the manuscript. All authors contributed to manuscript editing and have approved the final draft for publication.

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SUPPLEMENTARY MATERIAL

The Supplementary Material for this article can be found online at: <https://www.frontiersin.org/articles/10.3389/fpubh.2022.876062/full#supplementary-material>

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Implementing a Dutch Physical Therapy Intervention Into a U.S. Health System: Selecting Strategies Using Implementation Mapping

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Background: Coach2Move is a person-centered physical therapy intervention that has demonstrated success in changing physical activity behaviors among older adults in the Netherlands. In this manuscript, we describe how we developed an implementation plan for Coach2move in a U.S. population and healthcare system using Implementation Mapping.

Methods: We established an implementation planning team of researchers, patients, and clinicians. The Consolidated Framework for Implementation Research provided an overall structure for consideration of the context for implementation. Implementation Mapping guided the planning process. The implementation planning team worked sequentially through the five tasks of Implementation Mapping (1) Identify needs, program adopters and implementers; (2) Identify adoption and implementation outcomes, performance objectives, determinants, and matrices of change; (3) Choose theoretical models and implementation strategies; (4) Produce implementation protocols; (5) Evaluate implementation outcomes. In this manuscript, we identify our evaluation plan but not results as data collection is ongoing.

Results: Clinic managers and physical therapists were identified as program adopters and implementors. Performance objectives necessary steps to achieving implementation outcomes were linked to Coach2Move fidelity indicators with implementation by the physical therapist. These included delivery of person-centered care, motivational interviewing, meaningful goal setting, shared decision-making in planning, and systematic monitoring and follow-up. Determinants linked to these performance objectives included knowledge, outcome expectations, skills and self-efficacy, and perceived norms. Implementation strategies were selected based on a review of methods effective for influencing these determinants. This resulted in four primary strategies (1) educational meetings and dynamic training, (2) peer-assessment meetings, (3) changing

the electronic health record template, and (4) reminders and prompts. Measures of intervention acceptability, appropriateness, and feasibility will be collected after training and early in implementation. Fidelity and effectiveness measures will be collected over the next 12-months.

Conclusion: Implementation mapping provided a systematic process for identifying what physical therapists would need to implement Coach2Move with fidelity. The result was a matrix linking behavioral determinants and performance objectives. These matrices of change allowed for systematic identification and tailoring of implementation strategies to the needs of our population and setting. The process was acceptable to diverse stakeholders, facilitated communication across stakeholders.

Keywords: physical activity, implementation science, rehabilitation, musculoskeletal disorders, behavior change and communication

INTRODUCTION

Chronic musculoskeletal (MSK) conditions such as low back pain and osteoarthritis are a leading cause of years lived with disability globally (1). MSK conditions not only have a profound impact on function but are one of the most common reasons adults seek medical care (2). Clinical practice guidelines recommend physical activity (PA) as the cornerstone of disease management and many individuals are referred to physical therapy (3–5). While people with MSK report improved pain and function with increased PA (6–8), few successfully sustain PA after physical therapy and subsequently still struggle with symptom management (9–14). There is a critical need to develop and test implementation strategies that facilitate the delivery of evidence-based interventions to improve PA in the physical therapy setting.

Coach2Move is a physical therapist delivered intervention shown to increase PA after physical therapy in community-dwelling older adults (15). In collaboration with Coach2Move researchers, we adapted the intervention to a U.S. population of middle age and older adults with chronic MSK conditions. The aim of the current project was to identify implementation strategies appropriate for our clinical environment. Implementation mapping provided a systematic process, using five main tasks, for selecting and planning our implementation strategies (16). This process was developed based on the intervention mapping framework and uses community stakeholder input, behavioral and implementation theories, and empirical findings to guide the output (17).

The Consolidated Framework for Implementation Research (CFIR) and social cognitive theory guided our consideration of the context and individual determinants of change (18–20). The CFIR domains and menu of constructs provided a practical guide to assessing a range of potential barriers and facilitators to implementation in our environment. Social cognitive theory posits that cognitive, behavioral, and environmental factors influence behavior change and is often applied at an individual level (21). These factors interact and support a central premise that individuals strive for a sense of agency. Both the CFIR and social cognitive theory highlight the need to consider the environment in which a behavior occurs and the

interaction how an individual interacts with an intervention to influence implementation.

Coach2Move is a paradigm shift in the physical therapist's communication from a traditional approach of the physical therapist as expert to one which includes patient expertise. Despite known effectiveness of person-centered care, implementation in physical therapy has been challenging (22, 23). Physical therapists lack self-efficacy and skills in communication around sensitive topics such as mental health and emotional distress (23, 24). They also find it difficult to elicit motivation, address ambivalence, and partner with patients on strategies that change PA in everyday life (25). In Coach2Move, physical therapists train in motivational interviewing to engage patients in identifying meaningful goals, monitor progress, and plan for self-management through sustainable changes in PA (26). Coach2Move has demonstrated acceptability with patients and physical therapists, effectiveness in sustaining PA beyond an episode of physical therapy care, and cost-effectiveness (15, 27, 28). Differences between core components of Coach2Move and routine physical therapy are highlighted in **Table 1**. These core components were the essential structure for our performance outcomes within the Implementation Mapping process.

The goal of Coach2Move is to equip physical therapists with the tools to successfully promote PA behavior change in patients with chronic MSK conditions. This manuscript describes our approach to the development of a multifaceted implementation strategy, using Implementation Mapping, to facilitate delivery of Coach2Move in a U.S. health system.

METHODS

Setting

This study was conducted within an academic health system, University of Utah Health (UHealth). We considered all 7 outpatient physical therapy clinics located in the greater Salt Lake City area and Park City in our implementation planning. These clinics represent 122 physical therapists and 2 different management structures.

TABLE 1 | Comparison of Coach2Move core components and routine physical therapy.

| Routine physical therapy | Coach2Move physical therapy | Performance objectives |
|--|---|--|
| Diagnosis centered: focus on common conditions specific impairments | Person centered: focus on meaningful activities at home with help from social network | Tailors program to individual functional needs and readiness to change |
| Gathers information primarily through closed-ended questions, "provider-centric" | Gathers information using open-ended questions, reflections, and summaries | Uses motivational interviewing to elicit reasons to change physical activity |
| Goals often set by physical therapist | Shared decision-making about meaningful treatment goals | Identifies inspiring and measurable goals |
| Focused on impairment and short-term management of symptoms | Planning for long-term solutions to chronic symptoms management | Explicit conversation on physical activity and the relationship of physical activity and the MSK condition |
| Physical therapist directs plan ("Physical therapist as expert") | Physical therapist supports self-management and empowerment with negotiated planning (Identifies "Patient as expert" in their life) | Empowers patient to monitor their own progress and identify solutions |
| Varied application of standardized performance tests and patient-reported outcomes. Primarily performed at baseline. | Systematic monitoring using patient reported outcomes and performance measures throughout follow-up and discussed with patient. | Uses appropriate measurement to discuss progress across the episode of care |

Target Participants

Coach2Move will target patients who are 50 years and older with a chronic MSK condition (i.e., chronic low back pain, hip or knee osteoarthritis) and receiving outpatient physical therapy. Physical therapists will be eligible to participate if they work more within UHealth, are scheduled more than 19 h/week, and routinely treat middle-age and older adults with chronic MSK conditions (>30% of average workload).

Implementation Planning

We established a diverse implementation planning group to design the multifaceted implementation strategy. This group consisted of researchers, patient stakeholders, physical therapists, social workers with expertise in motivational interviewing, and Coach2Move developers. Patient and physical therapist stakeholders were recruited from UHealth. Patient stakeholders were 50 years or older and had a chronic MSK condition for which they had received physical therapy. Patient stakeholders had participated previously in participatory research. Physical therapist stakeholders were selected to represent clinics with differing management structures and routinely manage middle age and older adults with chronic MSK conditions. Researchers at the University of Utah guided the process and were the primary point of contact with each stakeholder group.

Logic Model

The planning group first reviewed the outline of implementation strategies used previously by Coach2Move researchers. From this foundation, we used the Implementation Mapping process and the Consolidated Framework for Implementation Research (CFIR) to consider constructs and domains likely to influence implementation within our setting. CFIR helped us identify potential contextual factors that could influence implementation both in the current study and with future implementation. We worked sequentially through each Implementation Mapping task. Throughout the process, we reviewed behavior change models and literature to help prioritize determinants of change

and implementation strategies most likely to be effective. An overview of the logic model is provided in **Figure 1**.

Implementation Mapping Tasks

Implementation Mapping starts with an implementation needs assessment and identifying program adopters, implementers, and maintainers (Task 1). Given our early stage of implementation, we focused on adoption and implementation. We identified adoption and implementation needs through structured and unstructured interviews of physical therapist and clinic managers. In Task 2, we created a logic model for determining how our implementation strategies would effect change. We started with identifying adoption and implementation outcomes. We then identified the performance objectives necessary to achieve our adoption and implementation outcomes and deliver the core components of Coach2Move (**Table 2**). Our final product of Task 2 was a matrix of performance objectives with determinants of change. This matrix identified what needed to be changed through the implementation strategy to influence performance objectives and subsequently achieve adoption and implementation outcomes. In addition, this matrix provided a structure for considering how we would evaluate change over the course of implementation. In Task 3, we matched the matrices of change with implementation strategies. With an understanding of the behavioral determinants to target, the context, and selected strategies, we produced the implementation protocol and materials (Task 4). Finally, we established a plan for evaluating implementation outcomes (Task 5) which included establishing methods for measuring implementation outcomes and process determinants. Implementation outcomes collection is ongoing and will not be reported here.

The planning team acknowledged that successful delivery of person-centered care is dependent on the health care system, external context, clinicians, and interactions between these components (29). In this project, we selected to focus primarily on determinants associated with individual clinicians, specifically the physical therapist. Analysis of implementation outcomes will include both clinician and patient level data. This project was

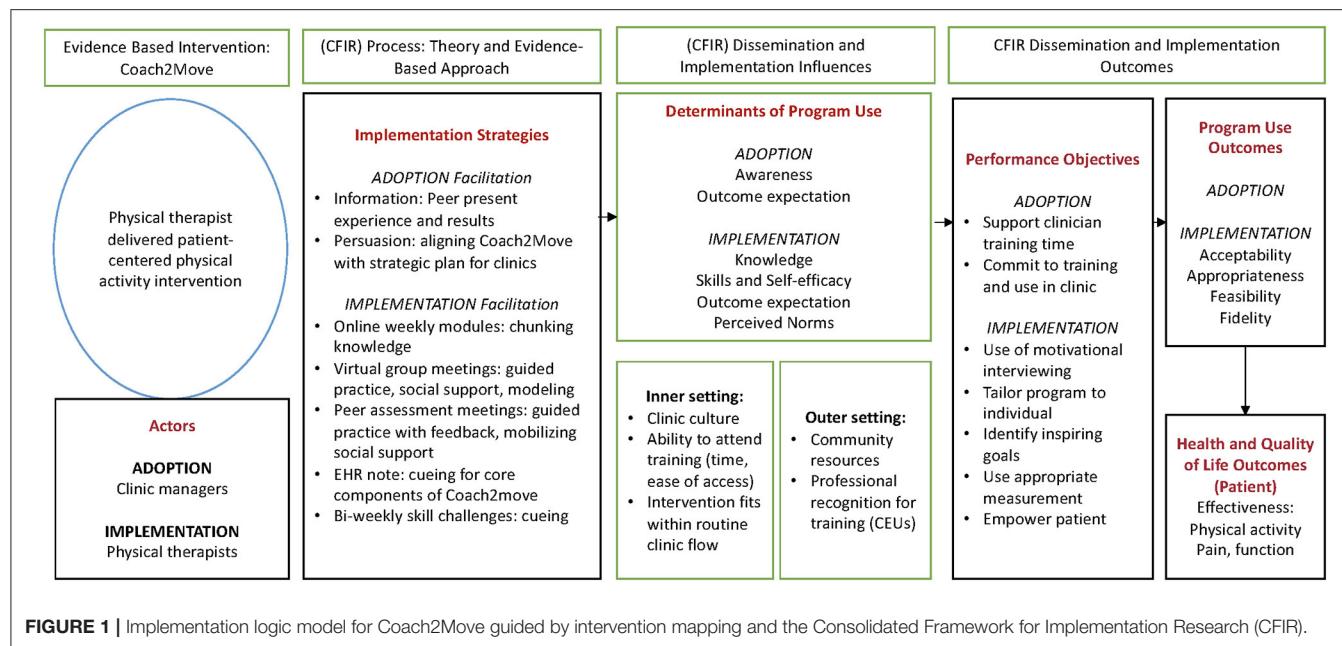


FIGURE 1 | Implementation logic model for Coach2Move guided by intervention mapping and the Consolidated Framework for Implementation Research (CFIR).

approved by the Institutional Review Board (ID 00109256) at the University of Utah and all participants were included only after providing informed consent.

RESULTS

Task 1: Conduct a Needs and Assets Assessment and Identify Program Adopters, Implementers, and Maintainers

In prior work, we identified strengths and limitations of routine physical therapy in supporting patients with chronic MSK conditions to sustain PA (30). Briefly, physical therapists strongly identified with their role in promoting PA and reported a desire to develop strategies for patients who were less engaged or ambivalent about behavior change. Physical therapists reported difficulty eliciting motivation and empowering patients with strategies for continued PA beyond the clinical episode.

The stakeholder group reviewed these assets and needs alongside the components and characteristics of the Coach2Move intervention. This step focused on identifying the actors for adoption, implementation, and maintenance (16). Discussions incorporated the need for adaptations based on clinical time constraints, training time and associated costs to the clinic, development of training materials, and incorporation of future cohorts. For example, stakeholders raised the question about using other clinical staff such as a physical therapy assistant or health coach to facilitate the behavioral change component and reduce the time demand on the physical therapist. Based on review of data from the original Coach2Move implementation, it was determined that the behavior change intervention was more effective when integrated into the clinical decisions about treatment.

Given the stage of the research, we also decided to focus on immediate adoption and implementation needs but identified considerations for future adoption, implementation, and maintenance. Results of Task 1 are summarized in **Table 2**.

Task 2: Identify Adoption and Implementation Outcomes, Performance Objectives, Determinants, and Create Matrices of Change

Working through Task 2, the implementation planning group discussed what actions would lead to successful implementation of Coach2Move. Adoption was focused on the clinic managers and physical therapists (**Table 3**) and considered the inner and outer context. Meetings with clinic managers outlined the training proposal and aims of Coach2Move highlighting benefits to physical therapists and patients. We reviewed the managers' needs and considered how they aligned with Coach2Move. Managers expressed a critical need to improve availability for new patient visits. We highlighted how Coach2Move was expected to reduce the overall number of physical therapy visits. By reducing the number of return visits, the schedule would have more availability for new patients. The managers also requested efforts to minimize the impact of scheduled training on clinic productivity. To accommodate these requests, we staggered training cohorts and scheduled peer assessment meetings at two different times of the day. Through these discussions and negotiations, we were able to garner management support to meet adoption performance objectives.

Physical therapists were invited to participate if they worked routinely with older adults who had chronic MSK conditions. To influence adoption, we obtained accreditation for the training program from our state physical therapy association. This allowed clinicians to schedule education time rather than

TABLE 2 | Implementation needs assessment, adopter, implementer, and maintainers.

| Role | Immediate | Future |
|--------------|---|--|
| Adopters | <p>Clinic managers <i>Rationale:</i> Advocate/Supports the importance of the program Support for training time Approval for change in documentation templates</p> <p>Physical therapists <i>Rationale:</i> Decision to actively participate in training</p> | <p>Health systems <i>Rationale:</i> Increase visibility of program, adapt environment, support maintenance and monitoring</p> <p>Referring Providers <i>Rationale:</i> Increase acceptability with patients</p> <p>Payers <i>Rationale:</i> Potential to change payment structure</p> |
| Implementers | <p>Physical Therapists <i>Rationale:</i> Core components of Coach2Move require physical therapist expertise alongside person-centered communication</p> | <p>Physical therapy assistants <i>Rationale:</i> Assistants assume a portion of patient care visits and can improve continuity of coaching toward goals</p> |
| Maintainers | <p>Coach2Move clinician leaders <i>Rationale:</i> Provides for professional development and leadership opportunities while supporting clinic processes</p> | <p>Coach2Move network of clinicians <i>Rationale:</i> Social network supports communication across settings and provides opportunity to examine adaptation needs</p> |

TABLE 3 | Implementation outcomes and performance objectives.

| Target/role | Adoption and implementation outcomes | Performance objectives |
|--------------------------------|--|---|
| Clinic manager adopter | Manager supports training of clinicians in Coach2Move | <ul style="list-style-type: none"> Agrees to participate in Coach2Move and promotes with clinicians Allows for 50% of training time to be schedule from normal clinic hours for continuing education credits Completes 80% of training activities Uses Coach2Move documentation template |
| Physical therapist adopter | Physical therapist acknowledges training commitment and agrees to participate | <ul style="list-style-type: none"> PT addresses each core component: Focused conversations on physical activity Uses motivational interviewing to elicit reasons to change PA Tailors program to individual functional needs and readiness to change Identifies inspiring and measurable goals Uses appropriate measurement to discuss progress across the episode of care Empowers patient to monitor their own progress and identify solutions PTs use peers to support in problem solving PTs identify missing information/skills and redundancies that could be addressed to improve acceptability |
| Physical therapist implementer | Physical therapist incorporates Coach2Move core components with eligible patient interactions with >70% fidelity | |
| Physical therapist implementer | Physical therapists reflect and improve on their implementation of Coach2Move core components | |

personal time to participate, which was preferred by both physical therapists and clinic managers. Performance objectives for physical therapist adoption included a commitment to participate in training and to use the training in clinical care.

Implementation performance objectives were structured around the core components of Coach2Move (Tables 1, 3). Using a list of quality indicators associated with positive Coach2Move outcomes (28), we outlined sub-behaviors a physical therapist would need to exhibit to implement Coach2Move with fidelity.

Next, we specified determinants for adoption and implementation. Researchers at University of Utah Health performed a literature review identifying factors associated with clinician delivery of behavioral interventions (13, 24–27). We met with Coach2Move developers to identify prior implementation

experiences and contrasted this with the literature review. With Social Cognitive Theory as an underlying structure, we presented proposed determinants to physical therapist stakeholders and social work partners for feedback (19, 31). The planning group prioritized determinants based on their strength of association with the performance outcome and their changeability. Primary determinants identified for delivering Coach2Move core components were knowledge, skills and self-efficacy, outcomes expectations, and perceived norms. These determinants were considered fundamental and have been shown to be associated with healthcare provider behavior (19). From these determinants we created matrices of change objectives. Table 4 demonstrates a sample of the matrix used for implementation performance objectives. These objectives were formulated by assessing what

TABLE 4 | Matrices of change objectives for implementation of Coach2Move by physical therapists.

| Performance objectives | Determinants | | | |
|---|---|---|---|--|
| | Knowledge | Skills and self-efficacy | Outcome expectations | Perceived norms |
| Evaluate personal strengths and challenges in delivering Coach2Move | Describe components of effective delivery strategies alongside self-evaluation | Expresses confidence reflecting on and assessing own practice | Expects reflective practice will improve proficiency | Recognizes responsibility for own professional development |
| Use motivational interviewing to elicit reasons to change PA | Describe key components of motivational interviewing | Demonstrate proficiency in motivational interviewing skills Take action, e.g., use Coach2Move template to guide conversations about PA | Expect that motivational discussions around physical activity will increase patient activation and engagement | Recognizes that motivational interviewing is within the scope of physical therapy practice and aligns with the vision of the profession. |
| Tailor program to individual functional needs and readiness to change | Describe potential analyses for common functional impairments Explain how to modify treatment to align with patient presentation | Design task analysis appropriate for patient goals Confident in adapting treatment plan to patient presentation | Evaluate how task analysis can improve patient engagement, efficiency, and treatment planning | |
| Identify inspiring and measurable goals | Describe how to identify and quantify an inspirational goal | Demonstrate how to progress from a functional impairment to understanding a patient's motivation to change | Describe how an inspirational goal improves patient adherence | |
| Use appropriate measurement across the episode of care | Select appropriate measurement tools for patient presentation | Explain how measurement relates to patient goals | Expect that regular measurement can improve decision-making | Recognize professional obligation to support clinical decisions through measurement |
| Empower patient to monitor their own progress and identify solutions | Identify different methods for negotiating a treatment plan with patient | Demonstrate ability to collaborate with patient on treatment planning Demonstrate MI techniques to elicit patient ideas and commitment to monitoring | Recognize that empowering patients will lead to improved adherence at the patient level and job satisfaction for the physical therapist | Recognize physical therapists need to improve person-centered communication to increase engagement and self-management |

factors needed to be present to achieve the performance objective and why a physical therapist might change their behavior to meet the performance objective. Creating this matrix provided a foundation for selecting implementation strategies. Consider the performance objective *“Uses appropriate measurement across the episode of care”* as an example of how to use this matrix. Essential to using measurement tools is having knowledge of the tool and how to interpret the results. Skills and self-efficacy are needed to enable discussions of these results with patients. Implementation strategies to address these determinants may include instruction or lecture, simulation, and feedback. Motivation to routinely use systematic measurement is also dependent on what a physical therapist can gain (outcome expectations) and what they believe is expected of them (perceived norms). Implementation strategies were then selected based on their ability to affect the determinant, such as using testimonials to influence outcome expectations or peer-assessment to change perceived norms.

Task 3: Choose Theoretical Models; Select or Create Implementation Strategies

For this task, we again reviewed the literature to identify effective implementation strategies for changing clinician behaviors. Continuing education courses are a common method for physical therapists to acquire new knowledge. These courses, whether in person or through e-Learning have a modest effect on

changing clinician behaviors that wanes over time (32, 33). Training components that improve implementation include multiple exposures, interactivity, longer training periods, and focusing on outcomes important to clinicians (33, 34). Specific to physical therapy, reflection, simulations, self- and peer-assessment improve self-efficacy and commitment to behavior change (35–37). Deliberate practice and structured feedback facilitates changes in person-centered communication (38). In summary, components identified with successful change in clinician practice include shaping knowledge, feedback and monitoring, social support, and social comparison (39). Using this summary, our prioritized list of determinants, select theories, and prior Coach2Move experience, we identified practical applications for addressing each determinant.

For an example, consider the performance objective presented in **Table 4**, *“Empower a patient to monitor their own progress and identify solutions.”* An associated change objective was *“Demonstrate the ability to collaborate with patients on treatment planning.”* To meet this change objective, physical therapists need skills and self-efficacy in communication strategies that support collaborative treatment planning (40). Active learning strategies that include practice, review, and repetition are effective methods for improving skills and self-efficacy (41–43). Having outlined this, we knew we needed to operationalize modeling, guided practice, and feedback in Task 4.

TABLE 5 | Coach2Move (C2M) implementation intervention plan.

| Stage | Determinants/change objectives | Theoretical change methods | Practical applications |
|---|---|---|---|
| Adoption Agent: Clinic Manager | Awareness Perception of C2M Outcome Expectations | Information Persuasion Role modeling | C2M presentations from Dutch colleagues Decisional balance handout on adoption of C2M |
| Adoption: Agent: Physical therapist | Awareness Perception of C2M Outcome Expectations | Persuasion Communication Mobilization | Email invitation to participate (template) Accredit training through professional organization to provide continuing education units C2M presentations from Dutch colleagues |
| Implementation Agent: Physical therapist | Knowledge Skills and self-efficacy Outcome expectation Normative beliefs Social influence | Chunking Modeling Guided practice with feedback Role-modeling Persuasion Cue altering Mobilizing social support | Core components in 6 modules completed weekly Virtual meetings for problem solving and guided practice Peer reports of positive outcomes Peer-assessment: skills practice and problem solving C2M specific charting template |
| Maintenance Agent: Clinician leader Clinic managers | Outcome expectations Skills and self-efficacy Feedback and Reinforcement | Information Persuasion Technical assistance | Face to face meetings to discuss maintaining Continued access to online training materials Public recognition of clinician leaders Promote use of clinic leaders for problem solving Continued managerial support Add-in modules recommended by participants |

Practical applications were cross-referenced with strategies as outlined by Expert Recommendations for Implementing Change (44). The end results was our multifaceted implementation plan (**Table 5**). Our strategy for adoption by the clinic manager was to develop a partnership and adapt the training approach to minimize disruption of patient care. Strategies aimed at adoption by physical therapists included incentives (continuing education time) and allowance structure (protected training time) and the identification of early adopters. Implementation strategies informed by Task 3 included: (a) educational meetings and dynamic training, (b) organizing three clinical implementation team meetings in which clinicians reviewed challenges of implementation with discussions of potential solutions and provided self- and peer- assessment of skills, (c) modifying the electronic health record system to include a Coach2Move template prompting the use of skills acquired in training and reflection on practice, and (d) reminding clinicians using bi-weekly emails reviewing information from training and provide clinical examples or prompts. Of note, physical therapists found the peer assessment meetings to be particularly helpful and motivating. They recommended scheduling more of these meetings over time for peer support and problem solving, prompting us to consider creating a learning collaborative as an opportunity to sustain the Coach2Move intervention.

We did not constrain participation to sites where the entire clinical site chose to participate. Instead, we described the study to physical therapists across six clinics in a metropolitan region and invited them to participate leveraging early adopters (19, 45, 46). Of 82 physical therapists, 32 (39%) participated and were considered to represent innovators and early adopters. We considered this an advantage for our stage in development as these individuals could further shape the intervention through

critical review of implementation components and stand out as opinion leaders (47).

Task 4: Produce Implementation Protocols

In Task 4 the planning group moved to designing the program components and materials. Prior Coach2Move implementation included a 2-day in-person training to address knowledge, skills, and self-efficacy. This is common practice for professional continuing education and has demonstrated prior effectiveness (15, 28). We were unable to adopt this method for two reasons: (1) COVID-19 restrictions, and (2) the clinic manager's request to limit the impact on clinical scheduling which did not allow for clinicians to schedule training time all on the same day. We altered training to provide asynchronous and synchronous learning. Online training modules were developed and delivered through a web-based learning management system, (Canvas, Instructure Inc, SLC, UT). We created 6 weekly modules of approximately 1-h covering the 6 core components of Coach2Move. Each module included interactive elements such as challenges for clinical application and discussion boards. Modules included knowledge dissemination, modeling the behavior using clinical examples, and an example of a Coach2Move trained physical therapist with a standardized patient. The online training was supplemented with two 2.5-h virtual meetings. This allowed time to discuss challenges, questions, and hear about peer successes. These meetings also used modeling, guided practice, and feedback for further skill development.

Peer-assessment meetings were held once monthly over 3-months for skills practice, feedback, and social influence. In preparation, we developed 2 common clinical scenarios, trained a standardized patient, and created feedback forms aligned with quality indicators for Coach2Move. Each physical therapist

recorded an interview intake with the standardized patient. In addition, physical therapists recorded a clinic encounter with a patient appropriate for Coach2Move. Using the recorded videos and feedback forms, physical therapists partnered with a peer for guided self-assessment and a peer-assessment. This provided opportunities to provide affirmations and discuss alternate strategies. Physical therapists were provided a Coach2Move chart template (integrated into the electronic health record) and bi-weekly email reminders to support clinical integration through cueing. **Figure 2** provides an overview of temporality and dose of our implementation strategies.

Task 5: Evaluate Implementation Outcomes

Our final task was planning evaluation of implementation. We planned outcome assessments at both the physical therapist level and patient level and across several different time points (**Figure 3**). We considered outcomes appropriate to the early phase of implementation (48, 49). Primary outcomes of interest included acceptability, appropriateness, feasibility, fidelity, and effectiveness. We surveyed physical therapists on the acceptability, appropriateness, and feasibility of Coach2Move using the Acceptability of Intervention, Intervention Appropriateness, and Feasibility of Intervention measures (12). Each measure has four items relevant to the concept of interest and 5-response options ranging from “completely disagree” to “completely agree.” For example, the Feasibility of Intervention asks the physical therapist to score their agreement with the statement, “Coach2Move seems doable.” A qualitative assessment of clinician and patient experience with Coach2Move after 6-months of implementation will further examine acceptability, appropriateness, and feasibility.

We also developed measures to understand the impact of our implementation on the determinants identified in our mapping process. For knowledge and self-efficacy, we created surveys to capture physical therapist beliefs and confidence in delivering Coach2Move. To measure skills, we created an observational coding tool to score physical therapists conducting an interview with a simulated patient across two different scenarios. The coding tool was developed using quality indicators from the original Coach2Move implementation and input from our social work and physical therapist stakeholders.

Coach2Move fidelity indicators previously developed for Coach2Move implementation in the Netherlands was added to the physical therapy documentation template (28). The template provides cueing for the core elements of Coach2Move. Effectiveness will be measured at the patient-level through self-reported PA and objective measures of PA using a commercially available activity monitor. Planned analyses include the increase in PA at 6-months with the Coach2Move intervention and the association between fidelity and effectiveness. Proximal outcomes of the training have been collected and are being analyzed while additional implementation outcomes are ongoing with an expectation for completion in January 2023.

DISCUSSION

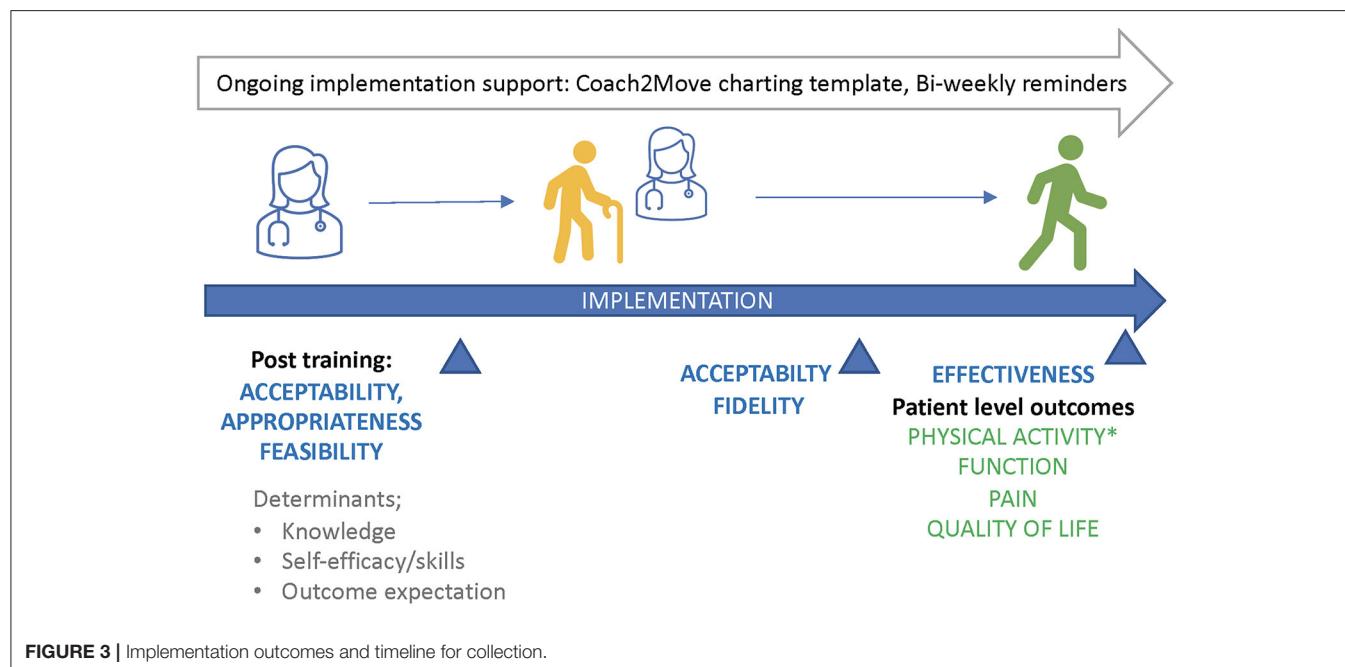
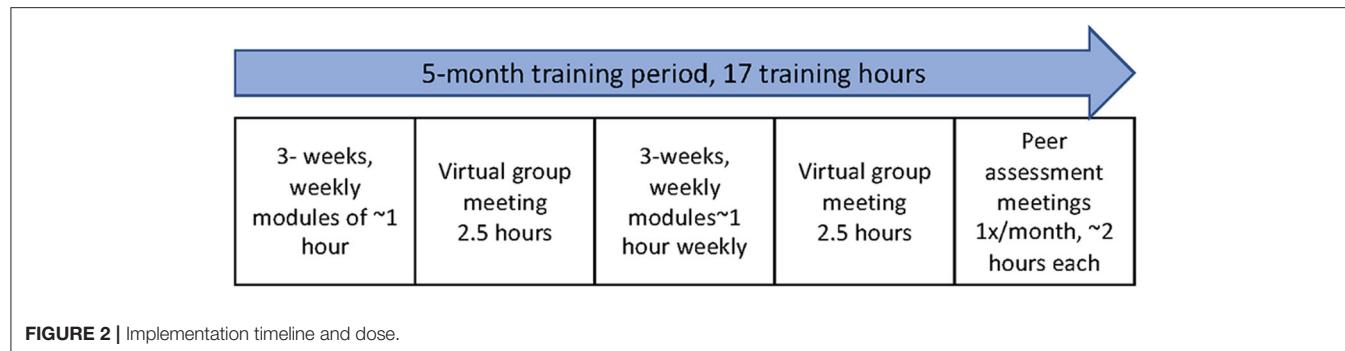
Person-centered care is a critical component in improving health behaviors and clinical outcomes in patients with chronic

MSK conditions (15, 50, 51). Successful delivery requires understanding the patient as a whole and adapting to the patient’s disease experience (35). Physical therapists acknowledge the need for a person-centered approach to care but continue to have difficulty implementing many components of person-centered care (22). The patient-physical therapist interaction is often characterized as practitioner dominant with physical therapists finding it challenging to balance their own agendas with that of the patient (52, 53). Coach2Move is an evidence-based intervention for physical therapists in which person-centered care is foundational and improves clinical outcomes for patients. In this study, implementation mapping allowed our team to identify determinants of change and develop a comprehensive implementation plan that would facilitate uptake of Coach2Move.

Implementation focused on the questions, “*Why would clinic managers adopt Coach2Move?*,” “*What do physical therapists need to implement Coach2Move?*” and “*Why is person-centered care difficult?*” Changing communication practice to elicit motivation and empower patients with self-advocacy requires new skills and patterns of practice for most physical therapists (25, 28). Person-centered care with a focus on behavior change has been described as “learning a new language” and requires restructuring of the consultation framework (25). Working through the implementation mapping process within the CFIR framework, we identified individual level determinants for change and the interplay between the context and actors. Knowledge, skills and self-efficacy, outcomes expectation, and perceived norms were identified as determinants to influence. These were the targets of the implementation strategies which included educational meetings, implementation team meetings, practice, and feedback. Context interventions including creating social support and using prompts within the electronic health record.

Explicitly identifying matrices of change allowed us to integrate and discuss behavior change models and identify intended proximal outcomes of our implementation strategy (54). Proximal outcomes allow us to better understand how our implementation strategies may be affecting change. For example, we hypothesized training would immediately improve motivational interviewing skills and that delivery of Coach2Move was dependent on proficiency in motivational interviewing. By assessing these skills pre- and post-training, we will understand the immediate impact of training. Through fidelity measures over the course of study enrollment, we will understand the relationship between motivational interviewing skill and Coach2Move delivery. If physical therapists demonstrate proficiency in motivational interviewing but fail to apply this skill in the clinic, we have evidence of the need to examine other determinants influencing implementation. The change matrices also highlighted the need to affect multiple determinants with our implementation strategies. Multifaceted strategies to change physical therapist behaviors have shown greater effect but their use remains limited with a strong dependency on educational meetings and reminders (55).

The planning group found implementation mapping to be particularly helpful in three ways (1) organizing discussions and input across stakeholders, (2) identifying how an implementation



strategy would affect change, and (3) creating a broad overview of the body of research. Using the logic model presented in Figure 1, all stakeholders had an overview of the intent and essential task of the mapping process. Each task helped to complete the logic model and was suitable for stakeholders of different expertise. It was difficult to schedule planning meetings with all stakeholders at the same time. Having the logic model and each implementation mapping task as a working document allowed us to get feedback from each stakeholder group without requiring a full planning group meeting.

The logic model and specificity of each task allowed the planning group to create a broad overview of research gaps and identify the specific purpose of this study. This prompted discussion about our stage of implementation research (early) (48) and influenced our focus. It also allowed for discussions about how moderators we leveraged in the current study might need to be addressed differently in the future. As noted, physical therapists self-selected to participate. This represents a sample of individuals motivated to adopt and implement

the training (46). Training across a broader population may require alternate strategies to address both moderators and mediators. Using the CFIR framework also prompted additional questions about the influence of the outer structure, inner structure, and individual actors. The framework allowed us to record these considerations to be addressed in future implementation efforts.

CONCLUSION

Through the process of Implementation Mapping, our multidisciplinary stakeholder group produced a comprehensive training program to implement Coach2Move, a physical therapist delivered PA intervention for patients with chronic MSK conditions. Many healthcare providers recommend PA, but there is often little structured support for behavior change. Training physical therapists to effectively support patients in PA behaviors fills a much-needed gap and has the potential to significantly reduce the burden of chronic MSK conditions for both individuals and health systems. This study highlights a

systematic approach for selecting implementation strategies to implement Coach2Move by considering how these strategies are expected to affect change. This study also highlights how Implementation Mapping can be used as a working document to integrate input from multiple stakeholders. Results of Coach2Move implementation will be reported at a future date.

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

The studies involving human participants were reviewed and approved by University of Utah Institutional Review Board. The patients/participants provided their written informed consent to participate in this study.

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AUTHOR CONTRIBUTIONS

AT, RH, JF, TH, MN-vD, MC, and MF contributed to conception and design of the study. AT, JW, MN-vD, and TH organized and gathered stakeholder feedback. AT wrote the first draft of the manuscript. All authors contributed to manuscript revisions, read, and approved the submitted version.

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Implementation mapping to plan for a hybrid trial testing the effectiveness and implementation of a behavioral intervention for HIV medication adherence and care retention

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Background: Implementation mapping is a systematic, collaborative, and contextually-attentive method for developing implementation strategies. As an exemplar, we applied this method to strategy development for Managed Problem Solving Plus (MAPS+), an adapted evidence-based intervention for HIV medication adherence and care retention that will be delivered by community health workers and tested in an upcoming trial.

Methods: In Step 1: Conduct Needs Assessment, we interviewed 31 stakeholders to identify determinants of MAPS+ implementation in 13 clinics serving people with HIV in Philadelphia County. In Step 2: Develop Logic Model, we used these determinants as inputs for a working logic model guided by the Consolidated Framework for Implementation Research. In Step 3: Operationalize Implementation Strategies, our team held a virtual stakeholder meeting to confirm determinants. We synthesized stakeholder feedback, then identified implementation strategies that conceptually matched to determinants using the Expert Recommendations for Implementing Change taxonomy. Next, we operationalized implementation strategies with specific examples for clinic settings. We linked strategies to behavior change

theories to allow for a mechanistic understanding. We then held a second virtual stakeholder meeting to present the implementation menu for feedback and glean generalizable insights for how these strategies could be operationalized in each stakeholder's clinic. In Step 4: Protocolize Strategies, we incorporated stakeholder feedback and finalized the implementation strategy menu.

Findings: Implementation mapping produced a menu of 39 strategies including *revise professional roles*, *identify and prepare champions*, *use warm handoffs*, and *change record systems*. The process of implementation mapping generated key challenges for implementation strategy development: lack of implementation strategies targeting the outer setting (i.e., sociopolitical context); tension between a one-size-fits-all and individualized approach for all clinics; conceptual confusion between facilitators and strategies; and challenges in translating the implementation science lexicon for partners.

Implications: This case exemplar advances both MAPS+ implementation and implementation science methods by furthering our understanding of the use of implementation mapping to develop strategies that enhance uptake of evidence-based interventions. The implementation menu will inform MAPS+ deployment across Philadelphia in an upcoming hybrid trial. We will carry out Step 5: Test Strategies to test the effectiveness and implementation of MAPS+.

KEYWORDS

implementation science, HIV - human immunodeficiency virus, implementation mapping, health equity (MeSH), stakeholder engagement

Introduction

The primary aim of this paper is to highlight our use of implementation mapping as a systematic, collaborative, and contextually attentive method for developing implementation strategies (1). Implementation mapping identifies context-specific determinants and generates stakeholder-informed implementation strategies, with an eye toward mechanisms (1–3). In this case exemplar detailing our application of implementation mapping in planning for a hybrid type 2 effectiveness-implementation trial, the evidence-based practice (EBP) of interest is MAPS+ and the setting of interest is 13 Ryan White-funded HIV clinics serving people with HIV (PWH) across Philadelphia, Pennsylvania.

Care gap

Despite steady declines in recent cases, Philadelphia is one of 48 counties in the United States with the highest number of new HIV diagnoses (4). In 2019, new diagnoses were mostly concentrated among people identifying as non-Hispanic Black (64%), people assigned male at birth (76%), and young adults aged 30–39 years old (26%) (5). In 2019, individuals not retained in care accounted for 36% of HIV transmissions, and individuals

not virally suppressed but retained in care accounted for 25% of HIV transmissions (6). Notably, Philadelphia is the poorest of the largest U.S. cities, with 23% of residents living in poverty (7). The Ryan White HIV/AIDS Program provides federal grants at the local level to provide care and services for low-income PWH who do not have sufficient health coverage or financial resources (8).

Evidence-based practice of interest

Managed Problem Solving (MAPS) is an EBP with long-term impact on viral suppression in PWH (9). MAPS consists of four individual-level sessions during the first 3 months of treatment, reinforced by ongoing telephone calls during the 1-year intervention period. The interventionist and participant work together to solve specific adherence barriers using the Problem Solving framework, with an emphasis on small and achievable goals (9, 10). Solutions are tailored toward the specific needs of the participant, empowering them to manage their health. A randomized clinical trial examining MAPS as delivered by college graduate-level interventionists vs. usual care in Philadelphia found that the intervention significantly increased adherence and viral suppression in both treatment-naïve and treatment-experienced patients up to 1

year following MAPS initiation (9). MAPS has been endorsed by the Centers for Disease Control and Prevention as an EBP that improves viral suppression (11); however, as is the case for many EBPs, adoption has been low. Through conversations with the Philadelphia Department of Public Health and HIV clinic directors, our research team learned that MAPS requires adaptation, specifically a need to ensure it can be delivered by non-medical specialists and has an added focus on care retention.

MAPS has been systematically adapted in two key ways to prime the intervention for implementation with the same target population and using the same clinical context as the original trial. First, the delivery system was changed to utilize community health workers (CHWs) instead of personnel with college degrees. Limited staffing in resource-stretched settings has contributed to low adoption. CHWs' inclusion addresses the fact that many health professionals, including medical case managers, do not have the time to offer the intervention within their current responsibilities. Moreover, CHWs function as "trusted liaisons" between health care systems and communities because they often share similar backgrounds as the patients they serve (12). Second, a focus on retention in care was added. In Philadelphia, the greatest barrier to ending the HIV epidemic is poor retention in care among people who are not virally suppressed. The MAPS adaptation process included editing the original MAPS manual to ensure plain language explanations of medical information, providing updated material on adherence supports, and adding material specific to care retention (e.g., explaining the value of regular HIV visits) and problem-solving strategies to address barriers to attendance. The intervention has been renamed MAPS+ to reflect these adaptations. MAPS+ is a valuable tool in service of achieving Ending the HIV Epidemic goals by 2030 (4).

Hybrid type 2 effectiveness-implementation trial planning

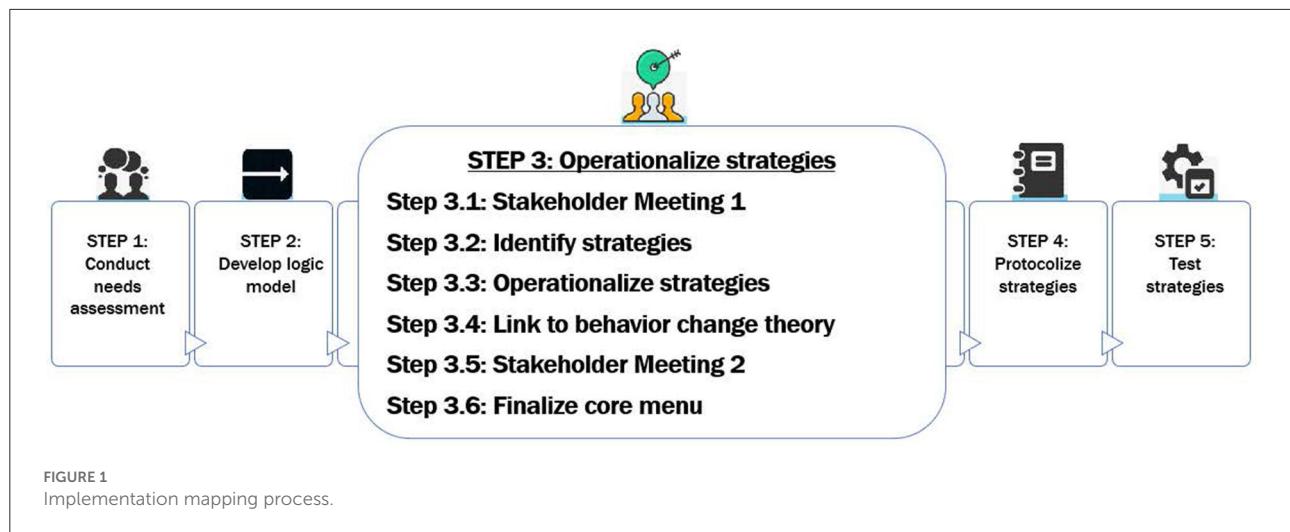
MAPS+ will be tested in an upcoming hybrid type 2 effectiveness-implementation trial in 13 Ryan-White funded clinics in Philadelphia County. Hybrid trials test both clinical effectiveness of interventions and implementation strategies (13), which are the approaches used to increase the adoption, implementation, and sustainment of EBPs (14). In other words, these methods and techniques are the "how" of implementation (14). Strategies are selected to target specific implementation determinants (i.e., barriers and facilitators). For the hybrid trial, we collaboratively identified three primary, multifaceted implementation strategies informed by our conversations with local stakeholders: (1) task-shifting (i.e., redistribution of tasks among health workforce teams from highly qualified health

workers to CHWs with less formal training); (2) initial training and ongoing support for CHWs; and (3) integration of the CHW within the clinical team. Examples of integration include developing structures to support information-sharing among the CHW and clinical team members, defining the CHW role and standard work procedures, and having the CHW accompany patients who they serve to their medical appointments. As part of this trial planning, our team also engaged in implementation mapping to elucidate additional implementation strategies that might be needed in collaboration with key partners.

Implementation mapping to develop implementation strategies

Implementation mapping harnesses insights from both implementation science and intervention mapping (1). It is an approach to implementation strategy development and selection that directly addresses calls to design strategies more systematically, bridging conceptual gaps between determinant identification and strategy selection. As originally described by Fernandez et al. (1), implementation mapping identifies specific, iterative tasks for planners to ensure that attention is paid to all implementers (i.e., individuals putting an intervention into practice), determinants, outcomes, and goals. The approach promotes implementation strategy selection that is shaped by theory and evidence, while also centering the voice of stakeholders and focusing on the mechanisms through which strategies achieve targeted outcomes (1). Selecting strategies to support a change effort is complex, as contextual differences across patient-, provider-, organization-, and system-levels generate variation in implementation (15). As such, the effectiveness of implementation strategies is not context-agnostic (2). Properly selecting strategies to match the multilevel determinants that may enable or hinder implementation is critical, and yet, the methodology of how to do so is underdeveloped. Furthermore, when strategies are developed through atheoretical, haphazard, or non-participatory approaches, it is more difficult to understand mechanisms, that is, the processes by which strategies generate effects on the specified implementation outcomes. Ultimately, care delivery should be informed by theory and stakeholder input (1–3).

Although the principal investigators (RSB, FM, RG) pre-selected three primary implementation strategies for the hybrid trial based on our preliminary understanding of key determinants, we elected to also use implementation mapping to obtain a more nuanced understanding of multilevel context, with an eye to the structural and systemic factors (e.g., power and resource allocation) that likely influence equitable implementation of MAPS+ in Philadelphia. In addition, the



strategies identified for the hybrid trial were conceptually broad, and we aimed to enrich our understanding and increase the precision of our strategies in collaboration with clinic stakeholders. Lastly, research suggests that organizations often need to deploy multiple implementation strategies in order to successfully implement an EBP (16–18). In the real-world context of our trial, we sought to further develop auxiliary strategies and track their use prospectively.

Modeled after Fernandez et al.'s (1) approach, our implementation mapping process involved five key steps: (1) Conduct Needs Assessment, (2) Develop Logic Model based on inputs from assessing context, (3) Operationalize Implementation Strategies, (4) Protocolize Strategies, and (5) Test Strategies. Implementation mapping contributed to the development of a detailed implementation blueprint to enhance the three pre-selected implementation strategies and maximize MAPS+ reach, fidelity, and clinical effectiveness. This blueprint will support widespread MAPS+ deployment and scale-up. The work presented here represents Steps 1–4; Step 5 is the hybrid trial. We describe our methods and resulting output as an exemplar of how to design implementation strategies systematically and collaboratively with stakeholders.

Methods and findings

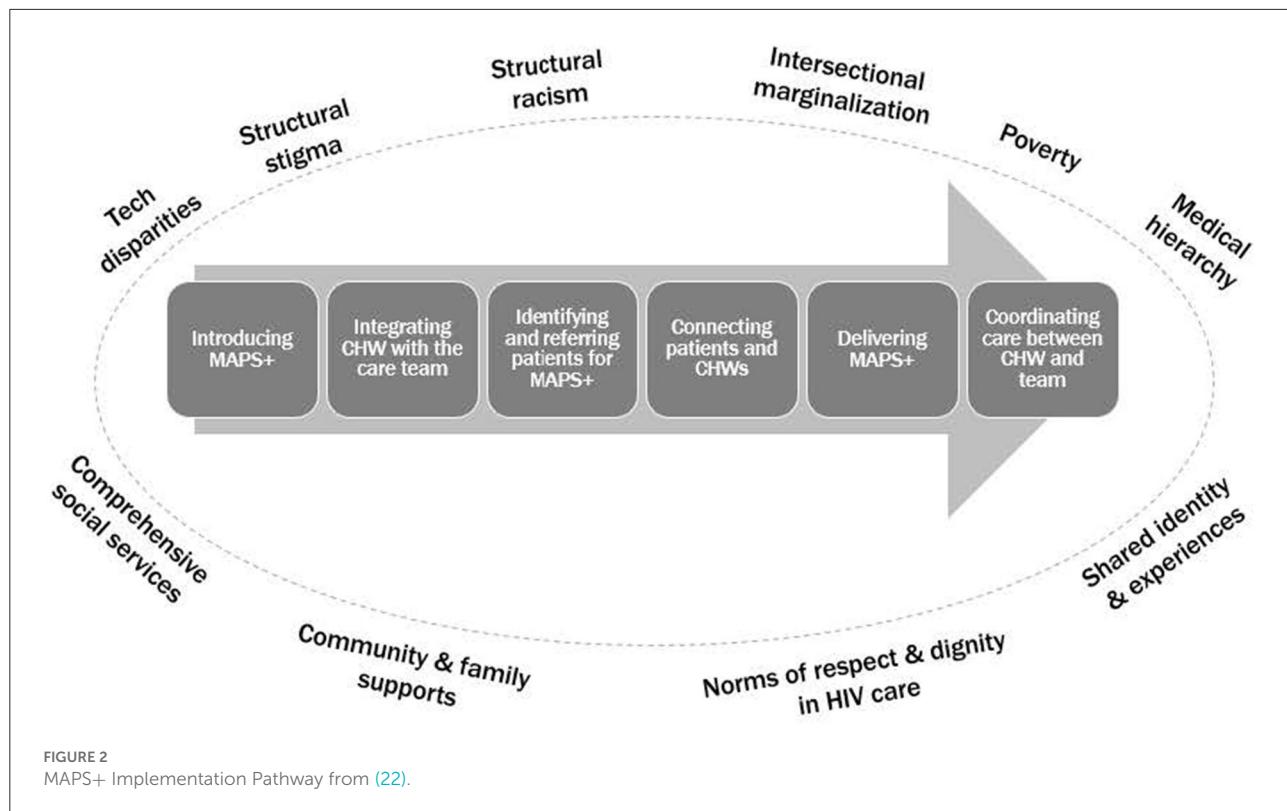
First, we conducted a needs assessment with stakeholders across 13 clinics serving PWH to understand contextual factors and expected determinants of MAPS+ implementation. Second, we developed a logic model organized by the Consolidated Framework for Implementation Research (CFIR) to conceptually ground our process (19, 20). Third, we operationalized implementation strategies. To do so, we held two stakeholder meetings, mapped strategies to determinants using the empirical dataset and Expert Recommendations

for Implementing Change (ERIC) taxonomy (21), generated specific operationalizations, and linked to theory. Fourth, we protocolized the resulting strategies in an implementation menu. We provide a detailed description of our process below and a summary is provided in Figure 1.

Step 1: Conduct needs assessment

In order to assess the context for our setting of interest, we completed semi-structured stakeholder interviews ($N = 31$) guided by the CFIR (19) across 13 Ryan White-funded clinics serving PWH in Philadelphia County (22). Our goal was to identify perceived determinants of MAPS+ delivery by CHWs to serve as inputs into the implementation mapping process. Stakeholders included prescribing clinicians ($n = 6$), non-prescribing clinical team members ($n = 4$), clinic administrators ($n = 7$), and policymakers ($n = 4$) from the Philadelphia Department of Public Health. Two research team members (ALS, KH) analyzed these interviews using rapid analytic techniques (23). We used structured interview summaries to populate matrices that aided data organization and pattern identification across stakeholder groups. We then organized determinants by main categories along a MAPS+ Implementation Pathway, which reflected the sequential process of implementing MAPS+ within each clinic (Figure 2). The categories in the pathway included: (1) Introducing MAPS+ to Clinics, (2) Integrating CHW with the Team, (3) Identifying and Referring Patients for MAPS+, (4) Connecting Patients and CHWs, (5) Delivering MAPS+, and (6) Coordinating Care Between CHW and the Team. This process has been described in detail previously (22).

In the Introducing MAPS+ to Clinics category, key determinants included *leadership and staff buy-in*, plus *team expectations for CHW-delivered MAPS+*, meaning expectations



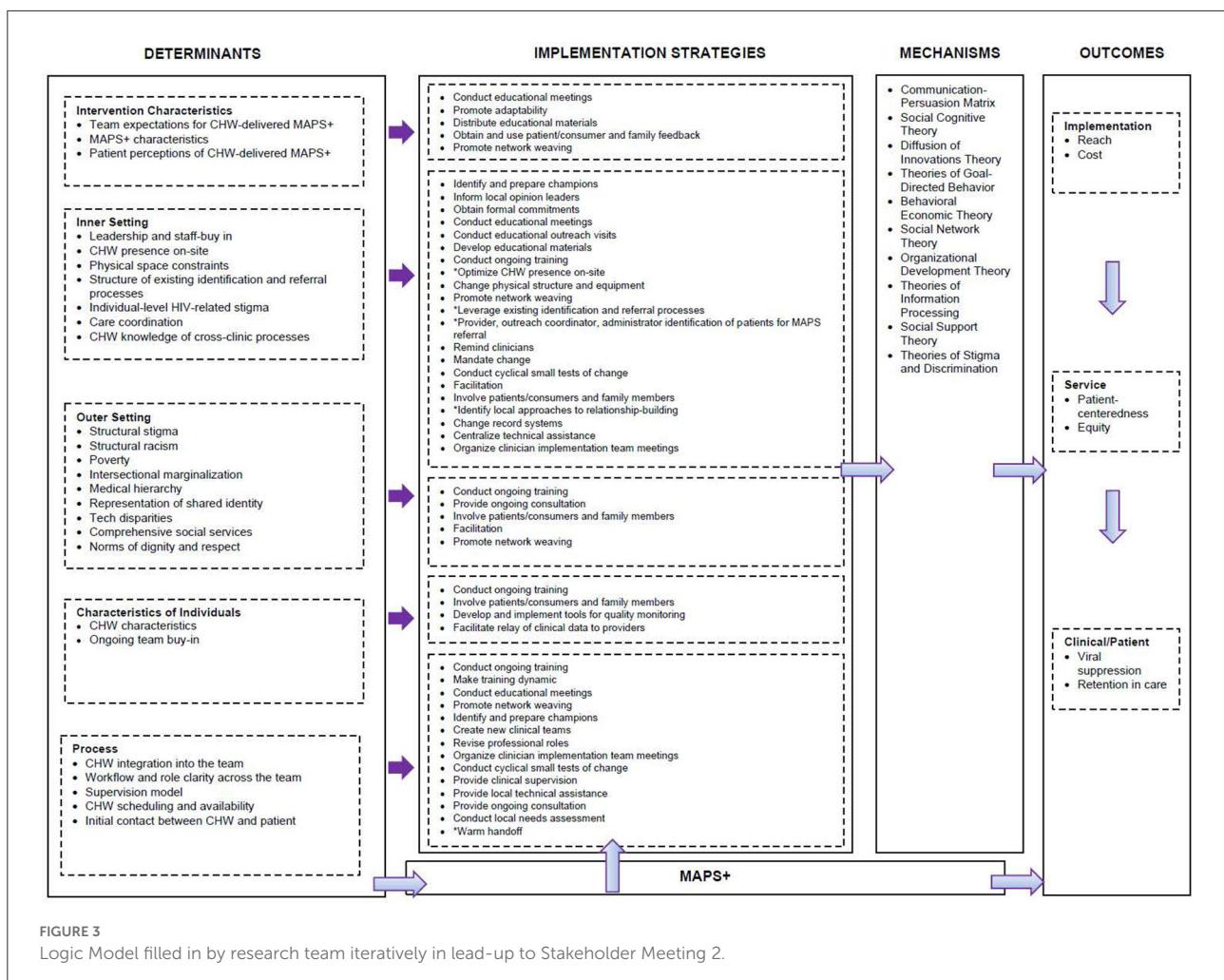
about both the CHW role and the purpose of the MAPS+ intervention. The determinants *CHW as core team member*, *CHW presence on-site*, *physical space constraints*, and *workflow and role clarity across the team* were important for Integrating CHW with the Team. Specific to the Identifying and Referring Patients for MAPS+ category, we learned that the *structure of existing identification and referral processes* (e.g., data-generated lists) was a key determinant to ensuring that eligible patients were reached. In the category Connecting Patients and CHWs, *CHW availability and scheduling* (and thus accessibility for patients and clinic team members) was key, as were *the initial contact between the CHW and patient*, and *CHW characteristics* (e.g., demographics, experiences, attitudes, skills). *MAPS+ characteristics and flexibility* were key determinants in Delivering MAPS+. *Care coordination* and *CHW knowledge of cross-clinic processes* (given that CHWs may work in multiple clinic settings) comprised the Coordinating Care Between the CHW and the Team category (22).

Lastly, we noted factors within the Outer Setting (which includes “the economic, political, and social context within which an organization resides,” (19) that perpetuate inequities, such as structural and systemic racism, intersectional marginalization, structural stigma, and poverty. Structural assets included norms of respect and dignity in HIV care, shared identity and experiences, community and family support, and comprehensive social services (22). Within our

analysis, explicitly situating determinants within the broader sociopolitical context of MAPS+ implementation heightened our attention to the complex, historical, and ongoing factors that shape HIV care delivery. Throughout implementation mapping, we anchored on these findings to ensure that implementation strategies were selected through an equity lens, consistent with growing calls to address health equity within implementation science (24–26). The needs assessment findings alerted us to key determinants beyond those associated with the three primary strategies selected for the trial (i.e., *workflow and role clarity*).

Step 2: Develop logic model

We used these determinants as key inputs into a working logic model (Figure 3). The model was organized by ecological levels aligned with the CFIR, specifically intervention characteristics, inner setting, outer setting, characteristics of individuals, and process domains. We modified the Smith et al. (20) Implementation Research Logic Model to increase clarity in the link between each specific CFIR level and relevant strategies and allow for better visualization of which strategies were relevant for each domain and which were applicable across multiple domains (e.g., both inner setting and process). This adapted model served as a conceptually-grounded



organizational tool throughout our implementation mapping process (20).

Step 3: Operationalize implementation strategies

Step 3.1: First stakeholder meeting

We held a 90-min virtual stakeholder meeting in May 2021 to present preliminary findings specific to identified determinants, confirm our interpretations, and center the voices of stakeholders. Our research team originally planned for an in-person meeting but pivoted to an online format given COVID-19 mitigation measures. We aimed for representation across a variety of stakeholder groups and clinic settings. To identify participants for the meeting, we collaborated with clinic leadership and contacted potential attendees by email. Eleven stakeholders from 10 different clinics attended, representing prescribing clinician ($n = 3$), medical case manager ($n =$

$n = 3$), administrator ($n = 4$), and behavioral health consultant ($n = 1$) stakeholder groups. The initial portion of the meeting involved providing an overview of the project, key goals of implementation mapping, and the details of the MAPS+ intervention approach. We then described determinants as categorized by the MAPS+ Implementation Pathway. While we provided a visual of the logic model for “big picture” overview of implementation mapping (Appendix A), we elected to use the pathway as a grounding reference to increase the accessibility of the content for the clinically oriented stakeholders.

Attendees were divided into three breakout groups along with two research team facilitators to support each discussion. Each core project team member (ALS, CH, KH) was paired with a principal investigator (RSB, FM, RG) for the hybrid trial to ensure additional technical expertise related to MAPS+, implementation science, and the upcoming trial. Facilitators all had extensive immersion in the project and were attuned to timing and flow. To support the discussion, facilitators used a guide with suggested discussion points to clarify and

confirm our research team's interpretations of determinants. For example, for the determinant *workflow and role clarity across the team* within the Integrating CHW with the Team category, the discussion prompt read as follows: "We heard that it's important for the CHW to have a clearly defined role and to understand specific roles across the multidisciplinary team. Can you tell us more about how to support role clarity for the CHW and for members of the team? What are ways that you have clarified roles for team members in positions that may overlap?" Facilitators and research assistants were provided with a note-taking template to capture detailed feedback. Given the breadth of determinants, each group focused on reviewing one or two categories along the pathway (e.g., Integrating CHW with the Team and Identifying and Referring Patients for MAPS+) to ensure that all categories were discussed. We also encouraged discussion of structural determinants (e.g., poverty) to enhance our understanding of the outer setting.

Following this first stakeholder meeting, the project lead (KH) synthesized the facilitators' meeting notes into a comprehensive document organized along the MAPS+ Implementation Pathway and then the investigative team debriefed. Within the Integrating CHW with the Team category, we learned that clear and consistent messaging related to MAPS+ implementation was critical for both staff and patient buy-in. Education on MAPS+ and the CHW role needed to be upfront with ongoing reinforcement to ensure understanding of the mission. Stakeholders reinforced that CHW role clarity and team cohesion—which included building trust with the new CHW team member—were essential. In addition, CHWs needed to feel valued by the local clinic community. In the Identifying and Referring Patients for MAPS+ category, stakeholders highlighted that staff knowledge about CHW-delivered MAPS+ is key for identification and referral of eligible patients. We also learned that each clinic had structured team meetings and processes to review adherence-related issues, but the timing and structure varied across clinics.

In the Connecting Patients and CHWs category, stakeholders emphasized the importance of CHW availability to patients, including in the evenings and via text message communication. Stakeholders described warm handoff processes in their own clinics. They emphasized the importance of a staff member introducing the CHW to the patient in order to review goals, increase comfort, and build trust. For Delivering MAPS+, stakeholders emphasized delivery flexibility in terms of schedules, setting (office or community), and format (in-person or video platform). To mitigate potential perceptions of burden by patients, they advised framing MAPS+ as an extra support to help patients achieve successful adherence and retention.

In Coordinating Care Between CHW and Team, stakeholders expressed consensus on the importance of clear communication and care coordination. They had contrasting views on the value of communication within the electronic health record (EHR). Some characterized the EHR

as an important tool, whereas others noted that providers would not read detailed notes given time scarcity. Alternative communication approaches included brief written treatment plans or HIPAA-secure group texting with action items. Despite clinics having distinct approaches to information-sharing, stakeholders uniformly valued efficiency and accountability. In terms of Outer Setting structural determinants, stakeholders echoed findings from the needs assessment, indicating that unstable housing, inconsistent phone access, limited transportation, and untreated severe mental illness were all major challenges.

Overall, the meeting output confirmed that our approach appropriately reflected stakeholder perspectives and we gleaned new insights to guide implementation strategy selection. We added the category Introducing MAPS+ to the Clinic to the beginning of our implementation pathway to indicate that *leadership and staff buy-in for CHW-delivered MAPS+ and team expectations for CHW-delivered MAPS+* were determinants highly relevant to stakeholders for pre-implementation; this category is described in the publication referenced in Step 1 (22).

Step 3.2: Identifying implementation strategies

Given consensus that the findings generated from the interviews were consistent with stakeholder perspectives, the next step was to identify potential implementation strategies that were conceptually matched to determinants. The interview dataset was then used to generate definitions for determinants, pull illustrative examples of determinants, and identify potential implementation strategies voiced by stakeholders (see [Appendix B](#) for template). Two research team members (ALS, KH) then independently mapped the determinants onto implementation strategies listed in the refined compilation of implementation strategies from the ERIC taxonomy (21). The documents were merged and reviewed before and during a virtual meeting. In the presence of disagreement, each team member provided rationale, and consensus was reached through productive discussion. After agreeing on key strategies, the project's principal investigator (RSB), an implementation scientist, reviewed the list as an additional confirmatory step. Next, we defined implementation strategies using the refined compilation ([Table 1](#)).

As a check that relevant strategies were not overlooked, we used the CFIR-ERIC Implementation Strategy Matching Tool (27) as an additional guide. After CFIR constructs are entered, the matching tool outputs a summary worksheet with a list of implementation strategies for consideration and prioritizes them based on the percentage of experts who endorsed a strategy as being a "top seven" strategy for the particular barrier (27). To use the matching tool, we mapped determinants to CFIR constructs. For example, the determinant *leadership and staff buy-in for CHW-delivered MAPS+* aligned with the construct "leadership and staff engagement" within the CFIR inner setting

TABLE 1 Example of identified determinant, strategies, definitions, operationalizations, and relevant theory per the implementation menu (Step 4 output).

| Determinant | Implementation strategies | Implementation strategy definitions | Implementation strategy operationalizations | Relevant theory |
|---|---|--|---|---|
| MAPS+ Implementation pathway: Introducing MAPS to the clinic | | | | |
| Leadership and staff buy-in for CHW-delivered MAPS+ Definition: Clinic leadership and staff agreement and support for CHW-delivered MAPS+ CFIR: Inner setting-leadership and staff engagement Interview data examples: <ul style="list-style-type: none">• Leadership may be resistant to EBP or resistant to change, concern that leadership/providers won't want to buy-in because they are busy and burned out. (Medical Case Manager)• A major facilitator will be getting buy-in from leaders. (Behavioral Health Consultant) | Identify and prepare champions Inform local opinion leaders Obtain formal commitments | <i>Identify and prepare champions:</i> identify and prepare individuals who dedicate themselves to supporting, marketing, and driving through an implementation, overcoming indifference or resistance that the intervention may provoke in an organization. <i>Inform local opinion leaders:</i> Inform providers identified by colleagues as opinion leaders or "educationally influential" about the clinical innovation in the hopes that they will influence colleagues to adopt it. <i>Obtain formal commitments:</i> obtain written commitments from key partners that state what they will do to implement the intervention. | <i>Identify and prepare champions</i> <ul style="list-style-type: none">• Identify and engage <i>Inform local opinion leaders</i> <ul style="list-style-type: none">• Identify and engage with opinion leaders (may not be administrators or prescribers) to support MAPS+ adoption and sustainment. Frame MAPS+ as an intervention that will add value for both the organization and patients. <i>Obtain formal commitments</i> <ul style="list-style-type: none">• Identify key asks of implementation partners and obtain written commitments. | <i>Identify and prepare champions:</i> Communication-Persuasion Matrix, Social Cognitive Theory, Diffusion of Innovations Theory <i>Inform local opinion leaders:</i> Communication-Persuasion Matrix, Diffusion of Innovations Theory <i>Obtain formal commitments:</i> Theories of Goal-Directed Behavior, Behavioral Economic Theory |

domain. The constructs were then entered into the matching tool. We reviewed the strategies generated by the tool that indicated $\geq 25\%$ expert endorsement as a top strategy for each barrier (28). We cross-checked these with our identified strategies. Of note, not all of the MAPS+ determinants mapped onto a CFIR construct, particularly determinants related to the sociopolitical context (e.g., medical hierarchy, intersectional marginalization, norms of dignity and respect).

In the process of cross-checking, we scrutinized our determinants and implementation strategies more closely and noted that a few of our facilitators could also be interpreted as implementation strategies. We went back to the original determinants list for reevaluation; using the empirical data, we inferred the determinants driving the miscategorized implementation strategies. For example, the original facilitator of *clinic-level consultation and supervision for the CHW* was actually a more detailed version of the ERIC strategy *clinical supervision* and mapped to the inferred determinant *supervision model* (barrier or facilitator). We also added a new category, *Sustaining MAPS+ Implementation*, to our implementation pathway after inferring the determinant *ongoing team buy-in* behind the previously identified facilitator *dissemination of*

effectiveness and outcomes. The *dissemination* facilitator was a version of the ERIC strategy *develop and implement tools for quality monitoring*, which was defined as "sharing MAPS+ positive outcome data with clinical team by CHW to promote ongoing buy-in."

Step 3.3: Operationalizing implementation strategies

After updating the determinants and implementation strategies, we further operationalized each strategy for clinics serving PWH with several examples generated from our immersion in the data and knowledge of the MAPS+ intervention (Table 1). For example, the strategy *remind clinicians* was operationalized as "bake time into established meetings to review automated (i.e., data generated) referrals as an engagement reminder." Similarly, *warm handoff* was operationalized as "enact MAPS+ referral in front of/with the patient, in which a team member with an established patient relationship connects the patient to the CHW, explaining why the CHW can address adherence challenges and emphasizing the

CHW's competence." Operationalized strategies were detailed and context-specific.

Step 3.4: Linking to theory

The project lead (KH) then linked strategies to relevant theories of behavior change with an emphasis on causal theories to provide a mechanistic understanding of their function. Causal theories included social cognitive theory (29, 30), organizational development theory (30, 31), social network theory (30, 32), and diffusion of innovations theory (30, 33), among others. For example, diffusion of innovations theory explicates the differential rates of intervention adoption across a social system, and interpersonal channels are important for facilitating adoption (30). This theory explains how the implementation strategy *identify and promote champions* works in context; champions are key change agents who support implementation across the organization. We updated this content in the logic model.

Our draft implementation menu included 34 strategies. Of note, six of these strategies were derived directly from the interview data rather than the ERIC compilation, meaning that stakeholders articulated the strategies themselves: *optimize CHW presence on-site; provider, outreach coordinator, administrator identification of patients for MAPS+ referral; identify local approaches to relationship-building; leverage existing identification and referral processes; match scheduling to clinic needs, and warm handoffs*. As an example of a non-ERIC strategy definition, *identify local approaches to relationship-building* was defined as "identify strategies that clinics use in routine care to build trust and rapport with patients." Additional ERIC strategies in the menu included *revise professional roles, promote adaptability, and change record systems*.

Step 3.5: Second stakeholder meeting

We convened a second virtual stakeholder meeting in July 2021 to present the operationalized implementation strategy menu and obtain feedback on (1) how these strategies might be applied in each stakeholder's clinic and (2) which strategies were most important to stakeholders given finite resources. Feasibility and impact were framed as key constructs in evaluating importance (34). As with our first stakeholder meeting, we strove for representation across a variety of stakeholder groups and clinic settings. We aimed also to include individuals who had not attended the first meeting. In addition, we invited policymakers from the Philadelphia Department of Public Health. Prior to the meeting, we emailed attendees a document listing the 34 implementation strategies and definitions to use as a resource during the presentation and discussion (Appendix C).

Eight clinic stakeholders ($n = 4$ administrators, $n = 2$ medical case managers, $n = 2$ non-prescribing clinical team members) and two policymakers attended the second

meeting. We asked clinic stakeholders to reflect on the operationalized strategy examples in order to glean insights that might generalize across clinics. To organize the content for our presentation, we grouped strategies into the nine conceptual clusters (e.g., support clinicians, engage consumers, use evaluative and iterative strategies) from Waltz et al.'s (35) concept mapping project. Appendix D provides an example visual from the meeting and Table 2 lists all strategies by cluster. We labeled each conceptual cluster with a one-word summary (e.g., "evaluate") for parsimony. Within each breakout group, stakeholders reviewed two or three assigned clusters (e.g., Group 1: Relate/Assist/Adapt clusters, Group 2: Educate/Structure clusters, Group 3: Support/Engage/Evaluate clusters). In light of potential power dynamics, the policymakers were assigned to their own group to reduce discomfort or self-censorship by clinic stakeholders. The policymakers focused on macro considerations, such as how the broader context of care for PWH in Philadelphia interplayed with MAPS+ implementation efforts. As in the first stakeholder meeting, each breakout facilitator used a structured guide. For example, questions in the Group 3 Support/Engage/Evaluate clusters included the following: "Do you foresee any specific challenges with revising and shifting clinical roles?" "What do warm handoffs look like in your clinic?" "Are some clinics better resourced with technology support and quality improvement expertise?" "Are positive outcomes celebrated?" Facilitators and research assistants took detailed notes during the discussion.

Following the meeting, the project lead (KH) synthesized the facilitator notes and prepared a report that mapped specific stakeholder feedback to each implementation strategy. The report highlighted key takeaways (e.g., highly salient points that included nuanced feedback) specific to operationalizations of several implementation strategies. The investigative team debriefed and discussed how the takeaways could further inform implementation strategy development. For the strategy *conduct educational meetings*, we learned that stakeholders viewed the meetings as key for MAPS+ implementation launch but felt they must be brief, focused, and tailored for each internal stakeholder group (e.g., prescribing clinicians vs. medical case managers). Stakeholders emphasized the value of *revise professional roles*, highlighting that role clarity is essential. Adding the CHW to the team requires addressing potential duplication of roles that may create burden for patients (e.g., needing to repeat the same component of their medical history to multiple team members). Moreover, good handoffs are tied to a clear understanding of team members' roles. Specific to the strategy *develop and implement tools for quality monitoring*, stakeholders noted that clinic teams receive numerous data-driven reports and that MAPS+ outcomes should be highlighted to increase attention from the team.

We also gleaned five new implementation strategies from this meeting. First, we heard that many clinics have already remediated problems and streamlined processes for other

TABLE 2 Implementation strategies ($N = 34$) grouped by conceptual cluster for Stakeholder Meeting 2.

| Conceptual cluster | Implementation strategy |
|--|--|
| Develop stakeholder interrelationships (Relate, $n = 6$) | Identify and prepare champions Inform local opinion leaders Obtain formal commitments Promote network weaving Organize clinician implementation team meetings Identify local approaches to relationship-building |
| Provide interactive assistance (Assist, $n = 5$) | Facilitation Provide clinical supervision Provide ongoing consultation Provide local technical assistance Centralize technical assistance |
| Adapt and tailor to context (Adapt, $n = 1$) | Promote adaptability |
| Train and educate stakeholders (Educate, $n = 6$) | Conduct educational meetings Develop educational materials Distribute educational materials Conduct educational outreach visits Conduct ongoing training Make training dynamic |
| Change infrastructure (Structure, $n = 6$) | Change physical structure and equipment Leverage existing identification and referral processes Provider, outreach, coordinator, or administrator identification of patients for MAPS+ referral Mandate change Match scheduling to clinic needs Change record systems |
| Support clinicians (Support, $n = 8$) | Create new clinical teams Revise professional roles Optimize CHW presence on-site Remind clinicians Facilitate relay of clinical data to providers Warm handoffs Involve patients and family members Obtain and use patient and family feedback |
| Use evaluative and iterative strategies (Evaluate, $n = 2$) | Conduct cyclical small tests of change Develop and implement tools for quality monitoring |

interventions. With this experience, clinic staff planned to identify how the CHW model for MAPS+ delivery can fold into their specific workflows. This information led us to create leverage existing processes and procedures specific to each clinic as

a distinct strategy. The other four strategies were derived from policymaker input: communicate feedback on structural barriers back to clinic leadership and Philadelphia Department of Public Health; integrate research team into learning collaboratives; have research team engage with a collaborative between HIV care and prevention service users and providers; and have research team present at community-based organization meeting. Overall, this second stakeholder meeting yielded concrete input on strategy operationalization as well as consensus on areas to prioritize (e.g., educational meetings).

Step 4: Protocolize implementation strategies

This feedback was further synthesized with input from the investigative team to finalize a core menu of 39 implementation strategies (Table 3), which aligns with prior research on specifying and reporting implementation strategies that has found a range of 11 to 45 strategies per implementation study (16–18). This core menu, referred to as the team's implementation blueprint, will inform the deployment of MAPS+. The menu is organized by determinants, matched implementation strategies, strategy definitions, strategy operationalizations, and associated theory. The full menu is available in Appendix E.

Challenges and lessons learned

In summary, our structured implementation mapping process generated 39 implementation strategies systematically and collaboratively with stakeholders. In Step 1: Conduct Needs Assessment, our analysis of stakeholder interviews yielded contextually-rich insights into the determinants of MAPS+ implementation across clinics in Philadelphia. These empirical data anchored our inquiry; we frequently returned to the interview dataset to clarify, confirm, and center stakeholders' experiences. In Step 2: Develop Logic Model, we linked determinants to CFIR domains and input these determinants into a modification of Smith et al.'s (20), Implementation Research Logic Model. We updated the logic model throughout the course of implementation mapping. In Step 3: Operationalize Implementation Strategies, we held Stakeholder Meeting 1 to confirm determinants (3.1); identified implementation strategies that conceptually matched to determinants from the ERIC compilation and interview dataset (3.2); and operationalized implementation strategies with specific examples (3.3). We then linked strategies to theories of behavior change (3.4) and held Stakeholder Meeting 2 to present the menu for feedback (3.5). In Step 4: Protocolize Strategies, we finalized the core implementation strategy menu. Each element of Steps 3–4 supported scrutiny of each identified

TABLE 3 Final list of implementation strategies (N = 39).

- 1 Centralize technical assistance
- 2 Change physical structure and equipment
- 3 Change record systems
- 4 *Communicate feedback on structural barriers back to clinic leadership and PDPH
- 5 Conduct cyclical small tests of change
- 6 Conduct educational meetings
- 7 Conduct educational outreach visits
- 8 Conduct ongoing training
- 9 Create new clinical teams
- 10 Develop and implement tools for quality monitoring
- 11 Develop educational materials
- 12 Distribute educational materials
- 13 Facilitate relay of clinical data to providers
- 14 Facilitation
- 15 Identify and prepare champions
- 16 *Identify local approaches to relationship-building
- 17 Inform local opinion leaders
- 18 *Integrate research team into learning collaboratives
- 19 Involve patients/consumers and family members
- 20 *Leverage existing identification and referral processes
- 21 *Leverage existing processes and procedures specific to each clinic
- 22 Make training dynamic
- 23 Mandate change
- 24 *Match scheduling to clinic needs
- 25 Obtain and use patients/consumers and family feedback
- 26 Obtain formal commitments
- 27 *Optimize CHW presence on-site
- 28 Organize clinician implementation team meetings
- 29 Promote adaptability
- 30 Promote network weaving
- 31 Provide clinical supervision
- 32 Provide local technical assistance
- 33 Provide ongoing consultation
- 34 Provider, outreach coordinator, administrator identification of patients for MAPS+ referral
- 35 Remind clinicians
- 36 *Research team engagement with a collaborative between HIV care and prevention service users and providers
- 37 *Research team presentation at community-based organization meeting
- 38 Revise professional roles
- 39 *Warm handoffs

*Non-ERIC implementation strategies derived directly from interviews and stakeholder meetings.

strategy to ensure both conceptual and practical relevance for implementation.

Throughout our implementation mapping process, we identified several challenges—lack of implementation strategies

targeting outer setting, tension between one-size-fits-all and individualized approach for all clinics, lack of clarity between facilitators and strategies, and challenges in translating the implementation science lexicon to make it relevant for partners—which we reflect on here. First, we noted a scarcity of implementation strategies targeting outer setting. The equity-related determinants (e.g., structural stigma, racism, poverty) highlighted in our needs assessment called for direct attention to the sociopolitical context of implementation. In addition to integrating consideration of outer setting into our stakeholder meetings, the team reviewed the literature. Engaging with theory beyond the realm of implementation science provided traction for understanding the historically-rooted cultural norms and institutional polices that can inhibit opportunities and wellbeing for PWH (36). We found little relevant literature for implementation strategies targeted to these structural determinants. We selected *conduct ongoing training*, *provide ongoing consultation*, and *involve patients/consumers and family members* as the most relevant strategies from the ERIC taxonomy to address these barriers. These strategies are limited in their application beyond the individual level, which is problematic given that the success of implementation is fundamentally bound by structural constraints enacted by upstream institutional policies, practices, and norms.

Aside from the limitations of equity-informed implementation strategies in the literature, policymaker engagement in our second stakeholder meeting elicited novel system-level strategies that we added to our core menu. Besides *engagement with an existing collaborative of organizations*, policymakers also identified the importance of a mechanism to *communicate feedback* for CHWs to inform clinic leadership and the Philadelphia Department of Public Health on patients' experiences with structural barriers that impede MAPS+ participation. Development of this communication mechanism could enhance implementation in two important ways: (1) institutional investment in the authority and value of CHW knowledge and (2) multilevel problem-solving in direct service of PWH. New models of “flipping the paradigm,” in which CHWs mentor health care system executives, hold promise for cultivating cultural humility and structural competency among agents who wield the most power (12). Methodologically in this project, diverse stakeholder input was essential for generating strategies across all ecological levels. Beyond the scope of this case, increased development and reporting of strategies that target outer setting (i.e., macro) determinants is critical to advancing more equitable implementation, particularly for historically marginalized groups with intersectional barriers.

Second, we observed a tension between a one-size-fits-all and an individualized approach for all clinics. Given the heterogeneity of internal processes across our 13 partner clinics, individual determinants differed across clinics. These

differences created considerations for adaptation and tailoring of implementation strategies. Although the same strategies derived from implementation mapping will be used in all clinics (e.g., *conduct educational meetings, develop educational materials*), they may need to be adapted to the local context (37). Strategy adaptations are planned, proactive modifications (38); the strategy might be different in form whereas the function is the same. Function attends to structural and procedural goals (i.e., the core purposes of the strategy), and the form is the operationalization (39). For example, *warm handoffs* serve the function of initiating a transparent transfer of care (40). In front of the patient, the established care team member signals trust and imbues confidence in the new CHW. How clinics plan to implement the form of *warm handoffs* may differ, with individual clinic variation in the handoff initiator (e.g., clinician or case manager) and timing (e.g., in the clinical encounter or during next appointment scheduling) based on workflow.

In contrast to adaptation, strategy tailoring reflects the presence or absence of a strategy based on clinic context. While we have pre-selected strategies based on context and the design of the study (i.e., task-shifting, initial training and ongoing support for CHWs, integration of the CHW within the clinical team), not all auxiliary strategies will be deployed in all clinics. Some strategies may be more germane to certain clinics than others based on context. Other strategies may be ancillary (e.g., *provide local technical assistance, provide ongoing consultation, organize clinician implementation team meetings*). As such, the use of implementation strategies can be tailored to the context-specific factors for each clinic identified during the pre-implementation needs assessment (4). Given the breadth of determinants across clinics, identifying which strategies should be deployed across all clinics (then adapted to context) vs. deployed to specific clinics (tailored to context-specific determinants) is a key consideration for our research team.

A third challenge was lack of clarity between facilitators and strategies. In analyzing the interview data, we had difficulty distinguishing facilitators from implementation strategies with regard to what would make implementation of MAPS+ easier. As described above, in reviewing determinants using the CFIR-ERIC Matching Tool, we identified a few facilitators that appeared to be implementation strategies and required recategorization (e.g., *CHW onboarding and training* was a distinct strategy, not a facilitator). To properly recategorize, we needed to return to the data to infer the determinants behind the articulated strategy. Inferring determinants from stakeholder-proposed solutions is an approach used in prior studies that has helped to identify the factors that may impede implementation of EBPs (41). We found that the mental heuristic of facilitators as “nouns” (extant key factors) and implementation strategies as “verbs” (added key actions) helped our team delineate facilitators from strategies. Overall, we noted challenges specific

to limited precision with facilitators and an outstanding question about the extent to which facilitators and strategies may overlap. This ambiguity highlights a need to increase conceptual clarity around enablers of implementation. Our need to return to the data highlights the flexibility and iteration required for implementation mapping.

Lastly, we experienced challenges in translating established implementation science lexicon and taxonomies to our partner stakeholders. We recognized that terminology related to conceptual frameworks, determinants, and implementation strategies (with dense names like “*facilitation*”) did not resonate with our stakeholders, who contributed their own deep, discipline-specific knowledge of HIV care within the city. Moreover, implementation strategy definitions were not always clear, even to our research team (e.g., defining “*network weaving*”). Our stakeholder meeting materials required multiple refinements to improve clarity. As described above, we also constructed a resource document with specific definitions of implementation menu strategies to increase accessibility. In addition, we realized that the MAPS+ Implementation Pathway, which grouped determinants sequentially and served us well in the first meeting, was less useful for presenting implementation strategies. Some strategies (e.g., *identify local opinion leaders*) were associated with determinants in pre-implementation only, whereas other strategies (e.g., *organize clinician implementation team meetings*) were identified across multiple stages. The temporality of implementation strategies—that is, whether the specific strategy was applicable within one implementation stage or across multiple stages—was particularly difficult to convey. Ultimately, organizing strategies by conceptual cluster was an efficient approach that resulted in meaningful output from the second stakeholder meeting.

Limitations

As only one team member (KH) had completed linkage between strategies and theory, our list represents a preliminary understanding of mechanisms. Use of theory will be further refined in future work. We did not use quantitative measures to obtain rankings of stakeholders’ preferences for implementation strategies in Stakeholder Meeting 2. And finally, in Step 4 we elected not to specify implementation strategies per Proctor et al.’s (14) reporting guidance with details about the actor, action, action targets, temporality, dose implementation outcomes addressed. This important work will be carried out in the context of the upcoming trial, described below.

Future directions

The implementation menu from Step 4 will populate an implementation strategy tracker with strategy specification per

reporting guidance (14). The tracker will be updated monthly during the trial. Our implementation blueprint facilitated more comprehensive planning for the trial, and we can now formally and prospectively track what strategies were planned in advance vs. modified in reaction to unanticipated barriers that arose in clinics during implementation (37). We will then describe how and why strategies succeeded (or failed) so they can be replicated or further refined in future implementation efforts (42). Our process thus far has yielded knowledge generalizable to other behaviorally informed EBPs for HIV/AIDS.

Our case exemplar illustrates a systematic process of designing implementation strategies for a broad-scale, multi-site implementation effort. Use of implementation mapping is a unique contribution to the HIV/AIDS research community with great promise for promoting Ending the HIV Epidemic goals and improving outcomes for PWH. The method may be especially valuable for other health domains in which the social context is complex and underexplored through an implementation lens. We see opportunities for further delineation of implementation mapping steps to increase the accessibility of this method for investigators new to implementation science. We also encourage investigators to expand on the solutions we generated specific to the challenges of this case exemplar.

Data availability statement

The original contributions presented in the study are included in the article/[Supplementary materials](#); further inquiries can be directed to the corresponding author.

Ethics statement

The studies involving human participants were reviewed and approved by the City of Philadelphia Institutional Review Board. Written informed consent for participation was not required for this study in accordance with national legislation and the institutional requirements.

Author contributions

KH, ALS, CH, FM, RG, and RSB contributed to the conception and design of the study. RSB served as project director of the supplement award. KH wrote the first draft of the manuscript. All authors contributed to manuscript revision, and read and approved the submitted version.

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Conflict of interest

RSB receives royalties from Oxford University Press, currently provides consultation to United Behavioral Health, and serves on the Clinical and Scientific Advisory Board for Optum Behavioral Health. ARP has consulted on research studies funded by AbbVie, RG serves on the data and safety monitoring board for Pfizer Inc.

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.

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Supplementary material

The Supplementary Material for this article can be found online at: <https://www.frontiersin.org/articles/10.3389/fpubh.2022.872746/full#supplementary-material>

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Using Implementation Mapping to develop protocols supporting the implementation of a state policy on screening children for Adverse Childhood Experiences in a system of health centers in inland Southern California

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Adverse Childhood Experiences (ACEs) are defined as traumatic events occurring before age 18, such as maltreatment, life-threatening accidents, harsh migration experiences, or violence. Screening for ACEs includes asking questions about an individual's early exposure to these types of events. ACEs screenings have potential value in identifying children exposed to chronic and significant stress that produces elevated cortisol levels (i.e., toxic stress), and its associated physical and mental health conditions, such as heart disease, diabetes, depression, asthma, ADHD, anxiety, and substance dependence. However, ACEs screenings are seldom used in primary care settings. The Surgeon General of California has addressed this care gap by introducing ACEs Aware, an ACEs screening fee-for-service healthcare policy signed into law by Gov. Gavin Newsom. Since January 2020, Medi-Cal, California's Medicaid health care program, has reimbursed primary care providers for using the Pediatric ACEs and Related Life-events Screener (PEARLS) tool to screen children and adults for ACEs during wellness visits. To achieve the goals set by the ACEs Aware state policy, it is essential to develop and test implementation strategies that are informed by the values, priorities, and resources of clinical settings, healthcare professionals, and end-users. To address this need, we partnered with a system of federally qualified health centers in Southern California on a pilot study to facilitate the implementation of ACEs screenings

in five community-based clinics. The health centers had broad ideas for an implementation strategy, as well as best practices to improve adoption of screenings, such as focusing on staff training to improve clinic workflow. This knowledge was incorporated into the development of an implementation strategy template, used at the outset of this study. We used the Exploration, Preparation, Implementation and Sustainment (EPIS) framework to guide the study and inform a participatory planning process called Implementation Mapping. In this paper, we describe how Implementation Mapping was used to engage diverse stakeholders and guide them through a systematic process that resulted in the development of the implementation strategy. We also detail how the EPIS framework informed each Implementation Mapping Task and provide recommendations for developing implementation strategies using EPIS and Implementation Mapping in health-care settings.

KEYWORDS

Implementation Mapping, EPIS framework, federally qualified health center, ACEs screenings, PEARLS, toxic stress, trauma informed care

Introduction

Adverse Childhood Experiences (ACEs) are defined as traumatic events occurring before age 18, such as maltreatment, neglect, life-threatening accidents, harsh migration experiences or exposure to violence (1). ACEs are pervasive, with 45% of children in the United States experiencing at least one ACE and 10% experiencing three or more ACEs, placing them at higher risk of negative physical and mental health outcomes (1). Addressing ACEs is critical to improving health equity, because these events are more prevalent among minority and immigrant communities due to exposure to poverty, discrimination, community violence, national disasters, and refugee experiences (2, 3). Screening for ACEs includes asking questions about an individual's early exposure to potentially traumatic events (4–6). Screening has the potential to facilitate a deeper understanding of the contributions of early experiences on an individual's developmental and health trajectory (4). The Surgeon General of the state of California has promoted the use of ACEs screenings in primary care by introducing an ACEs screening policy, called ACEs Aware, through the California Department of Health Care Services (7). This policy was funded through Proposition 56, which provides funding to improve health and increase interventions for youth. In January 2020, Medi-Cal, California's Medicaid health care program, began reimbursing primary care providers for using the Pediatric ACEs and Related Life-events Screener (PEARLS) tool to assess children and adults for ACEs during annual wellness visits (7). This state policy is unique in the country, as it promotes early identification of toxic stress, which is a prolonged physiological stress response that interferes with the brain, and its associated physical and mental health conditions, such as asthma, ADHD and anxiety, with the intention to connect these patients to needed services (8).

The ACEs Aware policy in California is a valuable pilot for the country. The economic and humanistic benefits of ACEs screenings remain debatable because it is important not only that screenings are completed in primary care settings, but that the information is used to engage families effectively with the goal of improving health. In order to be valuable, ACEs screenings must lead to timely, evidence-based interventions. Policymakers should consider how ACEs screenings are used, within a larger process of supporting families that have experienced traumatic events. Without the training necessary to implement trauma-informed care in healthcare settings, ACEs screening could re-traumatizing families; similarly, appropriate training is necessary for healthcare professionals to prevent compassion fatigue or burnout related to the process of discussing trauma with patients and caregivers on a daily basis.

The growing interest in ACEs screenings in primary care settings to address social determinants of health has been informed by research showing the benefits of this practice. Felitti et al. (9) stated that ACEs screenings can be therapeutic, as they allow the patient to reflect on the impact these experiences may have on their current health and to receive support from a health care professional. Identifying childhood adversity and offering appropriate interventions may ultimately decrease the risk of negative effects of ACEs, including problematic behavior and chronic illness in adulthood (10). Furthermore, screening may lead to earlier detection of patients who are at higher risk of mental and physical health challenges, prevent further ACEs among children, and present the opportunity to provide appropriate treatment (11–13). For example, Flynn and colleagues (13) conducted a systematic review of literature examining the use of trauma screening tools (e.g., Safe Environment for Every Child [SEEK; (14)] and Well Child Care, Evaluation, Community Resources, Advocacy,

Referral, Education [WE CARE; (15)] in primary care settings and described four randomized controlled trials (RCTs) that found evidence of reduced risk of experiencing trauma and increased referrals to community resources. On the other hand, ACEs screening questions may cause discomfort for the patient and possibly disrupt health care relationships (4, 16). Additionally, we lack evidence as to whether increased ACEs screening efforts translate into better access to care for children (17). However, without effective implementation, reach, and sustainment of ACEs screenings, it will be difficult to determine the benefits of such screenings and any subsequent engagement in health services. Thus, there is a critical need for evidence regarding suitable strategies designed to support the successful implementation of ACEs screenings.

Rariden and colleagues (18) conducted a systematic review to explore the acceptability, feasibility, and implementation of ACE screenings across diverse settings (i.e., pediatric clinics, adult primary care, perinatal settings, patients' homes, and academic environments). The review found that most parents were willing to complete ACEs screenings on behalf of their children, and many parents were supportive of such practices. When exploring the feasibility of ACEs screenings, nine studies indicated that clinicians had concerns about adding time for screenings in already-busy visits, expressed lack of confidence about the implementation process, had uncertainty in processing past trauma with patients, and felt potential discomfort for families. Despite these concerns, however, there were no major disruptions reported after the implementation of screenings, and only one study identified an increase (<5 min) in the duration of the office visit. Rariden and colleagues (18) also found that training aimed at increasing clinician confidence, knowledge, and comfort with these screenings was associated with clinicians viewing ACEs screenings as acceptable and feasible. Other promising strategies included ensuring all staff participated in training (18, 19) and providing staff with adequate resources and multi-disciplinary support before the implementation (18–20).

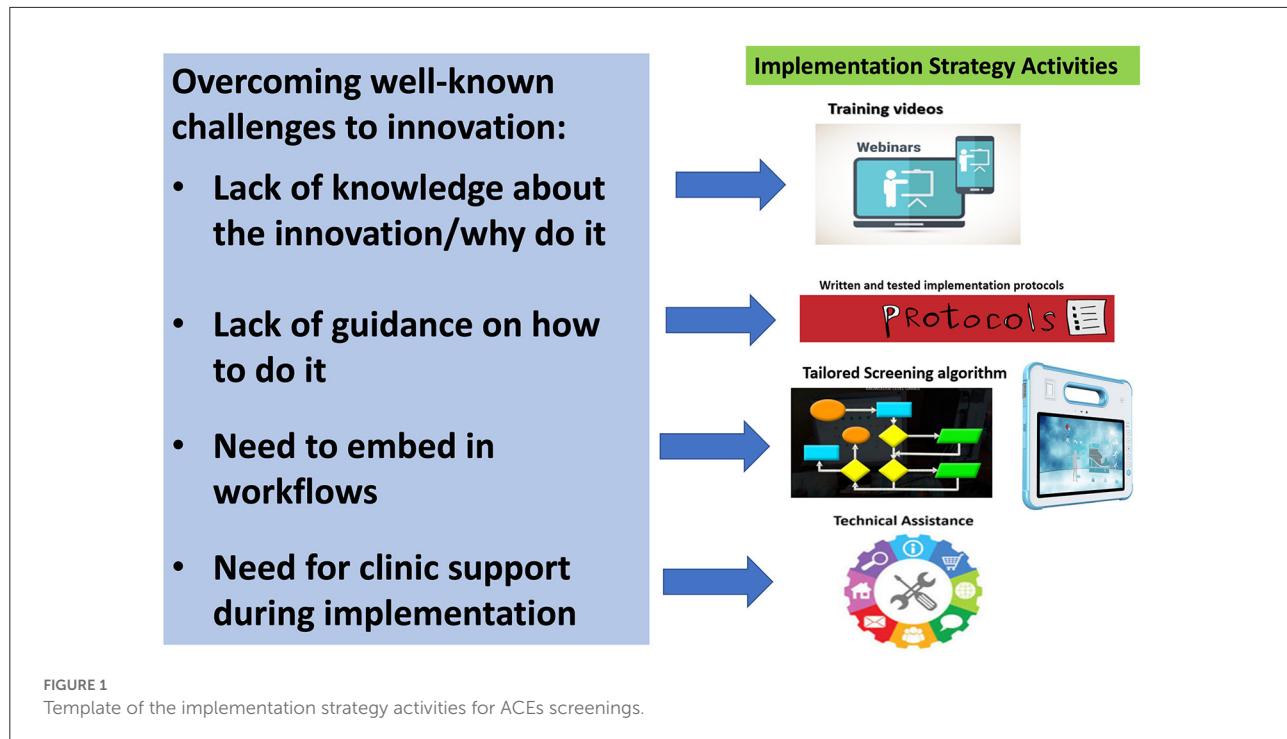
To achieve the goals set by the ACEs Aware state policy, it is essential to develop and test implementation strategies informed by the values, priorities, needs and resources of clinical settings, professionals, and end-users (18–22). Implementation strategies refer to “methods to enhance the adoption, implementation, sustainment, and scale-up of an innovation.” [(23); p2] To address this need, we partnered with a large Federally Qualified Health Center (FQHC) with multiple locations in inland Southern California to engage in a two-year pilot study scaling up ACEs screenings in five community-based clinics. The FQHC partner had a broad idea of which implementation strategies and best practices might improve adoption of screenings, such as focusing on staff training to improving clinic workflow. This rich knowledge was complemented by information from the literature and by researchers' expertise (24). Yet, the implementation strategy at the outset of this

study was lacking specific and comprehensive details necessary to effectively and confidently begin screening for ACEs. This study, funded by the National Institute of Mental Health, used the Exploration, Preparation, Implementation and Sustainment (EPIS) framework (25) to frame the project and to inform answers to questions posed using a collaborative process for planning implementation strategies called Implementation Mapping (IM) (26). IM is a systematic collaborative approach to develop and/or select and tailor multi-level implementation strategies. It uses a six-step iterative process that includes the explicit identification of all adopters and implementers, as well as a clear description of implementation outcomes, tasks, determinants, and change objectives. The process also includes delineation of the specific techniques (methods and practical applications of those methods) used to influence determinants and lead to implementation outcomes (26). EPIS is both a process and determinant framework that has been used in studies in widely varying healthcare systems, for different health conditions, and in multiple countries (27). The planning process started with the preliminary elements of an implementation strategy, and multiple collaborative mapping sessions were used to develop the details for each activity. The IM process was also used to tailor protocols to each participating clinic.

The purpose of this paper is to describe how the IM process and collaborations between the research team and diverse stakeholders representing healthcare leadership, clinic management, quality department, providers, staff, and caregivers contributed to the creation of a multi-faceted implementation strategy for ACEs screening implementation in five clinics. We report on the first four IM Tasks – Task 1: Conduct a needs and assets assessment and identify adopters and implementers; Task 2: Identify adoption and implementation outcomes, performance objectives, and determinants; Task 3: Identify and create implementation strategies; and Task 4: Produce implementation protocols and materials (26). We also describe how we used the EPIS framework and IM to guide the participatory process and plan implementation strategies. This process allowed the researchers and clinical health partners to collaboratively develop a detailed implementation strategy that reflected the nuanced and complex challenges of an FQHC operating during the COVID-19 pandemic.

Methods

This study represents a partnership with five clinical sites that are part of a large FQHC system serving largely Hispanic/Latinx patients in frontier, rural, semi-urban, and urban regions in California. In late 2019, the partner healthcare system decided to adopt the ACEs Aware policy and reached out to the first author to support implementation efforts. An overarching implementation strategy template, designed to address identified challenges to implementing innovations in

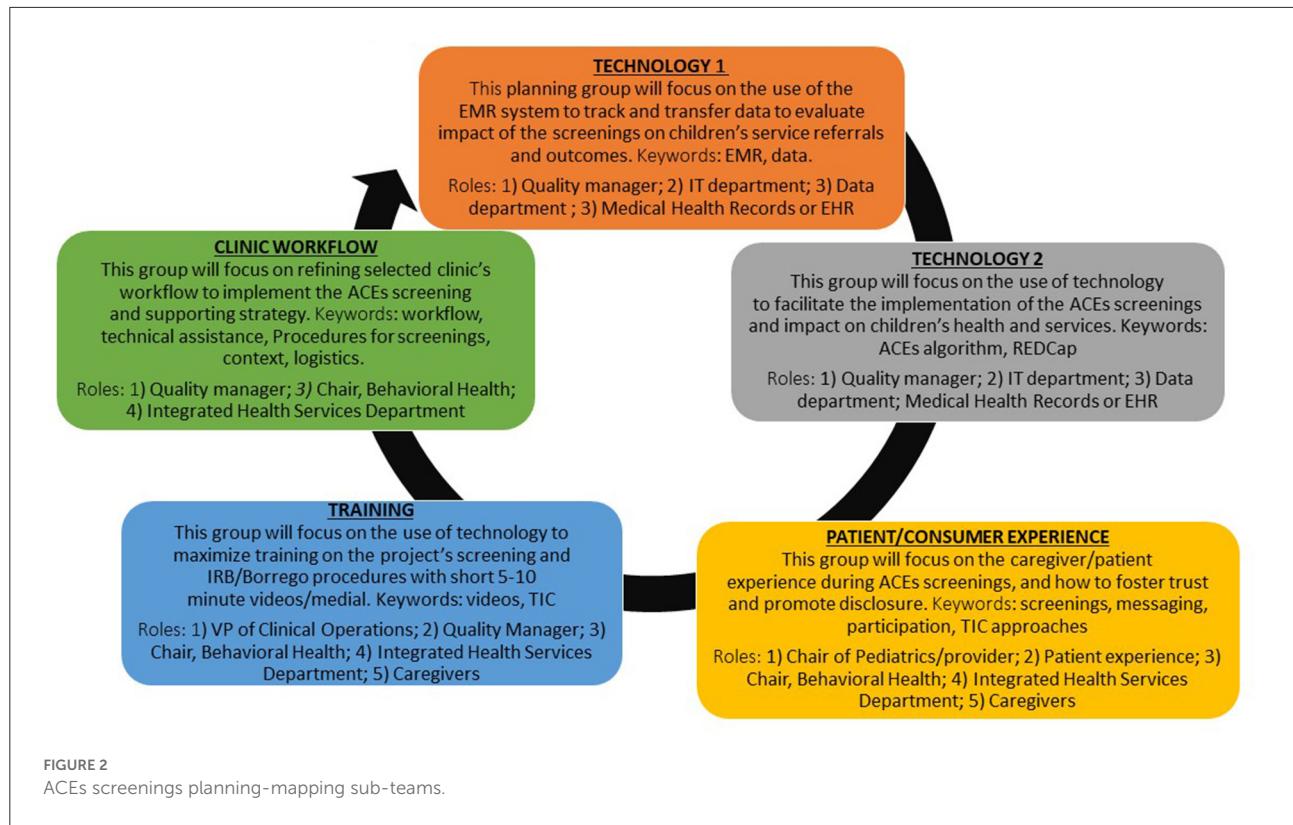


clinical settings and at the partner healthcare system (28–31), was co-created. As a sign of commitment to this effort, FQHC leadership gave approval for staff to devote the hours allotted to administrative duties to participate in implementation mapping activities and meetings. Figure 1 shows a slide used in planning meetings to introduce the strategy template with stakeholders. Conversations allowed for the expansion and development of the strategy with the use of EPIS and IM. The EPIS framework guided IM discussions for each of the phases [i.e., exploration, preparation, implementation, and sustainment; (32)]. In addition, this framework informed each IM task as related to the inner and outer contexts, the nature of the ACEs screenings as an innovation in the FQHC system, and bridging factors [i.e., formal arrangements and processes linking the outer system and the inner organization and clinic contexts; (32)].

The methods presented in this paper are novel in two ways. First, IM is a relatively new approach in terms of implementing practice change in community health centers to identify and/or design implementation strategies. In this case, IM was used to build on strategies that were identified during the development of the grant proposal, in which researchers collaborated with FQHC clinical partners (e.g., Director of the Research Department and Data Manager) and a Trauma-Informed Care (TIC) workgroup (which included the researchers) to develop a multi-faceted implementation strategy (33) to support ACEs screenings. The implementation strategies we selected (before beginning detailed planning using IM) included remote learning, use of technology to increase workflow efficiency during ACEs screenings, and

technical assistance during implementation. Despite having these preliminary strategies, specific content still needed to be developed, and strategies needed to be re-considered and tailored to fit the realities of each of the five clinical sites. We used the IM process as a protocol to guide strategy development and planning. The EPIS framework helped us answer the various IM Tasks' questions. The framework also placed those questions in the implementation process, within the FQHC's inner organizational context, and within the outer policy context of the ACEs Aware initiative. This planning process guided participants to systematically co-design implementation protocols by specifying who had to do what to implement program components, identifying the needs related to increasing motivation and capacity, and tailoring strategies to improve implementation for each of the local clinical settings.

Second, this project is novel because we used the EPIS framework to provide the conceptual framework for researchers to consider the context in which the ACEs screenings were going to be implemented and to help address IM questions designed to guide planning efforts (e.g., who does what during each of the EPIS phases, what inner context organizational dynamics are at play, what are the considerations for individuals such as health care providers). In sum, IM provided a structure for planning the implementation strategies and the EPIS framework provided specific processes and constructs to help answer those questions. Both EPIS and IM informed group decision-making and identification of key determinants of change. This approach exemplifies how IM can be used with implementation



frameworks to plan implementation strategies and advance the field of Implementation Science.

Results

Stakeholder engagement

Central to the integration of IM and EPIS is engagement of stakeholders across all IM Tasks. The project started in May 2020 with an implementation team from the partner healthcare system: Director of Research, Data Manager, and Director of Pediatric Programs. Due to turnover during the COVID-19 pandemic in late 2020, the first two individuals left the organization. The Director of Pediatric Programs (DPP co-lead hereafter) remained, and a new data coordinator (data co-lead hereafter) joined the project. These two individuals are referred to as internal project co-leads, or champions. The initial implementation team was comprised of researchers, healthcare leadership and implementers, and end-users (i.e., caregivers of children ages 0–5 years). The team held two brainstorming sessions to identify initial stakeholders to be invited to the IM process based on the needs and characteristics of each of the implementation strategy activities. These individuals were identified based on their roles within the healthcare system and previous experience collaborating in various research projects

with the first author since 2017. An email was sent to these 25 stakeholders, who represented key areas in the FQHC system that would support ACEs screenings and that were described in the previous section (i.e., technology transfer, use of technology, patient/caregiver experience, training, and workflow). Stakeholders were invited to an initial Zoom meeting, which was held 30 days after the study funding started. Based on this discussion, which touched on the specific IM tasks that would need to be accomplished throughout the project, attendees identified other colleagues whose expertise and enthusiasm for new programs would contribute to the planning and implementation process. Conversations in the initial meeting made it clear that stakeholders preferred to be involved in their area of expertise, and that administrative time was in short supply. As a result, stakeholders suggested the creation of subgroups based on selected strategy activities, and on areas of expertise/interest to improve the fit of the ACEs screenings for the participating clinics, and for FQHC system. Those areas included the use of technology to improve workflow, the transfer of data from EMR system for evaluation, training, caregiver (end-user) experience, and workflow (see Figure 2 for explanation of the goals set by the group for each mapping sub-team).

Changes to the composition of the sub-groups were made based on changes in the inner context (e.g., turnover), outer context (e.g., state mandate to isolate due to COVID-19

exposure and/or positive test), capacity to attend meetings and individual interest. Each group met two to three times throughout the IM process. This iterative process fostered the creation of tailored protocols to facilitate activities across the EPIS phases of preparation, implementation, and sustainment. Caregivers of pediatric patients provided feedback on ways to improve families' ACEs screening experiences. The IM planning meetings were structured to identify objectives and potential challenges, brainstorm ideas to overcome those challenges, and assign responsibilities to participants. Meetings with professionals were conducted in English, using the Microsoft Teams online platform, and each meeting was recorded and professionally transcribed to aid in analysis and identify ideas or tasks that would benefit from further discussion in later meetings or sub-groups. Meetings with caregivers were held mostly in Spanish on a conference phone call by the first author and a community health specialist. Due to the low quality of the call recordings with caregivers, two note takers were used to integrate and compare notes for accuracy. Caregivers received a gift card, delivered to their phones through text or *via* email, for their participation. The developed implementation protocols will inform the second phase of this study: a randomized stepped-wedge clinical trial to test the strategy in five clinical research sites.

Characteristics of stakeholders involved

Consistent with the principals of IM, the planning process was carried out using a collaborative group process with a diverse group of stakeholders who shared responsibility for knowledge building and direction of the ACEs screening implementation. Forty-four stakeholders (77% female) participated in 12 IM meetings. The 52% ($n = 23$) of meeting attendees who provided demographic data reported their race or ethnicity as Hispanic (43%; $n = 10$), Middle Eastern (9%; $n = 2$), Asian (9%; $n = 2$), Black (4%; $n = 1$), and White (35%; $n = 8$). Professional roles included medical doctors, clinic managers, medical assistants, medical scribes, nurses, and technology managers. Separately, we included a group of end-users (13 caregivers), who provided feedback on the screening process. All caregivers identified their ethnicity as Hispanic and their gender as female; the average age was 27 years old. Just over half of the caregivers preferred to participate in the IM conversations in Spanish, rather than English.

The EPIS framework informed the implementation mapping process

We considered each phase of the EPIS framework during each IM task. This helped ensure that we would have strategies that would be appropriate for the various phases of EPIS, from

Exploration through Sustainment. We also considered the inner context of the organization and clinics, the outer system and community context, and bridging factors that link outer and inner contexts (e.g., funding, policies, and characteristics of the ACEs screenings when identifying the most salient factors influencing implementation and making decisions across the IM strategy planning steps) (30, 31) (Figure 3).

This approach allowed us to account for the dynamic nature of the healthcare system due to inner and outer context characteristics and events in general and during the COVID-19 pandemic in particular, the nature of the ACEs screenings (i.e., benefits vs. burdens), and the need to approach planning through a lens of equity and inclusion (32). The main IM strategy development activities lasted seven months, with meetings of 40–60 min. Meetings were facilitated by the first author, second author, and by the DPP co-lead.

IM task 1: Conduct a needs and assets assessment and identify adopters and implementers

In 2020, the TIC workgroup conducted anonymous organizational surveys to assess training needs among service providers, awareness of the ACEs Aware policy, perceived ability to successfully screen for ACEs in their clinic after taking the state training, leadership support, and workforce morale. The survey was open online from 17 July to 4 August 2020, and a total of 162 individuals were invited to participate, with 52 individuals completing the survey (36% response rate). Of those, 32 (61%) were clinical providers (MDs and DOs), 17 (33%) were nurse practitioners, and 3 (6%) did not report. More than half of survey participants found the ACEs training relevant (52%) to their clinical practice, and most (74%) said they had the training and information needed to screen patients based on completing the state's required 2-h ACEs Aware training. Some participants were not clear on how the workflow would accommodate this new screening and suggested including nurses, medical assistants and case managers in the screening process and training. Results from a separate leadership survey conducted in early 2021 identified internal factors related to the partner healthcare system that could challenge the implementation of the ACEs screenings. Those factors included high levels of burnout at the FQHC and a need for leadership to improve self-care among employees and promote TIC across the organization.

EPIS framework contributions

The exploration and preparation phases of the EPIS framework informed this task by providing additional guidance on what to consider when examining needs, assets, and challenges based on organizational characteristics (i.e., inner

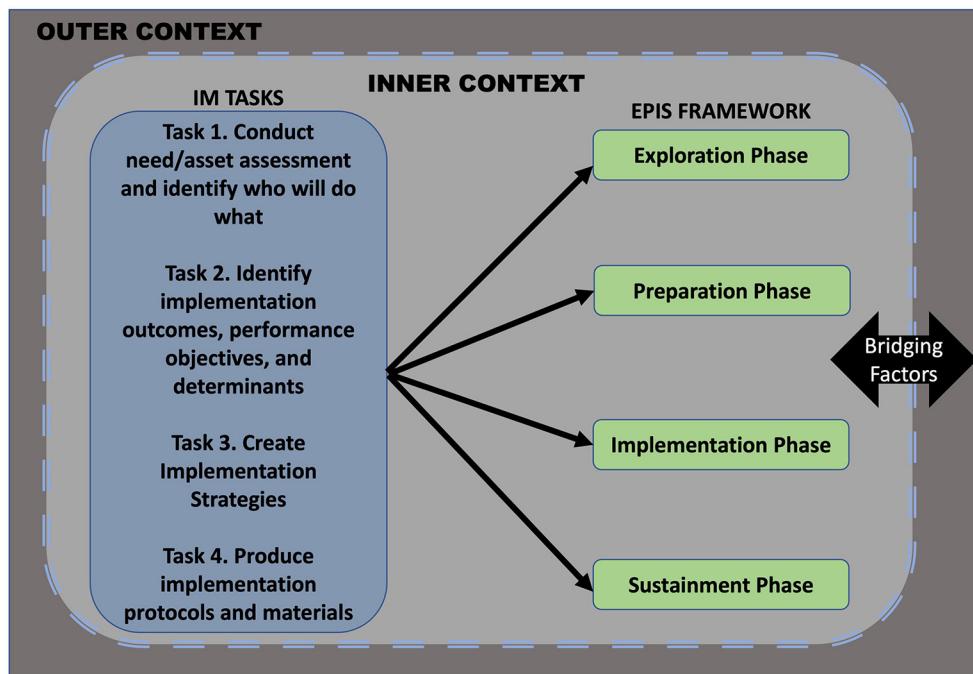


FIGURE 3
EPIS-informed implementation mapping process.

context) and their potential impact or fit on the implementation phase (see Table 1). The mapping sub-teams discussed these areas based on the outer (i.e., state ACEs Aware state policy), and inner (i.e., turnover and personnel reorganization) context characteristics as well as bridging factors (33). That mutual interdependence is seen in the state requirement to complete a 2-h online training for clinic personnel involved in conducting screenings and the submission of ACEs screenings scores, and the ability of clinics to submit billing codes to the state for financial reimbursement (i.e., \$29 for each completed ACEs screening, once a year for each patient).

This preliminary information informed the priorities for future planning, such as discussions about who would be leading and conducting the ACEs screenings. This was critical given the high staff turnover and shortages in clinic personnel at the time of these discussions because of the COVID-19 pandemic. With that agenda in mind, the first planning meeting was held using Zoom, for 60-min, with all stakeholders involved to introduce the new ACEs screenings initiative. The agenda included a description of the broad implementation strategy proposed in the funding proposal and the logic model behind it. (34) We followed IM guidelines to identify not only the barriers to implementation (Task 1) but also to consider the identification of specific implementation actions (i.e., performance objectives) and the determinants likely to influence them. To accomplish

this, we asked the following questions: “Why do you think [name of the healthcare system] has decided to adopt this state policy?” “Who will make the resources needed to support the screenings?” and “Who can champion these screenings at each clinic?” The group then discussed how they would like to organize themselves to tackle each implementation activity and further develop the details on “who, what, how and when.” These discussions allowed the groups to identify “Who will do what?” as well as potential gaps in key stakeholder involvement, such as a need for outreach to leadership (e.g., Chief Medical Officer, Director of Pediatrics Department, and Director of Adult Services) to provide needed resources and to collaborate on problem-solving. As a result, the first and third authors, and the DPP co-lead convened bi-monthly Zoom meetings with leadership starting early on during the EPIS exploration and preparation phases for planning processes. These meetings will continue throughout the duration of the study.

One example of the benefits of including end-users during the IM process, and early on during the EPIS preparation phase, was the fact that caregivers who participated in our project shared a need to add strength-based questions to the ACEs screenings to showcase families’ resilience. It was also deemed important to clarify that all caregivers of children ages 0–5 years were being asked the ACEs questions to avoid caregivers feeling singled out. The team added these strategies to the

TABLE 1 Implementation Mapping: task 1.

| Inner Context | Organizational characteristics | How it will impact implementation? | Who can do something about it? |
|-----------------------------------|---|--|--|
| Leadership | Hierarchical structure of the organization | Communication flows from the top down, which takes longer | Leadership: Behavioral Health Department Chair, Pediatrics Chair, Chief Clinical Officer |
| | Leadership at the organization as a whole not very integrated with leadership in the field (clinics) | Time needed for upper leadership to check in with clinic leaders and vice versa | |
| | Shift from a centralized system and into allowing more independence to decision-making at the clinical level | Take longer for access to clinics for planning | |
| Capacity | Severely diminished due to COVID-19 pandemic | Delayed start time for screenings | Clinic Managers; |
| | Research department dismantled and closed | Loss of implementation team members | Project Co-Lead/Director of Pediatric Practice* (DPP); |
| | Floating/admin personnel reduced to a minimum | Less time for implementation | Community Health Advisors |
| | Financial crisis due to COVID-19 impact | Shrinking workforce; less time for training or administrative activities | Trauma-Informed Care (TIC)** Workgroup; |
| | Extreme turnover | Lack of implementers; requires new team members to be introduced to project | |
| Organizational Structure/ Culture | Remote work and big size organization | Makes planning longer and through multiple groups/reliance on Microsoft Teams and zoom | Project co-lead/ champions |
| | Organizational re-structuring, new roles, layoffs, turnover, uncertainty, external monitoring; at the provider level, staff burnout, change fatigue, lack of staff understanding and little education about changes | Burnout and fatigue regarding innovate; role confusion | Leadership: Behavioral Health Department, Pediatrics, Chief Clinical Officer |
| | Co-Leads representing operations and data | Director of Pediatric Practice (DPP) and Data Coordinator (Data Co-Lead) | |
| General Mapping Group | Need to inform and educate patients about toxic stress, ACEs***, and the impact on their health outcomes. | Lower buy-in and engagement | TIC Workgroup |
| Workflow Mapping Group | Lack of trauma-informed care (TIC) awareness | Lower buy-in and engagement | TIC Workgroup |
| | Lack of staff at the clinics to champion/implement | Low readiness for change and few resources in place for implementation | Clinic managers; Leadership |
| | Competing demands for implementers' attention | Lower buy-in and engagement | Clinic managers |
| | Change fatigue and burn out | Lower buy-in and engagement | Leadership; Project co-leads/ champions; Clinic managers |
| | Lack of appropriate training and clarity on who is doing what, when, how; Confusion on what to do with caregiver declines and deviation from plans | Low readiness for change and resources in place for implementation | Pediatricians |
| | Not enough time to prepare for implementation (2 weeks or less) | Low readiness for change and resources in place for implementation | Academic partners |
| | Need to improve efficiency of workflows | Low fidelity and sustainment | Project Co-leads |
| | Instructions are complicated – too many arrows to follow to know what to do | Low buy-in and sustainment | Project Co-leads; Clinic Managers; Research Team |

(Continued)

TABLE 1 (Continued)

| INNER CONTEXT | Organizational characteristics | How it will impact implementation? | Who can do something about it? |
|---|--|---|---|
| Technology Mapping Groups | Lack of leveraging technology to improve efficiency Use of USC tablets too complicated Need to ensure consistent data entry – who is doing what, what is working, deviation from plans – that is necessary for refinement | Low fidelity and sustainment Low fidelity and sustainment Fidelity | Academic partners; Project Co-leads Project co-lead (EHR systems and dashboard) |
| Leadership Group; All Mapping Groups | Lack of personnel due to COVID-19 vaccine policy in California | Low readiness for change and lack of resources in place for implementation | ACEs Aware Leadership; Project Co-Lead/DPP; Clinic Managers; Research Team |
| Patient/ caregiver experience Mapping Group | Low reading levels from caregivers Patients not disclosing / refusing to complete forms Lack of resources in place for referrals after screenings Caregivers not knowing anything about the new program in advance; takes significant time to educate caregivers | Low disclosure; lower buy-in and engagement Lower public health impact; policy not meeting its goals Low buy-in and sustainment Lower buy-in and engagement; Lack of trust in providers/clinic | ACEs Aware Leadership; Project Co-leads; Clinic managers; Research Team |
| Leadership Group; All Mapping Groups | Lack of personnel due to COVID and Vaccine policy in California | Low readiness for change and resources in place for implementation | |
| Outer context | Organizational characteristics | How it will impact implementation? | Who can do something about it? |
| | Ongoing changes to the ACEs Aware policy in terms of procedures, expectations, tools Scripts for implementers to use made available in October 2021 (policy started reimbursing clinics in January 2020) No direct communication between ACEs Aware leadership and Health leadership | Creates confusion; requires ongoing feedback loops of rapid assessments Creates confusion; requires ongoing feedback loops of rapid assessments Gaps in knowledge; lack of up-to-date information; lower fidelity to state guidelines | PEARLS Developers; ACEs Aware Leadership; CALQIC*** Leadership Project DPP* Co-Lead has indirect communication through CALQIC** and can serve as liaison |
| Innovation characteristics | | How it will impact implementation? | Who can do something about it? |
| | Innovation is attached to state reimbursement (i.e., relative advantage) Addresses a key need identified in the patient population for this FQHC system: trauma | Strong incentive to adopt the innovation and do what is needed to obtain reimbursement; additional procedures not attached to reimbursement may not be prioritized Increased fit of the ACEs screenings with the FQHC mission and goals | Project co-leads/ champions; EHR systems co-lead Leadership; Project DPP* co-lead; Clinic managers; Pediatricians |

(Continued)

TABLE 1 (Continued)

| Outer context | Organizational characteristics | How it will impact implementation? | Who can do something about it? |
|---------------|---|--|---|
| | Visibility through service grants from the state; free training and access to resources | Learning from the community informs this pilot's efforts; shared lessons learned; access to policymakers | PEARLS Developers at [^] UCSF; ^{***} CALQIC |

Leadership: Behavioral Health Department Chair, Pediatrics Chair, Chief Clinical Officer; *DPP, Director of Pediatric Practice; **TIC, Trauma-Informed Care; ***ACEs, Adverse Childhood Experiences; ****CALQIC, California ACEs Learning and Quality Improvement Collaborative – State funded service grant; [^]UCSF, University of California San Francisco.

implementation protocol with the goal of improving families' experiences during ACEs screenings in primary care settings, and to address potential unintended consequences such as further stigmatization.

IM task 2: State adoption and implementation outcomes, performance objectives, and determinants; create matrices of change

Given the barriers and opportunities that had been identified in Task 1, the team continued to describe targets for change and desired outcomes. For this Task, the research team shared with stakeholders the original implementation strategy template and broadly defined intended outcomes (i.e., reach, acceptability, and feasibility of the implementation strategy activities) as a starting point for stakeholder discussions. The IM process allowed the team to refine the template by identifying concrete performance objectives (implementation sub-tasks/behaviors) that would lead to those outcomes and to confirm with stakeholders that those intended outcomes were relevant and valued. One example of this feedback was that stakeholders identified a need to support efficient workflows and clinical care team procedures during the planning and implementation of the ACEs screenings, to increase likelihood of sustainment. The overall goal of this step was to focus on identifying the appropriate "implementers" and concrete activities (or Implementation Tasks) for them to overcome key challenges identified during the needs assessment (Task 1; i.e., high turnover, financial stress, inefficient workflows). The performance objectives were framed in terms of specific Tasks and who would complete the Tasks to integrate ACEs screenings into existing organizational and clinic workflows and procedures. Identifying performance objectives for implementation and sustainment through the use of several IM Matrices of Change allowed us to identify key determinants (e.g., knowledge) for each specific performance objective. In this project, we organized the activities in this step according to EPIS phases.

EPIS framework contributions

The performance objectives and outcome discussions during this Task were integrated into a table framed around each of the phases of the EPIS framework (e.g., Who will be responsible for the identified objectives and outcomes during the preparation of ACEs screenings? During their implementation at the five clinical settings? During sustainment?) These questions were asked based on the inner and outer context characteristics of the FQHC system. Even though it was at times difficult for stakeholders to plan too much ahead (e.g., sustainment phase), they appreciated the systematic and sequential approach of this step. See [Table 2](#) for a summary of this step's products.

During this Task, having the voices of professional stakeholders with diverse backgrounds as well as the voices of caregivers allowed for sometimes difficult but needed conversations about the balance between the potential benefit of ACEs screenings [e.g., families perceiving the ACEs screenings as a preventive tool (Vides, B, oral communication, 7 January 2022)] and potential unintended consequences. Those potential consequences included stigmatization, given the high prevalence of ACEs among US youth, and among minority communities ([1–3](#)), and increasing discomfort and mistrust with caregivers as a result of being asked ACEs questions during a primary care visit. More specifically, caregivers shared that the questions in the PEARLS screening tool were too direct and feared that because of mandated reporting, families could become involved with child protective services and potentially separated as a result of answering the questions.

Actions to address these concerns included adding two strength-based questions to the ACEs screenings; informing caregivers in advance that these screenings were happening as "usual care" at their clinic; providing a comprehensive introduction to the ACEs screenings that explained that all caregivers were being asked these questions to avoid caregivers feeling singled out; explaining that the screenings were voluntary; and having concrete resources and services available to support caregivers after the screenings were completed, based on the child's needs. Champions were identified to carry out suggestions to overcome these concerns as reflected in [Table 2](#). In addition, stakeholders were concerned about children who

TABLE 2 Implementation Mapping: table of performance objectives by EPIS stage and constructs.

| | Responsible person | Performance objectives | Awareness and perceptions of ACEs screenings and implementation Activities | Implementation outcomes |
|----------------------|---------------------------------|--|---|---|
| Preparation | | | | |
| Inner context | | | | |
| | Leadership | PO1. Troubleshoot and remove obstacles related to the new health initiative PO2. Support employees' efforts to implement screenings, improve caregiver disclosure, and participate in study PO3. Facilitate Trauma-Informed Care (TIC) Training for clinics and advisory group | AP1. Troubleshoot and acknowledge availability of staff AP2. Prioritizes needs for this project AP3. Feel positive about overcoming barriers and maintaining quality | Use Task 1 assessment of challenges to develop a plan to integrate ACEs screenings into clinic's workflows and procedures |
| | Research team and DPP co-lead | PO1. Gain support from care team at each clinic for the ACEs screening and research study PO2. Increase awareness about TIC at each clinic PO3. Creates resource sheets for caregivers for support services and behavioral health referrals PO4. Convey support for clinic personnel during implementation PO5. Establishes clear standards for implementation | AP1. Describe ACEs screenings/TIC care as an improvement over usual care to ID toxic stress AP2. Perceive the academic-clinical partnership as contributing to the healthcare system mission and goals | |
| | Data Coordinator (Data Co-Lead) | PO1. Set up the data tracking system for the five new clinics using Tableau PO2. Set up coding and billing system for state reimbursement for the five new clinics | AP1. Clinics perceive the data tracking and billing process as easy to follow/already set up AP2. Screenings are embedded into each clinic's workflow and in an efficient manner | |
| | Clinic Managers | PO1. Agree to participate in the implementation effort for ACEs screenings PO2. Allow clinic care team to be part of workflow planning and training | AP1. Be inclusive AP2. Care teams perceive as knowing how to successfully screen (efficacy) | |
| | Information Technology Manager | PO1. Be available for questions on how to access REDCap from clinic tablets; ensure Wi-Fi access PO2. Make sure the PDF printing feature is active for screeners to print PDFs from REDCap system | AP1. Perceive the use of technology in ACEs screenings as part of clinics' screenings services | |
| | Training Department | PO1. Review training materials and provide feedback based on their expertise leading training efforts in the healthcare system | | |
| Outer context | Research Team and DPP co-lead | PO1. Reach out to ACEs Aware state policy makers and related state websites to stay abreast of changes to the ACEs Aware policy PO2. Reach out to ACEs screening tool developers (sub-contracted by the state) to share concerns from researchers, caregivers and clinic personnel and offer feedback for improvement to increase the cultural appropriateness | AP1. Clinic personnel perceive that they are abreast of ACEs Aware requirements, and that they are addressing unintended consequences and a need for cultural lens when implementing ACEs screenings | |

(Continued)

TABLE 2 (Continued)

| | Responsible person | Performance objectives | Awareness and perceptions of ACEs screenings and implementation Activities | Implementation outcomes |
|---------------------------|----------------------------------|--|--|--|
| Implementation | | | | |
| Inner context | | | | |
| Medical assistants | | | | |
| | | PO1. Attend ACEs screening and research procedures training | AP1. Knowledge / remote learning | Implementation of the ACEs screenings and strategy |
| | | PO2. Follow procedures before, during and after screenings | AP2. Perceived guidelines for research / consenting | activities with fidelity and documenting adaptations |
| | Community Health Advisors | PO3. Document to submit billing for state re-imbursement | | |
| | | PO1. Communicate with Medical Assistants and substitutes on screenings when clinic is short-staffed | AP1. Experience with CALQIC program | |
| | | PO2. Provide resources to caregivers and follow up after screenings | | |
| | Clinic Managers | PO1. Identify eligible children every week | AP1. Acknowledge and arrange for availability of screeners | |
| | | PO2. Supervise completion of screenings (5 per week) | | |
| | DPP Co-Lead | PO1. Motivates clinic staff to participate in study surveys and interviews | AP1. Experience with state-funded California ACEs Learning and Quality Improvement Collaborative (CALQIC) | |
| | | PO2. Schedules a visit to the clinic for coaching and follows up with consultation call (every 10 weeks) | | |
| Sustainment | | | | |
| Leadership | | PO1. Distribute study results within the healthcare system, and to board of directors and state | AP1. Experience disseminating research across the organization. AP2. Existing relationships with state policy makers. | ACEs screenings and strategy activities are scaled up to other clinics and become part of primary care visit practices |

Leadership: Behavioral Health Department Chair, Pediatrics Chair, Chief Clinical Officer; REDCap: (Research Electronic **Data** Capture) is a browser-based, metadata-driven EDC software and workflow methodology for designing clinical databases.

are deemed at intermediate or high-risk levels for toxic stress (based on ACEs screenings and state guidance on scoring thresholds), and in need of linkage to support services, not having access to supports due to lack of services in some of communities. As a result, the research team in collaboration with project co-leads and Community Health Advisors co-developed a centralized database using Excel with a list of family support services (including mental health services), organized by each of the clinics' counties. The database was updated bi-weekly by the PhD student, who called the main services mapped in the database to ask about estimated waiting time for patients at the time of the call. She also asked about agency closures, as well as the agencies' awareness of the ACEs Aware state policy. This database was shared with the referral specialist

and Community Health Advisor at each participating clinic to support pediatricians' efforts to link families to services after ACEs screenings.

One example of the benefits of this participatory and co-creation planning process became clear when the two initial implementation champions at the partner healthcare system (i.e., Director of Research and Data Manager) left the organization within the first 2 months of the study. Instead of causing a major disruption to the IM process, there was a relatively smooth transition, which was likely due to clearly articulated goals and planning processes. The Director of Pediatric Programs or DPP stepped in to assume a leadership role as a co-lead, and a new data manager project co-lead was promptly identified because

these two individuals had participated in Task 1 of the IM process.

IM task 3 and 4: Choose change methods and develop practical applications for program use; produce implementation protocols and materials

Given the dynamic nature and inter-dependence across the five mapping sub-groups, we are reporting the main activities of the last two Tasks together. The mapping sub-groups started by reviewing the list of factors that could serve as barriers to the ACEs screenings and strategy activities and by adding new stakeholders (e.g., caregivers during the preparation phase) and selecting the determinants that were a priority for the groups. These conversations informed the final linkage of who was doing what (agents), their performance objectives, relevant determinants of success, change methods, and practical applications in clinical settings and at the healthcare organizational levels. These linkages were built to expand and refine the implementation protocol for program use that was initiated in Task 2.

EPIS framework contributions

Given the characteristics of the ACEs innovation involving a pediatric screening procedure that requires coordinated actions from multiple implementers (e.g., clinic managers, medical assistants, pediatricians, and community health workers), and within a dynamic organizational setting, we focused on inner context areas such as workflow, training, information technology, and electronic healthcare records systems. See [Table 3](#) for a table mapping the sequence of activities and tailored practical applications and materials for the implementation protocols. Identification of effective leadership was included in the IM process, because the EPIS framework highlights this as a key factor in successful implementation of innovations. During the IM process of identifying performance objectives, the team discussed what leaders and champions can do to support implementation during all four EPIS phases and rationale for leadership support at multiple system and organization levels ([35](#)). This is an example of how frameworks can inform performance objectives and methods of change.

The lens of identifying determinants at the outer context during the planning group process also allowed the groups to identify the impact of new challenges that emerged during this phase of the process. One of those new challenges include the state of California, as a result of the COVID-19 pandemic, instituting a new policy requiring healthcare workers to show proof of vaccination by 7 October 2021 to remain in their jobs. As a result, our clinical partner lost clinic personnel (including Medical Assistants who were tasked with leading the ACEs

screenings), and the project's timeline for the implementation phase had to be postponed.

For Task 5 [i.e., evaluate implementation outcomes; ([26](#))] we will use mixed methods (e.g., REDCap, electronic health records, surveys, and interviews) to evaluate implementation outcomes by using a hybrid type 2, stepped-wedge cluster randomized trial design to test whether a multifaceted implementation strategy has a positive impact on fidelity, reach (i.e., proportion of eligible children screened for ACEs, and child level outcomes). Additional information on this IM Task 5 can be found elsewhere ([34](#)).

Discussion

Through a seven-month IM collaborative process, researchers convened and collaborated with healthcare managers, clinic personnel, and caregivers of child patients to co-create implementation protocols through an IM process, guided by the EPIS framework. A need to identify and report implementation science engagement in research has been identified as a gap in the literature ([36](#)). We utilized a systematic planning approach to capacity building at the organizational and clinic levels and within a complex FQHC safety net healthcare system. The COVID-19 pandemic lengthened the IM process from the original plan of 5 months to 6/7 months due to staffing shortages and operational challenges at the clinics, which made scheduling frequent group meetings difficult. COVID-19 also made it harder for clinic staff to plan several months into the future, given the many uncertainties associated with the pandemic. In addition, the timeline for starting ACEs screenings had to be delayed due to lack of clinic personnel due to pandemic-related turnover. All meetings were conducted online and using audio and screen sharing only. Minor technical difficulties were common but not serious enough to impact the group process. Conversations with caregivers were held using cellphones, with two note-takers also participating.

We faced challenges during this process. A few stakeholders, mostly representing the Information Technology department, shared concerns about already having a plan in place; they had worries about their time and about not being part of the initial grant proposal conversations. The first author explained that having all stakeholders available for grant writing was not feasible and that the initial work was done with members of the research department and TIC workgroup at the FQHC. In addition, through IM, we were able to engage in a participatory process that helped develop the specific activities that were suitable for stakeholders and each clinic's workflow. This information seemed satisfactory for stakeholders to move forward. In addition, we held 15 follow-up meetings with smaller groups of stakeholders (e.g., care team members only); and separately with those with less perceived power (e.g., clinic staff

TABLE 3 Implementation Mapping: Steps 3 and 4.

Preparation phase**Outcome: Develop a plan to integrate ACEs screenings into clinics' workflows and procedures**

| Agent | Performance objectives | Determinants (why would they do these things?) | Change methods | Practical applications and materials |
|--------------------------------|---|--|---|---|
| Leadership | PO1. Remove obstacles related to ACEs screenings and study procedures activities PO2. Support employees' efforts to implement screenings, improve disclosure from caregivers and participate in study PO3. Facilitate Trauma Informed Training for clinics and advisory group | Perceived added value to care/ improved care Perceived expectations / norms | Information transfer Persuasive communication through providing added care value | Quarterly meetings with academic partners and DPP Memo emailed to clinics endorsing the projects |
| DPP Co-lead | PO1. Gain support from care team at each clinic for the ACEs screening and research study PO2. Increase awareness about TIC at each clinic | Previous experience with CALQIC Time Familiarity | Persuasive communication | Power point slides and discussion points in webinars; Provide evidence of success of the ACEs screenings already in place at two other clinics since 2020 |
| Data Co-lead | PO1. Set up the data tracking system for the new five clinics using Tableau PO2. Set up coding and billing system for state reimbursement for the new five clinics | Time Expertise with data and billing systems for all programs at the organization | Skill building Modeling Persuasion | Dashboard system created for ACEs screenings data entry and retrieval (i.e., Tableau) |
| Clinic Managers | PO1. Agree to participate in the study PO2. Allow clinic care team to be part of workflow planning and training | Leadership support Time | Monitoring and feedback Facilitation | Emails and communications during staff meetings |
| Information Technology Manager | PO1. Agree to be contact person for technical problems with the iPad Tablets for screenings | Expertise in use of iPad Tablets in primary care | Information transfer Skill building Technical assistance/capacity building | Emails Phone number |
| Training Department | PO1. Lead future ACEs screening training efforts at the organization level | Expertise in leading personnel trainings | Facilitation Organizational planning | Training manual reviewed by this team and materials branded with the organization's logos, templates |

Implementation Phase**Outcome: Implementation of ACEs screenings and strategy activities with fidelity and documenting adaptations**

| Agent | Performance objectives | Determinants | Change methods | Practical applications and materials |
|--------------------|--|--|--|---|
| Medical Assistants | PO1. Attend ACEs screening and research procedures training PO2. Follow procedures before, during and after screenings PO3. Document to submit billing for state reimbursement | Having a working relationship with providers Time Proximity to patients / data Training | Skill building and guided practice Information transfer | Online videos Training manual and in-person orientation Trained coaches |

(Continued)

TABLE 3 (Continued)

Implementation Phase**Outcome: Implementation of ACEs screenings and strategy activities with fidelity and documenting adaptations**

| Agent | Performance objectives | Determinants | Change methods | Practical applications and materials |
|-------------------------------|--|--|--|--|
| Community Health Advisors | PO1. Communicate with Medical Assistants and sub on screenings when clinic is short of personnel PO2. Provide service and educational resources to caregivers as part of follow up after screenings | Training Expertise Trust from caregivers/patients Confidence on the care team's ability to support families after the ACEs screenings are completed and to address their needs | Modeling to ACEs screeners | Weekly updated excel database created for these screenings with local resources for mental health/behavioral referrals and waiting times Resource sheets for caregivers |
| Clinic Managers / DPP Co-lead | PO1. Identify eligible children every week PO2. Supervise weekly completion of screenings PO3. Emphasize clinics' procedures already in place to address mandatory reporting and risk management with patients, and as part of the ACEs screenings Confidence on the care team's ability to support families after the ACEs screenings are completed and to address their needs | Perceived benefits of ACEs screenings for patients PO2. Supervise weekly completion of screenings PO3. Emphasize clinics' procedures already in place to address mandatory reporting and risk management with patients, and as part of the ACEs screenings Confidence on the care team's ability to support families after the ACEs screenings are completed and to address their needs | Supervisor audit and monitoring Information transfer and skill building | Academic partners presenting at the clinics' staff meetings Clinic managers included in planning meetings and ongoing coaching site visits ACEs written manual and training of care team |

Sustainment phase**Outcome: ACEs screenings and strategy activities are scaled up to other clinics at the healthcare system and they become part of primary care visit practices**

| Agent | Performance objectives | Determinants | Change methods | Practical applications and materials |
|---------------------|---|-----------------------------------|---|---|
| Leadership | PO1. Distribute study results within the healthcare system, board of directors and state | Authority Outcome expectations | Increased commitment through results data | Short study results shared with leadership and scientific community |
| Training Department | PO2. Observe ACEs screenings trainings conducted in 3 of the five clinics PO2. Lead ACEs screenings trainings in the last two clinics PO3. Lead ACEs screenings trainings in future clinics | Training Expertise | Facilitation through templates and procedures | Include ACEs screenings training materials in the healthcare system website |

Leadership: Behavioral Health Department Chair, Pediatrics Chair, Chief Clinical Officer.

and caregivers) to make those individuals feel safer and more comfortable in speaking directly.

Despite these challenges, including those posed by COVID-19 and its impact on the partner healthcare system and workforce, we were able to convene diverse groups of stakeholders and gather important information using a participatory approach. This approach increased buy-in among stakeholders. This support is reflected in the fact that the partner healthcare system reduced its collaborations with academic partners in 2020, and our study was one of only three studies approved to move forward despite the organizational stress brought about by the pandemic. Having a template of an implementation strategy to begin with was helpful to move the mapping process conversations along in a structured manner, while allowing changes on the strategy activities (forms) and preserving its goals (functions) (37). Lessons learned to engage stakeholders prior to the start of the funded study included establishing an academic-clinical partnership to work on relevant pro-bonus projects, creating a TIC workgroup comprised of academic partners and clinical personnel, including clinic champions in the grant budget to cover some of their time from day one of funding, and for clinical champions to share the background of the research behind ACEs through a monthly newsletter.

We acknowledge limitations in this study. The project started during the COVID-19 pandemic in May of 2021, which strained the FQHC system even more in terms of financial losses and workforce shortages. Related to this challenge, we relied on online meetings and clinic personnel often had technical difficulties accessing the meetings, and several of the stakeholders did not have video capacity. Despite these challenges, we were able to complete the IM planning process by having a flexible timeline, close communication within and across IM subgroups, and by having back up meeting times.

There are many commitment strategies that we have used with the most important that we used to overcome the obstacles and barriers related to ACEs screenings was linking with and supporting initiatives focused on trauma-informed care that can be used within health systems and practices. It is also important to understand that health systems are not static and if ACEs screenings as a routine practice in primary care settings are to be sustained, there should be sufficient attention to institutionalizing screenings, the incorporation of ACEs in the mission and vision of organizations as well as in the policies and procedures needed to communicate to all providers and staff that this is something that is expected, supported, and rewarded in the organization. It is also essential to increase the capacity of healthcare systems to link families to services as a result of these screenings, while addressing the limited capacity of local communities, especially rural and under-resourced areas (38), to absorb those referrals.

This study can inform other efforts, as projects seldom start from a blank slate. Often, there are implementation

strategies already planned or discussed during the early phases of the implementation process. However, tailoring and adaptation are almost always needed, and collaboration can help to support and manage these processes (39). IM can be used as an evidence-informed approach for the exploration and preparation phases of the implementation process as a starting point for collaborative work with stakeholders. The goal of this process is to develop the protocols (who, how, why, when) and to tailor them to local clinic's workflows and procedures to increase the innovation's uptake. Mixed methods (REDCap, electronic health records, surveys and interviews) will be used to evaluate implementation outcomes by using a hybrid type 2, stepped-wedge cluster randomized trial design to test whether a multifaceted implementation strategy has a positive impact on fidelity, reach (i.e., proportion of eligible children screened for ACEs, and child-level outcomes).

Overall, the IM process that was informed by the EPIS framework facilitated consideration of outer system and inner organizational contexts as well as bridging factors that linked them. Our collaborative process allowed for a suitable approach for the inclusion of diverse stakeholders to co-engage in planning and pre-implementation of a complex health intervention. These interventions are delivered in dynamic and interdependent systems and require coordinated actions from multiple actors (40–42). For this study, the implementation of the ACEs screenings is immersed in a complex and dynamic outer state context related to the ACEs Aware screening policy, and to COVID-19 workplace requirements. In addition, the screenings require involvement of multiple individuals in a care team embedded within a clinic, which is in turn embedded in a large FQHC health system. However, inner context processes were the focus of much of the IM activities. For example, the community services representative person introduces the new health initiative to caregivers when they arrive at the clinic; medical assistants conduct the ACEs screenings; and pediatricians discuss the results of the screenings with families and make referrals to community services as needed. Then, referral service specialists follow up on those referrals with families to support engagement in services. One example of the benefits of stakeholder participation on these tasks was reflected in the fact that researchers observed higher buy-in and leadership from members of care teams and clinic managers who attended the IM sessions compared to those who were not part of the IM process. The former became champions within their own care teams and with their peers. In addition, the IM process allowed the research team to identify concerns among implementers and end-users related to health equity and unintended consequences of ACEs screenings and to set in place actions to address them early on during the preparation phase of EPIS. The focused IM process allowed the team to be more resilient to contextual changes and to be able to meet project milestones.

This study presented an example of how the team engaged diverse stakeholders across all IM Tasks. We also present how to integrate the IM process within a complex health system, while being guided by an implementation framework. The EPIS framework embodies process, determinants, and potential mechanisms in the implementation process. The synergy between IM and EPIS helped to frame conversations and discussions and to provide a conceptual starting point for this collaborative process. Integrating such an implementation theory with IM activities has the potential to advance implementation science while improving public health.

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.

Author contributions

MP is the principal investigator (PI) and had the main idea for this study. She was the lead for the IM process and meeting facilitator, wrote the first draft of this manuscript, and was responsible for all revisions. MF consulted with the PI on the use of the IM process in this project and attended IM sessions. GJ attended some of the IM sessions and coordinated the IM sub-groups' communication and logistics. JD attended an IM session and contributed to the literature review. GA has been involved with the project since conception, has supported the use of the EPIS framework in general and during the IM process

and attended IM sessions. All authors have read, edited, and approved the final manuscript.

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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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Implementation mapping for tobacco cessation in a federally qualified health center

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Background: Implementation mapping (IM) is a promising five-step method for guiding planning, execution, and maintenance of an innovation. Case examples are valuable for implementation practitioners to understand considerations for applying IM. This pilot study aimed to determine the feasibility of using IM within a federally qualified health center (FQHC) with limited funds and a 1-year timeline.

Methods: An urban FQHC partnered with an academic team to employ IM for implementing a computerized strategy of tobacco cessation: the 5A's (Ask, Advise, Assess, Assist, Arrange). Each step of IM was supplemented with theory-driven methods and frameworks. Data collection included surveys and interviews with clinic staff, analyzed via rapid data analysis.

Results: Medical assistants and clinicians were identified as primary implementers of the 5A's intervention. Salient determinants of change included the perceived compatibility and relative priority of 5A's. Performance objectives and change objectives were derived to address these determinants, along with a suite of implementation strategies. Despite indicators of adoptability and acceptability of the 5A's, reductions in willingness to adopt the implementation package occurred over time and the intervention was not adopted by the FQHC within the study timeframe. This is likely due to the strain of the COVID-19 pandemic altering health clinic priorities.

Conclusions: Administratively, the five IM steps are feasible to conduct with FQHC staff within 1 year. However, this study did not obtain its intended outcomes. Lessons learned include the importance of re-assessing barriers over time and ensuring a longer timeframe to observe implementation outcomes.

KEYWORDS

implementation science (MeSH), implementation mapping, tobacco cessation, 5A's smoking cessation guidelines, community health, community-engaged dissemination and implementation

Introduction

Community-engaged dissemination and implementation (CEDI) research is a process of collaboration and shared decision-making between academics and community-based healthcare providers and recipients (1). CEDI is presumed to mitigate health inequities by incorporating the perspectives of individuals typically marginalized from traditional research paradigms (1, 2). Implementation Mapping (IM) (3) is a CEDI method with growing popularity (2, 3). IM hybridizes implementation science principles with a process for multi-level health promotion called intervention mapping. IM defines five change management steps (3). Despite being touted as a promising strategy (4, 5) and multiple examples of planned use *via* study protocols (4, 6, 7) there are few publicly accessible descriptions of applying the IM process (8–10) and among these only one reported use through all steps (8). This complete example effectively illustrates IM as a feasible and effective method, however, it was also bolstered by significant resources (a 4-year timeline and five funding sources). We offer an example of using IM on a smaller scale within a busy, urban federally qualified health center (FQHC). The lessons learned from this pilot study offer perspective on the feasibility (11) of conducting IM in resource-limited settings.

Materials and methods

Tobacco cessation is an important public health effort (12). Despite declining rates of tobacco use in recent years, tobacco rates among low-income individuals remain unchanged (13). Community clinics and primary care providers are front line forces for the prevention and treatment of harmful health behaviors, including tobacco use. This project sought to use IM to implement an evidence-based tobacco cessation strategy within a community healthcare center. Table 1 provides the definitions of terms used throughout this text.

Setting: Federally qualified health center

Nationally, tobacco use rates are highest among those at or below 200% of the federal poverty level (13). In Durham, North Carolina tobacco use remains a leading cause of death in the area (14). At one local FQHC, 97% of patients have income at or below 200% of the federal poverty level (15). This FQHC serves over 34,000 adult and pediatric patients per year. In 2015, the FQHC attempted to implement an evidence-based specialty tobacco cessation clinic with trained tobacco treatment specialists. Despite early successes, the program was not sustained due to staff turnover. To address this concern, the FQHC's director of behavioral health (CC) partnered with an academic with expertise in implementation science and clinical

psychology (SW) to address patient tobacco use and design a sustainable program.

The present project sought to create a package of implementation strategies designed to facilitate uptake and sustainment of an evidence-based, technology-assisted tobacco cessation tool at the FQHC. In consultation with clinician and researcher colleagues, the CEDI leadership team selected computer-facilitated delivery of evidence-based 5A's due to its known impact increasing delivery of tobacco cessation treatment in medical settings (16, 17).

Intervention: 5A's intervention model for tobacco cessation

The 5A's intervention model (Ask, Advise, Assess, Assist, Arrange) was developed as a guide to help clinicians treat tobacco use (12). One method proposed to facilitate clinician use of the 5A's is to use a computerized process with handheld digital devices (16–18). While this strategy has proven effective, there are some implementation issues with introducing handheld devices into clinical encounters where they are not normally used (16). The present study sought to overcome implementation barriers to computerized 5A's by implementing this evidence-based intervention into the electronic health record (EHR) system at an FQHC. This would enable the 5A's to be completed with fidelity directly through the EHR rather than using any outside devices or manuals. However, it is recognized that technology-assisted smoking cessation tools may suffer significant challenges in implementation including limited staff knowledge of resources, limited familiarity with tobacco cessation practices, and lack of organizational support (16, 19). Numerous factors (20) may affect uptake and sustainment, including disruption of clinic workflow, as well as perceptions that technology is burdensome and ineffective (21, 22). Systematic implementation planning and support may improve uptake and sustainment of technology-dependent tobacco cessation interventions. In selecting an implementation method, the implementers prioritized equity-focused options that accounted for situations unique to community-academic collaborations.

CEDI method

Use of CEDI methods are critical in FQHC settings, as patients served by these clinics are often among the most disenfranchised (23). Derived from literatures on health promotion and implementation science, implementation mapping (IM) is a CEDI process that includes five steps for assisting organizations in planning and enacting change strategies. The steps detail (1) conducting a needs

TABLE 1 Definitions of key terms.

| Term | Definition |
|-------------------------|--|
| 5A | Ask, Advise, Assess, Assist, Arrange: A health provider-delivered tobacco cessation strategy. |
| Adopters | Decision makers who hold power to decide whether an innovation is adopted; in this example, clinic leaders like medical chiefs. |
| CEDI | Community-Engaged Dissemination and Implementation: a process of collaboration and shared decision-making between academics and community-based healthcare providers and recipients. |
| CFIR | Consolidated Framework for Implementation Research: a comprehensive model composed of determinants with empirical and theoretical support for implementation relevance, such as characteristics of the intervention, inner setting, and outer setting. |
| Change objectives | The behaviors necessary for each FQHC staff role to exhibit in order to successfully implement an innovation. |
| Determinants | Barriers and facilitators of successfully implementing the innovation. |
| EHR | Electronic Health Record: a digital system for managing patient health information. |
| EPIS | Exploration, Planning, Implementation, Sustainment: A four-stage conceptualization of the implementation process. |
| FQHC | Federally Qualified Health Center: Community-based health clinic that receives US federal funds for providing primary care services to underserved areas. |
| IM | Implementation mapping: A five-step change management process. |
| Implementation outcomes | Expected and observed indicators of successful innovation adoption, usage, and maintenance. These are markers of interim progress and may be assessed early, mid, or late in the project. |
| Implementers | Individuals responsible for regularly executing the innovation to ensure it becomes routine practice; in this example, healthcare providers. |
| Innovation | A policy, program, or process new to the setting, alternatively referred to as an intervention; in this example, the 5As. |
| Performance objectives | Tasks that define the specific steps or behaviors needed to obtain implementation outcomes. |

and assets assessment within the setting, (2) identifying implementation outcomes and performance objectives based on identified change determinants, (3) selecting a theory-based method and strategies to affect these determinants, (4) developing implementation protocols and materials, (5) evaluating implementation outcomes (3). Standardized measures or tools are not yet available for enacting each step, but guidelines exist to inform the process. Key among these is the use of theory to inform each step (3).

The current project used the Consolidated Framework for Implementation Research (CFIR) (24) to design needs assessment materials and identify determinants of change. Determinants are the barriers and facilitators affecting whether the innovation is adopted, scaled, and maintained; these are classified into discrete constructs related to the implementation process or the innovation itself (24). CFIR is a comprehensive model composed of determinants with empirical and theoretical support for implementation relevance, such as characteristics of the intervention, inner setting, and outer setting. This includes knowledge (staff familiarity with the innovation), compatibility (perceived fit between the innovation and organization), relative priority (perceived importance of the innovation), and the implementation climate (staff receptivity to the innovation) (24).

For designing implementation strategies (methods or techniques used to enhance the adoption, implementation, and sustainability of a clinical program or practice) (25, 26), a

systems science method (27) was used to assess the variable impact and effort of each potential strategy and adapted for developing implementation strategies within this FQHC (28). Consistent with community-engaged practices (2), this process enabled power-sharing by identifying staff-driven strategies, later mapped onto a taxonomy of expert-identified strategies (26) for consistency in reporting.

A well established conceptualization of implementation outcomes (29) assisted in reporting progress for the final step. Unlike service or population outcomes, implementation outcomes include both expected and observed indicators of successful innovation adoption, usage, and maintenance (30). These types of outcomes identify markers of interim progress in the implementation efforts and may be assessed temporally early, mid, or late in the project (29). Debate about conceptualizing implementation outcomes (30) unfolded in the literature within the timeframe this pilot study was conceptualized and executed. Reporting for step 5 considers the anticipated implementation outcomes as perceived acceptability [degree of satisfaction or palatability of the innovation (29)] and adoptability [the likelihood key decision-makers will decide to put the innovation into place (30)]. Actual implementation outcomes are adoption [the extent key decision makers decide to put the innovation into place (30)] and implementation [the extent the innovation is in place (30)]. Of note: throughout this paper the word “feasibility” refers to the common term for a preparatory study (11) rather than the “feasibility” as defined in implementation outcomes (29).

Data collection and analysis

Participants included multiple groups of FQHC clinical and administrative staff: physicians, advanced practice providers, behavioral health specialists, nurses, medical assistants, patient educators, and administrative and clinical leaders. Inclusion of different clinic roles aimed for diversity of opinions to generate staff-driven solutions. We used quota sampling (31) to ensure representation across clinic roles (physicians, advanced practice providers, behavioral health specialists, nurses, medical assistants, and patient educators) and settings (internal medicine, family medicine, and pediatrics). All clinic staff members who contacted the study coordinator for participation were included in the study. Participants ($N = 12$) were interviewed using open-ended prompts for the needs assessment and determinant identification. This sample size was selected given its high likelihood of reaching data saturation (51). These interviews were recorded, transcribed, and analyzed using a rapid analytic method in which data reduction occurred prior to coding (32). Concept codes were determined *a priori* with the goal to rapidly inform process (33). Interview results informed Step 4, the development of implementation protocols and materials. Surveys were then conducted with FQHC clinic and administrative leaders ($N = 7$), and descriptive statistics reported to identify performance objectives and gather early-stage implementation outcomes. Informed consent was obtained for all participants. Only non-FQHC study staff had access to identifying information of staff participants. All FQHC investigators saw only de-identified, aggregated data.

Figure 1 shows the project timeline by key activity, IM step, and implementation stage. Key activities here are data collection, analysis, and development of materials. Implementation stages are discerned from a common stage framework that determines the stages of change that occur within an organization: Exploration, Preparation/Adoption, Implementation, and Sustainment (EPIS) (47). Both IM and EPIS are heuristics for describing the process, but both can be iterative rather than linear processes. Therefore, key activities do not always occur sequentially according to these steps and stages.

Results

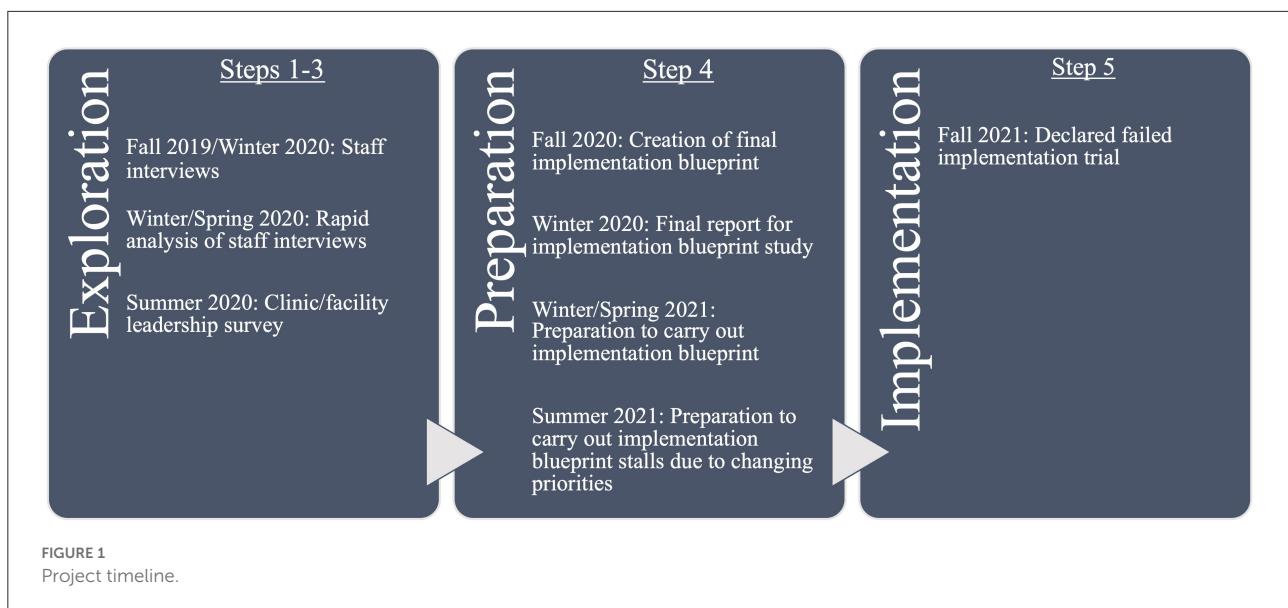
Over the course of 12 months, all five IM steps were planned and executed iteratively, as described in the original IM process (3). However, not all objectives and outcomes were achieved. Results below illustrate the process as it was planned and unfolded, but readers are advised to note that the implementation package described in Step 4 was not adopted, and therefore the planned activities and objectives in Step 3 were not undertaken. In Step 5, anticipated outcomes showed promising indicators of eventual actual implementation outcomes; this is further described in that step.

IM step 1: Needs assessment

Implementation adopters were identified by soliciting opinions about the most appropriate staff member to oversee the process of rolling out the 5A's tool in the FQHC's EHR. In IM, implementation adopters are the decision makers, such as leaders, who hold power to decide whether an innovation is adopted (3). There was not clear consensus on this question, with most staff endorsing multiple possible adopters, generally among those who already held clinic leadership positions. Most staff endorsed either the clinical chief for each department or the head of behavioral health. Three interviewees (25%) suggested that providers be the ones to decide to adopt the intervention.

Once implementation adopters are identified, IM indicates adopters be involved in the subsequent planning process. Throughout planning, preparation, and implementation there was shared decision-making and collaboration between adopters (CC, HE) and academic partners (SW, JD, PC), in activities including brainstorming sessions, planning meetings, and addressing issues around participant selection, qualitative methodology, selection of implementation framework, and identifying staff engagement strategies.

Choices of appropriate implementers varied across the 5A's steps. Implementers, per IM, are the individuals responsible for regularly executing the innovation and ensuring it becomes routine practice (3). Clinic staff interviewees ($N = 12$) were given options to endorse one or more roles for each step, thus number of endorsements exceeded the number of interviewees. Clinic staff unanimously identified medical assistants as having the knowledge and skills to conduct the first 5A's step of asking patients about tobacco use. Per the second 5A's step of advising on tobacco cessation, most ($N = 11$) staff stated that medical providers were the most appropriate implementers. Concerning the third 5A's step (assessing patient willingness to quit) several staff identified multiple potential implementers. Most staff endorsed that medical providers should conduct the motivational interviewing (34) necessary for this step, yet there were also four mentions each of behavioral health providers and medical assistants being capable of conducting this portion of the intervention. The fourth 5A's step (assist the patients to quit) was seen as a joint effort between medical and behavioral health providers, with nine endorsements of medical providers conducting this step and prescribing nicotine replacement therapies, and six endorsements of behavioral health support as necessary for counseling or consultation. No staff suggested medical assistants as implementers for this step. For the fifth 5A's step (following up with patients), staff were divided on the optimal implementers. There was equal endorsement for the medical provider, behavioral health provider, and whomever was conducting the primary intervention (e.g., pharmacotherapy, counseling, etc.). Responses at this step were contingent upon who the interviewee had identified as the primary responsible party in the previous step. Collectively,



identified implementers of the 5A's intervention were clinical staff members, particularly medical assistants, nurses, primary care providers, and behavioral health providers.

IM step 2: Identify adoption and implementation outcomes, performance objectives, determinants, and change objectives

Performance objectives and implementation outcomes

Performance objectives were derived from surveys administered to FQHC leadership ($N = 7$) and from follow-up meetings with the CEDI leadership team (CC, SW, HE, PC, JD). These objectives intend to define the specific steps or behaviors needed to obtain implementation outcomes. Performance objectives gleaned from leadership surveys are displayed in Table 2.

Determinants

Interviewers asked FQHC staff open-ended questions pertaining to potential determinants [i.e., barriers and facilitators of successfully implementing the intervention (24)]. These determinants included staff knowledge of the 5A's intervention, compatibility of 5A's with current clinic practices, implementation climate (i.e., staff receptivity to 5A's), and relative priority of implementing 5A's. Most ($N = 9$) staff reported no familiarity with the 5A's intervention, while the remaining staff ($N = 3$) stated they had a vague recollection of having learned this previously, such as in graduate training.

All reported perceiving the 5A's as compatible with current practices, and several staff said they routinely one or more of the steps as part of usual care. One respondent clarified that they would be opposed to the process if it were mandated, preferring it to be optional and limited to patients who were known tobacco users. Two respondents indicated more information would improve perceived compatibility, such as further education on the 5A's or seeing evidence of the innovation's efficacy in other clinics. Five respondents noted that one barrier to compatibility is the perceived burden of time and effort to conducting the 5A's, which could be mitigated by streamlining the documentation process. Regarding implementation climate, the majority ($N = 8$) of respondents were in favor of integrating the 5A's into the EHR, some expressing strong optimism about its potential. Three interviewees expressed neutral or ambivalent sentiment, such as: "Adding [this to the] chart is both great and challenging. [There are already] so many other things to [the EHR]." One staff member at the pediatric clinic was opposed to the innovation, stating that they already had a template for asking teenagers about smoking and thought the yield would be low in this population. Per the perceived priority, three participants indicated the tobacco cessation intervention was a priority while four staff members indicated it was a low priority. Six respondents did not state whether it seemed like a priority: five of those indicated the intervention seemed feasible and one stated it would depend on the clinic flow.

Change objectives

Change objectives were developed by cross-walking previously identified performance objectives with determinants of change. Change objectives are the behaviors necessary for FQHC staff to exhibit in order to successfully implement the

TABLE 2 Performance objectives and implementation outcomes.

| Target role | Implementation outcomes | Performance objectives (tasks/behaviors) |
|---|---|--|
| Medical chiefs: Adopter | Decide to adopt the 5A's intervention package for integration into EHR. | 1. Agree to integrate 5A's into clinical care 2. Agree to integrate 5A's into EHR 3. Dedicate time for clinic staff training 4. Gain support from clinic staff |
| Medical assistants: Implementer (5A steps 1–2) | Complete first two steps of 5A's intervention, appropriately document and communicate to clinicians. | 1. (Ask) Ask whether patient is a current or past tobacco user, then classify in EHR 2. Communicate results to clinician. |
| Clinician (physicians, advanced practice providers): Implementer (5A steps 3–5) | Receive information completed by Medical Assistants, complete final three steps of 5A's intervention, appropriately document. | 1. (Assess) Assess if the patient is willing to make an attempt to quit tobacco use. Document in EHR. 2. (Advise) If current user, advise patient to quit using clear and personalized manner. Document in EHR. 3. (Assist) Use brief motivational interviewing to increase likelihood of quit attempt. Deliver appropriate prescription. Document in EHR. 4. (Arrange) Refer to behavioral health or state quitline as needed. Schedule follow-up visit as needed. Select tobacco use after-visit summary with information on free cessation resources. Document in EHR. |
| Behavioral health chief: Maintainer | Leverage relationship with clinic leadership to ensure ongoing evaluation and quality improvement of 5A's process. | 1. Talk with clinic leadership about implementation plans and concerns. 2. Participate in the planning team. 3. Advocate for ongoing time and resources for assisting implementers. |

5A's. In *Table 3*, a sample of change objectives is shown with columns corresponding to the necessary change in attitudes, knowledge, and skills for various FQHC roles. Each cell lists an observable behavior that would be indicative of a change in attitude, knowledge, or skills. These are marked by the expectation that each change objective would affect the perceived compatibility of 5A's or the perceived relative priority of 5A's.

Step 3: Select theoretical methods and design implementation strategies

The selection of implementation strategies requires identifying techniques to influence determinants gleaned from the previous step. There is much debate in the literature about best methods for selecting strategies, with general consensus that a systematic and constituent-influenced approach is

optimal, with the entire IM process often cited as an option (35, 36). Here, a three-component approach was adapted from the effort-vs-impact assessment method of operations planning, fully described elsewhere (28). In brief, this approach charted strategies according to effort (low/high) and impact (low/high). The first component assessed the potential effort to make the technological strategy usable according to availability (i.e., how accessible the technological infrastructure is to clinic staff) and familiarity (i.e., how much training would be required for staff). The second component assessed potential impact of the strategy (i.e., improving monitoring, communication, or data collection). The third component assessed whether to use or abandon the strategy by cross-referencing results from the previous two components. Rapid analysis of staff interviews and leader surveys were coded according to a spectrum of perceived effort and impact (28). Results identified seven priority strategies, primarily enacted by the CEDI support system (37) (SW, CC) to target behavioral change in the delivery system (medical assistants and clinicians). See

TABLE 3 Change objectives by implementation role.

| Role | Change objectives | | |
|---|--|---|--|
| | Attitude | Knowledge | Skills |
| Medical chiefs: Adopter | <p>P: Express importance of addressing tobacco use</p> <p>P: Express that 5A's process is everyone's job</p> <p>C: Express ease of use with computerized process</p> | <p>P: Clarify each staff member's role in the process</p> <p>C: Clarify process and room for flexibility within existing clinic workflows</p> | <p>C: Monitor success in implementation using data for audit and feedback</p> |
| Medical Assistants: Implementer (5A steps 1-2) | <p>P: Express importance of addressing tobacco use</p> <p>C: Identify parts of 5A's that are already routine practice</p> <p>C: Express ease of use with computerized process</p> | <p>P: Explain role of tobacco use for long-term health outcomes</p> <p>P: Describe number of patients who are tobacco users</p> <p>P: Note differences in 5A's depending on age of patient</p> <p>C: Explain role in 5A's process</p> | <p>C: Demonstrate ability to use computerized 5A's process, including locating and entering patient tobacco use information into EHR fields</p> <p>C: Demonstrate ability to notify appropriate provider(s) of next steps in 5A's</p> |
| Clinician (physicians and advance practice providers): Implementer (5A steps 3-5) | <p>P: Express importance of addressing tobacco use</p> <p>P: Express pro/cons of 5A's process</p> <p>C: Identify parts of 5A's that are already routine practice</p> <p>C: Express ease of use with computerized process</p> | <p>P: Note differences in 5A's depending on age of patient</p> <p>P: Explain why early intervention is important for health outcomes</p> <p>C: Explain interventions for tobacco use by type (e.g., combustible, vaping, dip/chew)</p> <p>C: Explain amount of time expected for 5A's process</p> <p>C: Explain role in 5A's process (e.g., prescribing, referring)</p> <p>C: Explain information to be included in patient after-visit summary</p> | <p>C: Demonstrate ability to use computerized 5A's process, including locating and entering patient tobacco use information into EHR fields</p> <p>C: Demonstrate use of age-appropriate brief behavioral interventions (e.g., MI) for tobacco use</p> <p>C: Demonstrate ability to successfully prescribe tobacco cessation medications</p> <p>C: Demonstrate ability to provide referral options</p> |

C, Compatibility; P, Relative Priority.

Table 4 for a breakdown of the proposed strategies [described with best-practice language from a common taxonomy of implementation strategies (26)], with corresponding change objectives, and specification per best practice guidelines for describing implementation strategies (25).

Step 4: Produce implementation protocols and materials

This step aims to enact the implementation strategies through content development. For the strategy of incorporating elements of the 5A's intervention into the EHR, the implementation support team enlisted assistance from EHR analysts (from the FQHC and academic affiliate) and tobacco cessation experts from the academic affiliate. This team created pharmacy order sets within the EHR to speed clinician access to different prescription options for the Arrange step

while completing the patient visit, and a sample after visit summary page—including cessation tips and guidance on how to use medication therapies—to be provided to patients. The team also created a data analytic strategy for pulling summaries of tobacco users and completion of 5A's steps (i.e., advice to quit, pharmacotherapy prescriptions, printing patient after-visit summaries, and referrals for behavioral treatment).

Educational materials for adopters included workflow diagrams and detailed flowcharts of decision points and documentation requirements for each of the 5A's steps. Different flowcharts were created for the adult and pediatric clinics to account for differing algorithms. These specified when in the patient visit the innovation was to be enacted (i.e., after taking vital signs) and suggested prompts to start the conversation with patients (e.g., during the Advise step a clinician could state “Can I share with you why I think it is important to your health for you to stop using tobacco products, and how I can help you?”). To enhance usability, these flowcharts were limited to one page with clear font and large text.

TABLE 4 Implementation strategies generated by implementation mapping.

| Strategy | Change objective | Specification |
|------------------------------------|---|--|
| Change EHR record systems | Skills for adopters and implementers | |
| Use data experts | | Data experts at academic partner and FQHC will add optional 5As-concordant smart forms and patient after-visit summaries on a trial basis (3 months) to the EHR that will be activated by tobacco fields already being used. |
| Remind clinicians | Skills for implementers | Automatic reminders will be added on a trial basis (3 months) to the EHR to address tobacco use. These will not be mandatory to complete. |
| Develop academic partnerships | Attitude and knowledge of adopters and implementers | The IM protocols and materials will be co-produced by the FQHC and academic partner at the beginning of the implementation period. |
| Work with educational institutions | Attitude, knowledge, and skills for implementers | The academic partner will create 5As educational materials and facilitate educational sessions with FQHC clinicians and staff over the course of 3 months during catered lunch breaks. |
| Develop educational materials | | |
| Conduct educational meetings | | |
| Auditing and feedback | Skills for adopters and implementers | Data experts at the academic partner and FQHC will create an audit tool for supervisors to easily pull tobacco measures, prescriptions, and quitline referrals by clinic. |

Faculty from the local academic affiliate (which runs a tobacco treatment specialist training program) provided sample lecture slides and quick-reference handouts for the development of clinician and staff educational materials.

Step 5: Evaluate implementation outcomes

Since this study was an implementation pilot, outcomes focus on the broad feasibility of the IM process (11). The IM process took approximately 12 months. True to the iterative nature of IM, feedback from FQHC staff and leadership informed revisions of the implementation package. The process of conducting the needs assessment and defining determinants, objectives, and strategies was feasible with a small, collaborative team.

Per anticipated implementation outcomes, in the early IM stages staff interviews indicated a majority were either in favor (67%) or neutral toward (17%) implementing the computerized 5As process, indicative of good acceptability. Similarly, the majority (86%) of clinic leaders were in favor of proceeding with the plan to implement the computerized 5As, indicative of adoptability. However, during review of the final implementation package, FQHC executive leadership expressed reductions in willingness to integrate the 5As intervention package as shown in the protocols and materials.

In meetings following the development of the implementation package, leadership and clinicians involved

in the CEDI team reported that the COVID-19 pandemic had caused significant strain on the FQHC, as well as its staff and clinicians. Specific barriers to proceeding with implementation were consistent with those originally voiced by both staff and clinic leadership during IM steps 1 and 2. Although in the early steps of IM limited clinical appointment time and risk of staff burnout were perceived as manageable barriers to implementation, they later became salient to organizational leadership as barriers—and perhaps insurmountable due to the pandemic.

Given the limited time frame of the study funding period and competing priorities of FQHC staff and leadership, further work on revising the implementation package has not been possible. Changes to the EHR have not yet been made, trainings have not been completed, and requests have not been made to the medical staff to change care or documentation of tobacco cessation. Despite promising early indicators of acceptability and adoptability, at time of publication the actual implementation outcomes for implementers (medical assistants and clinicians) were unfortunately not achieved.

Discussion

The five steps of implementation mapping were conducted with an FQHC for implementing a computerized tobacco cessation intervention. Despite following IM recommendations and achieving early implementation outcomes of acceptability and adoptability, the intervention was not adopted. While not yet successful in its intended efforts, this project offers important

lessons for future use and improvement of IM application in community clinics.

Lessons learned

The most significant barrier to achieving intended outcomes is not accounted for by standard implementation methods: a global pandemic. CFIR and other implementation models recognize the vast effect of broad external factors on implementation success (24, 37). Changes in outer context (local, national, and global) affect the inner context (individual, team, organizational). Without data to investigate the salient factors after the onset of the COVID-19 pandemic, the authors surmise that the substantial effect of the pandemic on healthcare organizations altered FQHC staff perceptions about 5A's priority and compatibility. This is likely due to rapid rollouts of new disease mitigation processes and a sudden increase in telehealth technology needs. Additionally, the determinants may have been affected by the changing financial, temporal, and logistical resources of the FQHC. The initial needs assessment was instrumental for understanding the performance objectives and change objectives and developing the initial implementation package, but a repeat assessment of determinants could have assisted in understanding evolving barriers to uptake and optimal strategies to address them.

Identifying implementation strategies requires assessing and addressing both individual and organizational-level components, a point reinforced by successful IM examples (8). While this project developed multi-tiered strategies by involving multiple stakeholders and conducting IM as an iterative process, logistical barriers preventing this project from including the intended recipients of this innovation. Patients were unavailable for participation in the project during the early phases of the COVID crisis. This omission highlights that patient perspective may be a critical component for IM success.

Additionally, this IM process took 12 months. Compared to other examples that unfolded over several years (8) the time elapsed may have been too brief to achieve practice utilization. In interviews, FQHC staff noted the need for time and resources to adopt and scale this innovation. This highlights the stressors of using limited external funding, which follows grant cycles and stipulations, and may require much greater funds to follow the full implementation process through to the maintenance phase. Here, the external support was limited to one year. It is well documented that successful implementation requires long-term support and strategies (38), which requires funders' long-term investment of implementation projects (39, 40). While external funding sources provide critical supports for knowledge transfer, there remains a lag between the significant resources needed for successful implementation (38) and the structure of funding mechanisms (39, 41).

Implementation mapping

IM remains a promising and feasible method for effectively planning and strategizing implementation efforts (8–10). The method is continuing to be tested and improved. Several large studies using IM are planned or underway (4, 6, 7), which will further describe and refine the process. While the evidence base grows, the practice-based evidence supplied here bridges implementation practice to implementation science.

Based on this project's findings, IM does not sufficiently guide how to manage contextual changes that occur over time. It is well documented that determinants display variable salience across implementation stages (42–44). In our example, during early IM steps the FQHC adopters and implementers reported enthusiasm for the innovation. Yet the relative priority may have changed, likely due to the COVID-19 pandemic shifting organizational needs. Accounting for external disruptions to the implementation process is necessary for both building organizational resilience and enhancing implementation success (45). Relatedly, regardless of changing priorities, preliminary work identified that some strategies are relevant in earlier versus later stages of change (46). Although IM is proposed as an iterative process, it is unclear when and how often users should re-assess determinants and revise strategies. This is likely to vary by context, however—as originally suggested by the IM developers (3)—implementation practitioners would benefit from expanding the literature on how IM can be synchronized with frameworks that account for other influences on the implementation process. Frameworks of implementation stages (47–49) may be critical supplements for IM. Timely re-assessment of determinants and strategy selection—with appropriate resources for doing so—could have assisted in effectively adapting implementation protocols for the rapidly changing FQHC context.

Similarly, given resource constraints in certain care settings, *prioritization* of change objectives is an essential element that should be added to the IM process. Translating determinants into change objectives is a critical step. This effectively decides, across roles and systems, which key elements are needed to affect change. Here, relative priority and compatibility of the 5A's were identified as highly important in the data. However, among the actions prescribed by Table 3, which are most influential? Ideally, implementation protocols would enact strategies to address all the change objectives, yet this is not feasible in practice. IM developers suggested one determinant framework of organizational readiness may aid in the second and third steps (3). Since the initial IM publication, guidelines (5) and tools (45) for systematically prioritizing determinants have been developed for this readiness framework along with proposals to validate readiness measures in FQHCs (50). Relatedly, models accounting for the behaviors, capabilities, opportunities, and motivations (52) of staff could sharpen assessment of determinants and match them appropriately to change objectives. Use of these instruments by implementation

practitioners are consistent with IM recommendations to be both integrative and iterative.

Conclusion

Although this pilot did not result in adoption of the computerized 5As intervention, IM was feasible to conduct in an FQHC with limited resources. Future IM use should allocate more than one year for reaching intended outcomes and re-assess determinants and change objectives at regular intervals. IM users would benefit from explicit instructions for when to re-assess determinants and how to merge IM with other implementation frameworks. These considerations may improve ability to reach sustainment in future projects.

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 study protocol was reviewed and approved by Duke University Health System Institutional Review Board. The need to obtain written informed consent was waived by the review board. Prior to beginning study procedures, the participants provided either verbal consent or reviewed a consent script in digital format.

Author contributions

This work was conceived, designed, and executed by SW and CC with assistance from HE, KP, JD, and

PC. AD analyzed data and drafted the majority of the manuscript. HE, KP, JD, CC, and SW provided substantial revisions. Additionally, PC provided design oversight, consultation, and critical comments. All authors contributed to final read and provided approval for publication of the content.

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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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Using implementation mapping to develop strategies for preventing non-communicable diseases in Japanese small- and medium-sized enterprises

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Introduction: Workplace programs to prevent non-communicable diseases (NCDs) in the workplace can help prevent the incidence of chronic diseases among employees, provide health benefits, and reduce the risk of financial loss. Nevertheless, these programs are not fully implemented, particularly in small- and medium-sized enterprises (SMEs). The purpose of this study was to develop implementation strategies for health promotion activities to prevent NCDs in Japanese SMEs using Implementation Mapping (IM) to present the process in a systematic, transparent, and replicable manner.

Methods: Qualitative methods using interviews and focus group discussions with 15 SMEs and 20 public health nurses were conducted in a previous study. This study applied the Consolidated Framework for Implementation Research and IM to analyze this dataset to develop implementation strategies suitable for SMEs in Japan.

Results: In task 2 of the IM, we identified performance objectives, determinants, and change objectives for each implementation stage: adoption, implementation, and maintenance; to identify the required actors and actions necessary to enhance implementation effectiveness. Twenty-two performance objectives were identified in each implementation stage. In task 3 of the IM, the planning group matched behavioral change methods (e.g., modeling and setting of graded tasks, framing, self-re-evaluation, and environmental re-evaluation) with determinants to address the performance objectives. We used a consolidated framework for implementation research to select the optimal behavioral change technique for performance objectives and determinants and designed a practical application. The planning team agreed on the inclusion of sixteen strategies from the final strategies list compiled and presented to it for consensus, for the overall implementation plan design.

Discussion: This paper provides the implementation strategies for NCDs prevention for SMEs in Japan following an IM protocol. Although the identified implementation strategies might not be generalizable to all SMEs planning

implementation of health promotion activities, because they were tailored to contextual factors identified in a formative research. However, identified performance objectives and implementation strategies can help direct the next steps in launching preventive programs against NCDs in SMEs.

KEYWORDS

Implementation Mapping, implementation strategies, workplace, non-communicable diseases, health promotion, implementation science

Introduction

Non-communicable diseases (NCDs) kill 41 million people each year, equivalent to 71% of all deaths globally (1). Tobacco use, physical inactivity, harmful use of alcohol, and an unhealthy diet increase the risk of dying from NCDs (1). In Japan, four of the top five leading causes of mortality in 2019 are NCDs (i.e., Alzheimer's disease, stroke, ischemic heart disease, and lung cancer), and NCDs account for more than 80% of all health losses measured using the disability-adjusted life years (2, 3). The World Health Organization has identified workplaces as valuable access points for providing interventions targeting NCD prevention (4). In effect, workplaces provide many adults with opportunities for health promotion. Workplace health promotion programs are effective in modifying dietary behavior (5), tobacco use (6), and physical activity (7, 8). Furthermore, workplaces have existing infrastructure to provide comprehensive health promotion and disease management programs (9). Thus, workplace health promotion activities could make a significant contribution to population level reductions in chronic disease risk (10, 11).

Companies in developed countries are increasingly providing workplace health promotion programs, but the implementation in small- and medium-sized enterprises (SMEs) is limited compared with that in larger companies. For example, in 2018, 82% of large firms and 53% of small enterprises in the United States offered a wellness program (12). Similarly, occupational health activities at SMEs in Japan are lagging in large companies (13). A recent national survey in Japan showed that although SMEs have become increasingly interested in workplace health promotion, only 20% are engaged in any type of health-promoting activities (14).

The challenges smaller workplaces face in offering workplace health promotion programs include having few vendors to serve them, low commitment to and internal capacity for program delivery (15), and limited direct or administrative costs of running programs (16). The identified barrier in Japanese

SMEs also includes the beliefs held by the employer/manager that health management is one's own responsibility (17). Furthermore, as smaller workplaces often have high employee turnover rates, investing in workplace health promotion programs designed to prevent chronic diseases made little sense to employers (18).

New approaches are needed that are tailored to each context to overcome these barriers at SMEs. Implementation strategies are defined as “methods or techniques used to enhance the adoption, implementation, and sustainability of a clinical program or practice” (19). Empirical studies in clinical settings show that implementation strategies, such as audit and feedback (20), training (21), and academic detailing (22), improve the implementation of evidence-based policies and practices. A systematic review regarding implementation strategies to improve health promotion policies or practices at the workplace identified six studies and found no conclusive evidence regarding the effects of those strategies (23), which may be partly due to the limited use of theory to design implementation strategies (24). Four out of the six included studies reported using theoretical, practical, or conceptual frameworks; however, these studies were used to understand the context rather than for the development of implementation strategies (23). Since the process of identifying implementation strategies is not clearly documented, it is difficult to understand which strategies work and why they work (25). Therefore, identifying implementation strategies that address barriers to implementation after a comprehensive formative evaluation with theoretical frameworks may be the most effective approach for maximizing the impact of implementation strategies in the workplace (23).

Implementation Mapping (IM) is derived from intervention mapping, which is one of the several methods (concept mapping, group model building, conjoint analysis, intervention mapping, etc.) that can be used to select implementation strategies to address the barriers and facilitators of specific evidence-based practices (26). Specifically, IM identifies implementation strategies that have the greatest potential impact on implementation and health outcomes and addresses the barriers to implementation after a comprehensive formative evaluation using theoretical frameworks (27). Moreover, IM can provide a systematic process for selecting the implementation

Abbreviations: CFIR, consolidated framework for implementation research; IM, Implementation Mapping; NCD, non-communicable disease; SMEs, small- and medium-sized enterprises.

strategies needed to overcome the barriers to implementation (27). The use of a systematic process has the advantage of increasing reproducibility, and the use of relevant theory has the advantage of increasing the likelihood of identifying the mechanism of action of implementation strategies (25). Therefore, in this study, we decided for IM as it can be used to systematically design implementation strategies. The purpose of this study was to develop implementation strategies for health promotion activities to prevent NCDs in Japanese SMEs using IM, to present the process in a systematic, transparent, and replicable manner.

Methods

Theoretical framework

In this study, we designed the implementation strategies for health promotion activities to prevent NCDs by using the IM framework, the Consolidated Framework for Implementation Research (CFIR) (28), social cognitive theory (29), and behavioral change taxonomy of Kok et al. (30) (Figure 1).

We selected evidence-based interventions that public health nurses as external change agents could support for implementation in the workplace in Japan: modifying dietary behavior (e.g., menu modification at cafeteria with nutrition education) (5), tobacco use (e.g., in combination with counseling, pharmacological treatment, and smoke-free policies) (6), and physical activity (e.g., physical activity program with pedometer delivery and tailored e-mail message) (7, 8).

The IM process consisted of five tasks: tasks 1 to 5. In this study, we used tasks 2 and 3 to develop implementation strategies for the adoption, implementation, and maintenance of workplace cancer prevention programs (Figure 1). CFIR, a meta-framework, includes five domains: intervention characteristics, outer setting, inner setting, characteristics of individuals, and the process (28). We used CFIR because it is important to have a comprehensive understanding of the barriers and facilitators affecting the implementation process at different levels in SMEs, which can then be used to identify context-specific implementation strategies (17). In this study, we used CFIR primarily to identify performance objectives and determinants for task 2. Similarly, we also used the social cognitive theory model (29), which can identify personal determinants and predictive relationships that promote implementation behavior, to identify the determinants of task 2. In task 3, behavioral change techniques had to be logically followed based on the determinants (27). Therefore, we used the behavior change taxonomy provided by Kok et al. (30) as prominent health behavior theories are known to influence behavioral determinants. The social cognitive theory

was also used as a reference when selecting the method of behavioral change.

Task 1: Conduct needs and assets assessments and identify actors

Task 1 was conducted prior to this study and has been published as an original publication (17). In this previous study, we identified several barriers and facilitative factors of SMEs using CFIR through the semi-structured interviews with employers and health managers (17). Semi-structured interviews were conducted with health managers and/or employers in 15 enterprises with <300 employees and four focus group discussions with 20 public health nurses/nutritionists at the Japan Health Insurance Association (JHIA) branch offices that support SMEs in four prefectures across Japan. In the previous study, we reported that of the 39 CFIR constructs, 25 were facilitative and 7 were inhibitory for workplace health promotion implementation in SMEs at individual, internal, and external levels. In particular, the leadership engagement of employers in implementing the workplace health promotion activities was identified as a fundamental factor that may influence other facilitators, including “access to knowledge and information,” “relative priority,” and “learning climate” at organizational level, as well as “self-efficacy” at the health manager level. The main barrier was the beliefs held by the employer/manager that “health management is one’s own responsibility” (17). Thereafter, we identified employers and health managers as actors because health managers are the implementers of health promotion activities, and employers have the greatest influence on SMEs. Thus, we aimed to develop implementation strategies targeting employers and health managers. In this study, we translated the barriers and facilitators identified in the previous study (17) at the individual level and used them primarily to identify performance objectives and determinants for task 2.

Formation of an implementation strategy planning team

We formed an implementation strategy planning team to guide the IM process. The group consisted of an academic team whose members specialized in psychology, public health, and epidemiology, as well as three public health nurses with at least 10 years of experience in workplace health promotion activities affiliated with the JHIA. JHIA is the largest medical insurer in Japan covering ~2.4 million enterprises (31, 32). Since most of the member companies of JHIA are SMEs (33), JHIA represents the insurers of SMEs, and more than 90% of them have <30 employees (33). In Japan, public

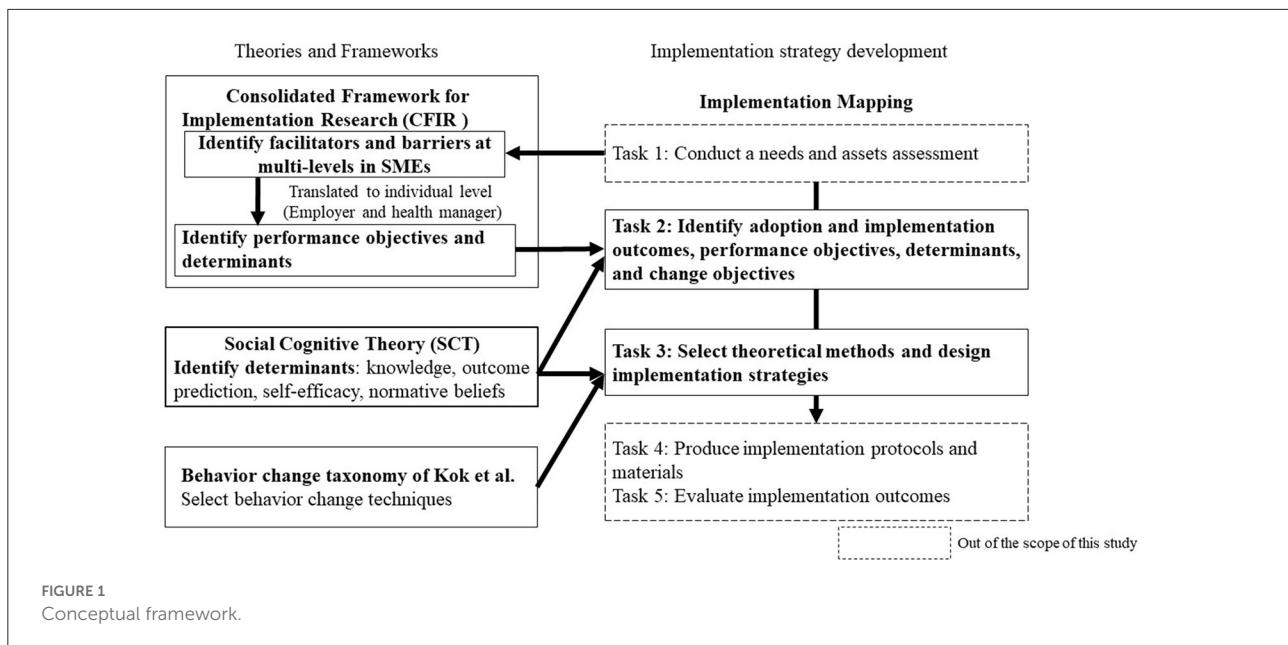


FIGURE 1
Conceptual framework.

health nurses work at various health care facilities, including publicly funded or government health insurance associations that provide health care services for workers in SMEs (34). In addition, public health nurses have recently been providing support to promote health promotion activities in SMEs and in envisioning enterprises that are members of the JHIA, as sites for implementation. We held discussions with the JHIA head office and obtained their agreement and full cooperation to promote health promotion activities in SMEs. Considering this background of public health nurses' activities in Japan along with the previous research and literature reviews conducted by the academic team and the importance of JHIA's role in scaling up the intervention, we pre-determined public health nurses affiliated with the JHIA as stakeholders for the adoption, implementation, and maintenance of health promotion activities.

Task 2: Identifying adoption, implementation, and maintenance outcomes; performance objectives; determinants; and change objectives

In task 2, we identified the program-use outcomes and the performance objectives for each implementation stage as adoption, implementation, and maintenance because the actor who adopts, and those who implements and maintains programs will be often different. First, we determined the program-use outcomes based on each implementation stage definition (35): "adoption is the decision to use a new program; implementation is the use of the program over a long enough period to

allow for evaluation regarding the innovation and whether it meets the perceived need; and maintenance is the extent to which the program is continued, and then becomes a part of normal practices." We then selected the performance objectives necessary to achieve the program-use outcomes. The performance objectives denoted specific behaviors of those who needed to act if the change was to occur. As such, the performance objectives are action-oriented and do not include cognitive processes such as knowing and believing (27). To formulate the determinants, we used the barriers identified in task 1 and social cognitive theory (Figure 1). The academic team developed draft performance objectives that should be achieved by employers and health managers to implement the programs based on the facilitators identified in task 1, and used CFIR to provide answers to "What do the program implementers need to do to deliver the essential program components?" Since the interventionists envisioned in this workplace health promotion activities are public health nurses in JHIA, we focused on performance objectives in which public health nurses can intervene. We refined the draft performance objectives, through discussion with the public health nurses, and divided them into implementation stages of adoption, implementation, and maintenance to achieve the program-use outcomes. We then sought input from the SMEs employers and health managers who participated in the task 1 interviews, and selected performance objectives based on the feasibility, especially in terms of financial and human resources. This was done to overcome one of the barriers to implementing health promotion programs in SMEs: low available human resources and limited economic costs (15, 16). Subsequently, a matrix based on the combination of performance objectives and individual determinants of the theory of action was created. Next, we

identified the personal determinants of the actors. Determinants answered the question “why,” and the barriers and facilitators of adoption were also deemed as determinants (27). We identified the determinants for each stage in a brainstorming session where the academic team answered the questions, “why do employers not understand their employees’ health issues?” and “why are employers not making workplace health promotion activities a priority?” Therefore, we derived the personal determinants from the barriers identified in task 1 and the social cognitive theory model (29). In [Tables 1–3](#), the second column of the matrix contains the performance objectives, while the other column headings are the determinants. The change objectives required to achieve each performance objective are listed under the headings in the determinant’s column of the matrix. Three different matrices were created for each implementation stage of the program: Adoption ([Table 1](#)), Implementation ([Table 2](#)), and Maintenance ([Table 3](#)). In developing the matrices for task 2, the academic team held weekly discussions to reach a consensus and asked the employers and health managers of the SMEs who participated in the interviews in task 1 to share their opinions on the draft performance objectives. We sent an email to the SMEs with a draft of the performance objectives, followed by a 30-min telephonic interview with each SME. We then spent a month to make decisions after two 1-h discussions with the public health nurses. Specifically, the academic team developed a draft matrix, held online meetings with public health nurses, and revised the matrix, confirming that the change objectives were feasible and capable of achieving the performance objectives.

Task 3: Select theoretical methods and design implementation strategies

Task 3 aimed to select a theoretical method and design implementation strategies. We selected suitable behavioral change techniques using the behavior change taxonomy of Kok et al. (30) for each determinant of the matrix created in task 2. This taxonomy outlines ways to change perceptions, attitudes, beliefs, outcome expectations, skills, abilities, self-efficacy, environmental conditions, social norms, social support, organizations, communities, and policies. In selecting behavioral change techniques, as in task 2, the academic team created a draft and revised it through online or in-person discussions with the public health nurses. These discussions were held over the course of a month and involved two 1-h discussions with the public health nurses on two occasions.

Results

The results are presented by IM task.

Task 2: Identify adoption, implementation, and maintenance outcomes; performance objectives; determinants; and change objectives

For this task, we identified the program-use outcomes, performance objectives (“What had to be done by whom to implement the program?”), determinants (“Why would an actor perform the program as planned?”), and change objectives (“What has to change in this determinant in order to bring about the performance objective?”), for each implementation stage. [Tables 1–3](#) show the program-use outcome, the subsequent specific steps required to meet them (i.e., performance objectives), determinants, and change objectives for each implementation stage. For the adoption stage, we set the program-use outcome as “choosing health promotion activities that are suitable for the company’s health issues.” Therefore, we set the performance objectives as the process of team building to adopt health promotion activities, such as “employer identification of employee’s health issues” and “building trust between employers and health managers.” We selected these performance objectives from the facilitators at the “inner setting” and “process” CFIR domains (in particular “readiness for implementation,” “implementation climate,” and “formally appointed internal implementation leaders”) ([Table 1](#)).

We set the program-use outcome for the implementation stage as implementing health promotion activities appropriate to the company’s health issues ([Table 2](#)). For instance, we chose the performance objective to include the health manager assessing the needs of the employees and customizing the intervention, and the employer setting the objectives and goals of the health promotion activities, and declaring them to the employees. We selected these from the “outer setting” (e.g., “needs and resources of those served by the organization”) and “inner setting” (especially “leadership engagement” and “goals and feedback”) facilitators of the CFIR domains. In addition, we also chose “employers to connect with other businesses and exchange information on health promotion” for the performance objectives, based on information from the CFIR domain “cosmopolitanism.” We set the program-use outcome for the maintenance stage to sustain health promotion activities ([Table 3](#)). Therefore, we chose the performance objectives to include mid-to long-term goal setting and evaluation of health promotion activities. These were selected from the facilitators of the “process” (“reflecting and evaluating”) CFIR domain.

Subsequently, we identified the determinants of the barriers to task 1 and social cognitive theory. The primary barrier was the belief held by the employers or managers that “health care is a self-responsibility” with information from the CFIR domain characteristics of individuals (17). We adopted this as a determinant factor as “attitude”, which implies a low awareness of the importance of health promotion activities in

TABLE 1 Implementation Mapping process Task 2: Adoption.

| Program-use outcomes | Performance objective | Knowledge | | Attitude | Outcome expectations | | Self-efficacy | | Normative beliefs | | | |
|---|-----------------------|--|----|---|----------------------|--|---------------|---|-------------------|---|-----|--|
| Adoption: Choose a suitable health promotion activity | PO1 | The employer and health manager understand employees' health issues. | K1 | Recognize the types and proportions of health issues faced by employees and specify risks when leaving them without addressing. | A1 | Perceive the importance of understanding health issues of employees' health issues. | OE1 | Expect that understanding the health issues of employees makes it smooth to introduce the health promotion program. | SE1 | Demonstrate confidence in the ability to understand employee's health issues. | NB1 | Believes that understanding employee health issues is a required role for employers and health managers. |
| | PO2 | The employer agrees with the need for employees' health promotion. | K2 | Defines the benefits of introducing health promotion and the risks when it is not introduced. | A2 | Describes the importance of improving employees' health for the sake of the company. | OE2 | Expects positive changes in employees' health and performance by health promotion. | SE2 | Expresses confidence in the ability to implement health promotion. | NB2 | Believes that the employers in other companies agree on health promotion. |
| | PO3 | The employer appoints a health manager to improve employees' health as part of his/her duties. | K3 | Describes the benefits when introducing health promotion activities. | A3 | Recognizes that it is important for health managers to be responsible for health promotion in their work. | OE3 | Expects that health promotion activities will improve employees' health. | SE3 | Demonstrates the ability to get the health manager to take on health promotion as part of their work. | NB3 | Believes that initiating health promotion as part of the health manager's duties is a role the employers should perform. |
| | PO4 | The employer builds a relationship of trust with the health manager. | K4 | Describes the impact of a good relationship between the employer and the health manager on project promotion. | A4 | Describes that a good relationship between the employer and the health manager is important for promoting/proceeding with the project. | OE4 | Expects that the good relationship between the employer and the health manager will improve the project's progress. | SE4 | Demonstrates the ability to improve the relationship between the employer and the health manager. | NB4 | Perceive that building a good relationship between employers and health managers is essential for introducing health promotion activities. |

(Continued)

TABLE 1 (Continued)

| Program-use outcomes | Performance objective | Knowledge | Attitude | Outcome expectations | Self-efficacy | Normative beliefs |
|----------------------|--|---|--|---|--|--|
| PO5 | The health manager builds cooperation with public health nurses. | K5 Defines the benefits of cooperation with a public health nurse during the company's health promotion initiatives. | A5 Perceives that cooperation with public health nurses is important for the health promotion of the company. | OE5 Expects that cooperation with a public health nurse will improve the health promotion of the company. | SE5 Demonstrates confidence in the ability to cooperate well with public health nurses. | NB5 Recognizes that cooperation between health managers and public health nurses is also practiced by other companies. |
| PO6 | The employer and health manager understand the details of intervention for the health promotion activity (e.g., physical activity, programs for reducing hypertension, and encouragement to quit smoking). | K6 Describe the intervention used in the health promotion activity in detail. | A6 Understand the importance of comprehending the details of intervention to the health promotion activity. | OE6 Expect selecting the best activity for the company by understanding interventions for health promotion activity in detail. | SE6 Demonstrate confidence in being able to understand the details of the intervention regarding the health promotion activity. | NB6 Recognize that understanding the interventions related to health promotion activities is a role of employers and health managers. |
| PO7 | The employer identifies the resources (human resources, costs, and goods) required to implement the health promotion activity. | K7 Defines funding flow, available resources, and required resources. | A7 Perceives that the identification of resources that will be needed and the funding flow is important to determine health promotion activity. | OE7 Expects that identifying the funding flow and available resources will facilitate the decision to implement health promotion activity. | SE7 Demonstrates the ability to identify funding flows and available resources. | NB7 Recognize that it is the role of the employers to clarify funding flow and available resources. |

(Continued)

TABLE 1 (Continued)

| Program-use outcomes | Performance objective | Knowledge | | Attitude | Outcome expectations | | Self-efficacy | | Normative beliefs | | |
|----------------------|---|-----------|--|----------|--|-----|---|-----|--|-----|---|
| PO8 | The health manager selects the health promotion activity to introduce in the company. | K8 | Defines which health promotion activities are appropriate to solve the health issues in the company. | A8 | Perceives that choosing the suitable health promotion activity is important for solving health problems and facilitates convincing the employees for introducing the activity. | OE8 | Expects that it is possible to improve employees' health if the health promotion activities chosen are appropriate. | SE8 | Expresses confidence in the ability to choose the appropriate health promotion activity. | NB8 | Believes that selecting the most appropriate health promotion activities is a required role of health managers. |
| PO9 | The employer agrees to introduce health promotion activities. | K9 | Defines the impact of health promotion activities on company health promotion. | A9 | Perceives that the optimal health promotion activity is important for improving employees' health and increasing company productivity. | OE9 | Expects that appropriate health promotion activity will lead to improvement in employees' health. | SE9 | Expresses confidence in the ability to introduce the health promotion activity. | NB9 | Recognizes that selecting appropriate health promotion activities is a role expected of employers by employees. |

TABLE 2 Implementation Mapping process Task 2: Implementation.

| Program-use outcomes | Performance objective | Knowledge | Attitude | Outcome expectations | Self-efficacy | Normative beliefs |
|--|---|---|---|---|--|---|
| Implement the suitable health promotion activity | PO10 The employer and the health manager receive the evidence based knowledge about the intervention of the health promotion activity to be implement. | K10 Define the benefits of gaining knowledge of the intervention. | A10 Perceive that it is important for the employer and the health manager to have the correct knowledge about the intervention in implementing the activity. | OE10 Expect that the health promotion activity can be implemented smoothly if the employer and the health manager acquire evidence-based knowledge about the intervention. | SE10 Demonstrate confidence in the ability to acquire the evidence based knowledge about interventions. | NB10 Believes that employers and health managers at other companies are also obtaining evidence-based knowledge. |
| | PO11 The employer facilitates employee communication. | K11 Define smooth communication between the employer and employees. | A11 Perceive that communication between the employer and the employees is important for facilitate health promotion activities. | OE11 Expect that smooth communication between the employer and employees will facilitate implementation of the suitable health promotion activity. | SE11 Demonstrate confidence in the ability to facilitate communication between the employer and employees. | NB11 Recognize that smooth communication with employees is a required behavior of employers. |
| | PO12 The health manager facilitates employee communication. | K12 Define the benefits of smooth communication between personnel and employees. | A12 Describe that communication between the health manager and employees is important for advancing health promotion. | OE12 Expect that smooth communication between the health manager and employees will facilitate the advancement of health promotion. | SE12 Demonstrate confidence in the ability to facilitate communication between personnel and employees. | NB12 Recognizes that smooth communication with employees is a required behavior of health managers. |
| | PO13 The health manager grasps the needs of employees in implementing the health promotion activity. | K13 Explain that understanding the needs of your employees will make it easier to proceed with the activity. | A13 Perceive that understanding the needs of employees is important in implementing the health promotion activity. | OE13 Expect that understanding the needs of employees in implementing health promotion activity will lead to an increase in the level of implementation. | SE13 Express confidence that gathering employees' needs for health promotion activities will be successful. | NB13 Recognizes that assessing the needs of employees is required behavior of health managers. |

(Continued)

TABLE 2 (Continued)

| Program-use outcomes | Performance objective | Knowledge | | Attitude | | Outcome expectations | | Self-efficacy | | Normative beliefs | |
|----------------------|---|-----------|--|----------|---|----------------------|---|---------------|---|-------------------|--|
| PO14 | The health manager customizes interventions of health promotion activity to meet employee needs. | K14 | Define customization of interventions to meet the needs of employees. | A14 | Perceive that it is important to customize interventions to meet the needs of employees. | OE14 | Expect to increase the rate of health promotion activity implementation by providing interventions tailored to employees' needs. | SE14 | Express confidence that you have the ability to customize according to needs. | NB14 | Recognize that customizing to needs is a required role of a health manager by employees. |
| PO15 | The employers put health promotion activity as a priority. | K15 | Define the benefits of putting health promotion programs as a priority. | A15 | Perceive that it is important to put health promotion programs as a priority in the implementation of the health promotion activity | OE15 | Expect that prioritizing health promotion programs will increase the implementation rate of health promotion and improve the health of employees. | SE15 | Demonstrate confidence that put health promotion programs as a priority | NB15 | Believe that other companies with successful health promotion prioritize health promotion programs |
| PO16 | The employer and the health manager set the purpose and goal of implementing the health promotion programs. | K16 | Define the purpose of health promotion activity | A16 | Describe that setting the purpose and goal of activity implementation in order to implement the health promotion activity is important | OE16 | Expect that the implementation rate will increase upon setting the purpose and goal of activity implementation. | SE16 | Demonstrate confidence in ability to set goals for activity implementation | NB16 | Recognize that employer should set goals before activities are implemented. |
| PO17 | The employers declare to employees the purpose and goals of implementing the health promotion activity. | K17 | Define the significance of the employer to declare the purpose and goals to employees. | A17 | Perceive that it is important for the employer declare to the purpose and goals to employees in implementing the health promotion activity. | OE17 | Expect that the implementation rate will increase and the health of employees will improve if the employer will declare the purpose and goals to employees. | SE17 | Demonstrate confidence that employers can declare health promotion goals and purposes to employees. | NB17 | Recognize that declaring objectives and goals to employees is a role expected of employers by employees. |

(Continued)

TABLE 2 (Continued)

| Program-use outcomes | Performance objective | Knowledge | Attitude | Outcome expectations | Self-efficacy | Normative beliefs |
|----------------------|--|---|--|---|--|--|
| PO18 | The health manager customizes the evidence based information and delivers it to the employee. | K18 Define the benefits of getting evidence-based information, and define the benefits of customizing the information. | A18 Perceive that it is important for implementation to customize and deliver evidence-based information. | OE18 Expect that the understanding and knowledge of employees and the activity implementation rate will increase by customizing and delivering evidence-based information. | SE18 Demonstrate the ability to customize and deliver evidence-based information. | NB18 Believes that providing customized, evidence-based information to employees is a role of health managers. |
| PO19 | The health manager finds a champion. | K19 Define the benefits of the existence of a champion. | A19 Perceive that the presence of a champion is important for health promotion activity implementation. | OE19 Expect to have a positive impact on employee health by finding a champion. | SE19 Express confidence that you can find a champion. | NB19 Recognize that finding champions is a role of the health managers. |
| PO20 | Employers create connections with other companies to exchange information on health promotion. | K20 Define the benefits of create connections with other companies to exchange information on health promotion. | A20 Believe that exchanging information with other companies is important for implementation health promotion activity. | OE20 Expect to be able to implement good practices in their own companies by exchanging information with other companies. | SE20 Express confidence that you can exchange information with other companies. | NB20 Recognize that other employers with successful health promotions are also exchanging information with other companies. |

TABLE 3 Implementation Mapping process Task 2: Maintenance.

| Program-use outcomes | Performance objective | Knowledge | | Attitude | Outcome expectations | | Self-efficacy | Normative beliefs | | | | |
|--|-----------------------|--|-----|---|----------------------|--|---------------|---|------|--|------|--|
| Sustain the suitable health promotion activity | PO21 | The health manager sets medium- to long-term goals. | K21 | Define the benefits of setting medium- and long-term goals. | A21 | Perceive that setting medium- to long-term goals is important for continuing health promotion activity. | OE21 | Expect that the sustainability of health promotion activity implementation will increase by setting medium- to long-term goals. | SE21 | Demonstrate confidence in the ability to set medium- to long-term goals. | NB21 | Recognize that it is the role of the health managers to set mid- to long-term goals. |
| | PO22 | The health manager creates an evaluation mechanism and rotates the PDSA cycle. | K22 | Create an evaluation mechanism and define the benefits of running the PDSA cycle. | A22 | Understand that it is important to maintain the health promotion activity by creating an evaluation mechanism and rotating the PDSA cycle. | OE22 | Expect to maintain a health promotion activity by building an evaluation system and implementing a PDSA cycle. | SE22 | Express confidence to create an evaluation system and rotate the PDSA cycle. | NB22 | Recognize that it is essential for health managers to create a system of evaluation and to run the PDSA cycle to maintain health promotion activities. |

Abbreviations: PDSA, Plan-Do-Study-Act.

the workplace. Furthermore, from the theoretical determinants of the social cognitive theory, we employed knowledge, outcome prediction, self-efficacy, and normative beliefs as the determinants of relevance for performance objective.

With the performance objectives and determinants established, task 2 outcomes were used in the creation of the matrix of change objectives for each stage. We identified 22 performance objectives and 5 determinants (i.e., knowledge, attitudes, outcome expectations, self-efficacy, and normative beliefs). Change objectives (written where the matrix rows and columns intersect) reflected the changes in the five determinants that were needed for the performance objectives to be completed successfully for each implementation stage of health promotion activities. We received opinions from the employers and health care managers, primarily for performance objectives, whether they were appropriate to achieve program use outcomes in each implementation stage, and whether they were feasible with the support of public health nurses. The public health nurses advised the academic team, based on their experience in health promotion support activities, to set feasible performance objectives with respect to cost and human resources. The academic team revised and finalized the performance objective based on their advice.

Task 3: Select theoretical methods and design implementation strategies

The planning team selected discrete implementation strategies to operationalize performance objectives.

First, we selected behavioral change techniques from the taxonomy of behavioral change methods (30) (e.g., modeling and setting of graded tasks [social cognitive theory], framing [protection motivation theory], self-re-evaluation, and environmental re-evaluation [transtheoretical model]). These behavioral change techniques were selected according to the following three criteria: (1) the interventionists could use convincing language to encourage the adoption and implementation of the program, (2) the methods could be used even by non-expert health professionals, and (3) they considered the real-life work environment and Japanese culture. We decided on these criteria through discussions with the public health nurses.

Second, we selected behavioral change techniques for each determinant regarding social cognitive theory and designed practical applications. For example, the behavioral change technique, modeling, is known to be associated with normative beliefs, outcome expectations, and self-efficacy (29).

Information on health promotion activities in other SMEs could improve organization leadership's receptiveness to adopting workplace programs. Furthermore, information on the role of other employers in health promotion activities could

help them acquire their own role models and predict positive outcomes. Therefore, modeling was selected as a method of behavioral change for the determinants of normative beliefs, outcome expectations, and self-efficacy. We then designed the practical application of modeling to address the performance objective-14 as, "to provide employers with precedents of how their own health promotion activities have been successful as a result of sharing information regarding health promotion activities with other companies." In addition, the interventionist would explain that it is desirable for employers to take the lead in creating relationships with other companies (Table 4). This task was completed in 1 month with the planning team meeting weekly to review the outputs of task 3, review and discuss the literature, and iteratively update the list of change methods and practical applications. The team discussed the determinants most strongly associated with each performance objective and agreed to include 16 discrete strategies in the overall implementation plan design. Table 4 summarizes the agents, determinants, methods of change, and discrete strategies used according to the implementation phase of the health promotion activities in the implementation strategies. In addition, to compare with previous reviews, the academic team discussed and reached a consensus on where the practical application corresponds to the Expert Recommendations for Implementing Change (ERIC) taxonomy and included it in Table 4.

Discussion

In this paper, we described how we developed implementation strategies for health promotion activities to prevent NCDs in SMEs. Sixteen strategies for implementing health promotion activities were developed from multiple perspectives of employers and health managers from SMEs, public health nurses, and researchers, including how to improve the programs, while receiving feedbacks from within and outside the company and being aware of social desirability.

In this study, we selected discrete implementation strategies according to the context and determinants of the organizations. Implementation strategies have different effects depending on the determinants (barriers and facilitators) (36), and the context and barriers to implementation need to be properly understood to select strategies that best address them (37). Moreover, we involved the stakeholders, the headquarters of JHIA, to build the strong partnerships needed for implementation. Strong partnerships must be necessary when it comes to changing organizational-level systems (38). For example, when considering methods to change physician behaviors, individual doctors cannot be expected to change without corresponding changes in healthcare teams and the overall organization (39). Likewise, in this study, partnership with public health nurses in JHIA was an essential element because the implementation of health promotion activities requires system changes that need

TABLE 4 Implementation strategies in health promotion activities within small- to medium-enterprises.

| Stage | No. | Actor | Performance objective | Determinants and change objectives | Theoretical method (parameters) | Practical application | ERIC |
|----------|-----|-------------------------|--|--|--|--|---|
| Adoption | 1 | Employer/health manager | PO1. Understand employee health issues. | Knowledge: Recognize the types and proportions of health issues faced by employees and define the risks of leaving them unattended. | Framing (Requires high self-efficacy expectations.) | Intervenors emphasize the many benefits and effectiveness of employers' understanding of employees' health issues in conducting health promotion activities. | Use evaluative and iterative strategies |
| | 2 | Employer | PO2. Agrees with the need for employee health promotion. | Attitude: Recognize the importance of improving employee's health for the sake of the company. | Environmental re-evaluation (May include awareness about serving as a role model for others.) | Discuss with public health nurses and health manager and recognize the wide range of impacts of whether or not to engage in health promotion activities in the workplace. | Develop stakeholder interrelationships |
| | 3 | Employer/health manager | PO4. Builds a relationship of trust with the health manager. | Normative beliefs: Perceives that building a good relationship between employers and health managers is essential for the introduction of health promotion activities. | Belief selection (Requires investigation of the current attitudinal, normative and efficacy beliefs of the individual before choosing the beliefs on which to intervene.) | Intervenors explain that when implementing workplace health promotion activities, it is important for employers and health managers to share the same beliefs and collaborate. | Develop stakeholder interrelationships |
| | 4 | Health manager | PO5. Builds cooperation with public health nurses. | Attitude: Perceives that cooperation with public health nurses is important for the health promotion of the company. | Forming coalitions (Requires collaboration across various agendas; requires attention to stages of partnership development.) | Intervenors will make the health manager aware that building a partnership with the public health nurse can make a difference in the rate of implementation of health promotion, and will mediate the relationship building. | Develop stakeholder interrelationships |
| | 5 | Employer | PO9. Agree with the need for employee health promotion. | Outcome Expectations: Expect positive changes in employees and business performance by promoting health. | Self-re-evaluation (Stimulation of both cognitive and affective appraisal of self-image.) | Intervenors will explain the significant role that employers play in health promotion activities and the positive impact on the company. | Develop stakeholder interrelationships |

(Continued)

TABLE 4 (Continued)

| Stage | No. | Actor | Performance objective | Determinants and change objectives | Theoretical method (parameters) | Practical application | ERIC |
|----------------|-----|-------------------------|---|--|---|---|---|
| Implementation | 6 | Employer/health manager | PO10. Get the evidence-based knowledge regarding the intervention of the health promotion activity to be implement. | Attitude: Perceive that it is important for the employer and the health manager to have the correct knowledge regarding the intervention in implementing the activity. | Environmental re-evaluation (May include awareness about serving as a role model for others.) | Intervenors will explain the impact of actors obtaining or not obtaining appropriate evidence-based knowledge and encourage knowledge acquisition. | Train and educate stakeholders |
| | 7 | Employer | PO11. Facilitate communication with employees. | Self-efficacy: Show confidence that employee communication can be facilitated. | Modeling (Appropriate models will vary by target.) | Intervenors will facilitate communication between the employer and the health manager by using precedents of similarly sized companies and other companies in the same industry to facilitate discussion. | Engage consumers |
| | 8 | Health manager | PO13. Understand the needs of employees in implementing the activity. | Self-efficacy: Be confident that you can successfully assess employees' needs in implementing the activity. | Set graded tasks (The final behavior can be reduced to easier but increasingly difficult sub-behaviors.) | Intervenors facilitates the health manager to list and take actions necessary to identify needs for health promotion of employees. | Use evaluative and iterative strategies |
| | 9 | Health manager | PO14. Customize interventions to meet employees' needs. | Normative beliefs: Recognize that customizing to needs is a required role of a health manager by employees. | Environmental re-evaluation (May include awareness about serving as a role model for others.) | Intervenors will ask the health manager how the employee perceives and feels regarding the health manager who will/will not customize (intervene) to the employee's needs. Then, through discussion with the health manager, make the health manager aware that customizing health promotion activities to their needs is the ideal behavior. | Adapt and tailor to context |
| | 10 | Employer | PO15. Make health promotion activity as a priority. | Self-efficacy: Demonstrate confidence that put health promotion activities as a priority | Reinforcement (Reinforcement need to be tailored to the individual, group, or organization.) | Intervenors will identify measures that employers have prioritized to improve health and benefit employees, highlighting their experiences and providing positive feedback. | Change infrastructure |

(Continued)

TABLE 4 (Continued)

| Stage | No. | Actor | Performance objective | Determinants and change objectives | Theoretical method (parameters) | Practical application | ERIC |
|-------|-----|-------------------------|--|---|--|---|---|
| | 11 | Employer/health manager | PO16. Set the purpose and goals for health activity implementation. | Outcome Expectations: Expect that the implementation rate will increase by setting the purpose and goal of activity implementation. | Modeling (Appropriate models will vary by target.) | Intervenors will provide information on precedents where health promotion activities have been successfully developed with appropriate goal setting and will facilitate goal setting. | Use evaluative and iterative strategies |
| | 12 | Employer | PO17. Declare the purpose and goals of the health activity to employees. | Self-efficacy: The employer is confident that he can directly convey the purpose and goals of health promotion to the employees and resonate with them. | Set graded tasks (The final behavior can be reduced to easier but increasingly difficult sub-behaviors.) /Provide contingent rewards (Rewards need to be tailored to the target.) | Intervenors will identify graded tasks, such as preparing manuscripts and conducting role-plays and enable employers to successfully implement the health declaration. Positive feedback is given when tasks are successfully completed. | Change infrastructure |
| | 13 | Health manager | PO18. Customize evidence-based information and deliver it to employees. | Normative beliefs: Believes that providing customized, evidence-based information to employees is a role of health managers. | Information about others' approval (Positive expectations are available in the environment.) | Intervenors instructs the health manager to devise a method of providing the information (e.g., make the letters larger in the areas to be emphasized, mark them in a prominent color, write the subject's name on them and distribute them, etc.). Then, provide feedback on the comments received from employers and employees. | Engage consumers |
| | 14 | Employer/health manager | PO20. Create connections with other companies to exchange information on health promotion. | Normative belief: Recognize that other employers with successful health promotion are also exchanging information with other companies. | Modeling (Appropriate models will vary by target.) | Intervenors will provide employers with precedents of how their own health promotion activities have been successful as a result of sharing information about health promotion activities with other companies. The interventionist will explain that it is desirable for employers to lead the way in creating relationships with other companies. | Develop stakeholder interrelationships |

(Continued)

TABLE 4 (Continued)

| Stage | No. | Actor | Performance objective | Determinants and change objectives | Theoretical method (parameters) | Practical application | ERIC |
|-------------|-----|----------------|--|---|--|--|---|
| Maintenance | 15 | Health manager | PO21. Set medium- to long-term goals. | Normative beliefs: Recognize that it is the role of the health managers is to set mid- to long-term goals. | Cultural similarity (Using surface characteristics of the target group enhances receptivity.) | Intervenors explains that setting medium- and long-term goals is an action that should be taken as a health manager, based on prior examples of companies that are similar in size, structure, and philosophy and that do not compete with the target establishments. | Use evaluative and iterative strategies |
| | 16 | Health manager | PO22. Create a mechanism for evaluating measures and running the PDSA cycle. | Outcome Expectations: Expect to maintain a better activity by creating an evaluation mechanism and rotating the PDSA cycle. | Shifting perspective (Initiation from the perspective of the learner; needs imaginary competence.) | Intervenors asks the health manager to consider a shift in perspective, specifically discussing what you would do to structure an evaluation if you were an employer or another employee or what you would advise if you were consulted by a colleague about circulating a PDSA. | Use evaluative and iterative strategies |

Abbreviations: ERIC, Expert Recommendations for Implementing Change; PDSA, Plan-Do-Study-Act.

to be integrated into the usual workflows at the organizational level, and also the importance of JHIA's role in scaling up the intervention in the future.

Moreover, the discrete implementation strategies we derived through IM have been reported in a systematic review of implementation strategies (23) as follows: the “develop stakeholder interrelationships” (40) (e.g., the employer agrees with the need for employees' health promotion and the health manager builds cooperation with public health nurses) in the adoption phase of our intervention; “train and educate stakeholders” (40) (e.g., the employer and health manager receive the evidence-based knowledge about the intervention of the health promotion activity to be implemented) in the implementation stage; and use evaluative and iterative strategies” (40) (e.g., the health manager sets medium- to long-term goals) in the maintenance stage. These consistencies with well-established barriers and strategies enhance the validity of our process and results and predict a degree of generalizability to other settings.

However, we identified two implementation strategies that were not found in the previous systematic review. The first strategy was to “engage consumers” (40), which is related to attentiveness and communication. For example, the health manager at SMEs customizes the content and delivery methods of evidence-based information according to the characteristics of each employee. This strategy would reflect the advantage of SMEs, which is more accommodating (16) and provides a more intimate work culture due to fewer employees, thus encouraging employees to participate in health promotion activities (41).

The second strategy involves “change in infrastructure” (40), wherein employers prioritize health promotion programs and establish the purpose and goals of implementing health promotion activities among their employees. Furthermore, it involves the “development of stakeholder interrelationships” (40), wherein employers build connections with other companies to exchange information on health promotion in the workplace; and this may generate a modeling effect across companies. These strategies, newly identified in our study, appear to reflect the Japanese culture. The declarations made by employers have a strong impact on Japanese employees, who tend to be obedient to their superiors. In the interviews conducted as part of our previous study, there was an opinion that the progress of the business would be different if there was “a word from the top” or the employer (17). In addition, the creation of horizontal connections makes “modeling” possible and makes it easier to create behavioral changes with an awareness of social norms. In Asian societies, especially in Japan, social norms are strict, with duties and obligations taking precedence (42, 43). Therefore, learning about health promotion activities in other companies generates a belief that the activities being performed in other companies should also be performed in their companies. Moreover, those norms and beliefs are often created by the opinions and attitudes of employers in SMEs.

Therefore, it is an effective implementation strategy aimed at fostering the norms about health promotion activities in the company by encouraging employers to change their knowledge, attitudes, and norms.

These newly identified implementation strategies for workplace health promotion could be attributed to the focus on SMEs and the fact that we used IM to derive strategies based on real-world opinions. The implementation strategies of large businesses cannot be generalized to SMEs due to their different contexts (16), and there is a need for strategies that are optimal for the challenges faced by SMEs. Further studies to identify implementation strategies that consider the characteristics of SMEs would promote the efforts of the SMEs to overcome the barriers to the adoption and implementation of workplace health promotion.

The implementation strategies designed in this study are primarily for health promotion activities in SMEs, focusing on five NCD prevention measures (i.e., tobacco use, alcohol consumption, diet, physical activity, and health check-ups). We are currently developing protocols and materials according to task 4 of IM, which is being evaluated in a researcher-led pilot study, to implement an intervention focused on one (smoking cessation) of these five topics (44). The main focus of the workplace smoking cessation strategy is to encourage healthcare managers to encourage smokers in the workplace to quit smoking, so that SMEs with limited resources can implement it. The goal is to reduce the prevalence of smoking while providing implementation strategies tailored to the disincentive. If the pilot study confirms the effectiveness of the implementation strategies, public health nurses at JHIA will participate in the national scaling up of the program. Among employees in SMEs, the proportions of health and behavioral problems, such as hypertension, obesity, and smoking, were higher than those in employees from larger organizations (45). Therefore, employers in SMEs must make a serious effort to promote the health of their employees and prioritize health-promoting programs.

This study has several limitations. In the selection of behavioral change techniques and development of practical applications (task 3), there was insufficient involvement of SMEs. Furthermore, in task 2, employers and health managers of the SMEs were involved, but not their employees. In addition, planning with public health nurses was not a participatory approach, but rather a form of listening to their opinions. This is because it is not yet common in Japan for stakeholders in the field to be actively involved in research. Since this was our first implementation study with SMEs and JHIA, we had to be careful not to place a burden on SMEs and JHIA during this period. As a result of this background, it is possible that the opinions of the SMEs and public health nurses were not fully reflected in the field, or that they were insufficient to foster a proactive attitude among SMEs and public health nurses toward health promotion activities in the workplace. Additionally, it may take time for SMEs and public health nurses to incorporate

these strategies into their workflow. This is because researcher-led implementation creates a perception of “somebody else’s business,” i.e., that an external change agent, the researcher, will take care of the company’s health activities.

The selection of the implementation strategies was tailored to the context of SMEs in Japan, where health promotion activities are already being implemented, and may not be effective in other settings because the strategy may not resonate with other settings, such as the limited readiness of the employer to implement the health promotion. However, in countries and communities like Japan, where the social norms influence behavior, it may be effective, but this needs to be verified.

This study developed implementation strategies for health promotion activities in SMEs in Japan by applying IM in conjunction with the constructs of the CFIR framework, social cognitive theory, and behavioral change techniques. To our knowledge, there are only a few studies that applied and integrated these three frameworks and techniques simultaneously to develop implementation strategies. The IM protocol provided a valuable guideline for the development of comprehensive implementation strategies. The identified performance objectives and implementation strategies can help direct further steps in launching health promotion activities to prevent NCDs in SMEs.

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

The studies involving human participants were reviewed and approved by Ethical Committee of the National Cancer Center. Written informed consent for participation was not required for this study in accordance with the national legislation and the institutional requirements.

Author contributions

MO and TS conceived of the paper and designed the study. MO, JS, AY-S, and TS were members of the academic team

of the implementation strategy planning group and developed the implementation strategy according to the IM protocol. MO drafted the initial manuscript and all authors revised the manuscript for important intellectual content. TS was the principal investigator of the study. All authors read and approved the final manuscript.

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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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The *Healthy Native Youth Implementation Toolbox*: Using Implementation Mapping to adapt an online decision support system to promote culturally-relevant sexual health education for American Indian and Alaska Native youth

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Background: American Indian and Alaska Native (AI/AN) youth experience serious disparities in sexual and reproductive health, including the highest teen birth rate among racial/ethnic groups, and disproportionate rates of sexually transmitted infections (STI), including HIV. A growing number of evidence-based programs (EBPs) that integrate the strengths and cultural teachings of Native communities exist. Yet, multiple factors, including lack of trained personnel, limited resources, and geographic isolation, may hinder their adoption and implementation. Innovative implementation strategies that facilitate the adoption and implementation of sexual health EBPs in Native communities may help reduce these disparities.

Methods: We applied Implementation Mapping, a systematic planning framework that utilizes theory, empirical evidence, and community input, to adapt a theory-based, online decision support system, iCHAMPSS (CHoosing And Maintaining Effective Programs for Sex Education in Schools), to support underlying dissemination and implementation processes unique to Native communities. We used an iterative design process, incorporating input from Native practitioners and academicians, to ensure that the adapted decision support system reflects cultural identification, community values, and experiences.

Results: Grounded in diffusion of innovations, organizational stage theory, and social cognitive theory, the *Healthy Native Youth Implementation Toolbox* supports Native practitioners through five phases (Gather, Choose, Prepare, Implement, and Grow) to adopt, implement, and maintain a culturally-relevant, age-appropriate sexual health EBP. The *Toolbox* provides tools, ready-to-use templates, and guidance to plan, implement, and grow a culturally-relevant adolescent health program with their Tribe or community. Hosted within the Healthy Native Youth website (www.healthynativeyouth.org), the *Toolbox* comprises: (1) a curriculum portal with access to 15 culturally-relevant, age-appropriate evidence-based health promotion programs for AI/AN youth; (2) a “resource library” comprising 20+ support tools, templates, and links to external resources, and (3) “stories from the field” comprising testimonials from experienced Native educators, who have implemented sexual health programs.

Conclusion: There is a continued need to design, test, and evaluate D&I strategies that are relevant to Native communities. The *Healthy Native Youth Implementation Toolbox* contributes to the dissemination and implementation of evidence-based, culturally-relevant sexual health education programs in diverse Native communities. Implementation Mapping provided a systematic approach to guide the adaptation process and integrate community voice with the ultimate goal of enhancing sexual health equity among AI/AN youth.

KEYWORDS

adolescent, sexual health promotion, American Indian and Alaska Native, interventions, dissemination and implementation research, Implementation Mapping

Introduction

The federal government recognizes 574 distinct American Indian/Alaska Native (AI/AN) tribes that represent 2% of the United States (U.S.) population (1). Overall, the AI/AN population is young, with 30% under 18 years-old compared to 24% of the U.S. total population (2). As a result, the need for adolescent health promotion resources is particularly relevant in Native communities.

Despite recent declines in teen birth rates in the U.S., racial and ethnic disparities persist (3). AI/AN females ages 15–19 years have the highest teen birth rate among racial/ethnic groups (3) and the highest repeat teen birth rate (4). AI/AN youth are also disproportionately affected by sexually transmitted infections (STI), including HIV (5, 6). These health disparities may be ameliorated by the implementation of effective, culturally-relevant sexual health education programs (7). A growing number of evidence-based programs (EBPs) (8) that integrate the strengths and cultural teachings of Native communities have been developed or adapted for AI/AN youth (9–14). In 2016, our research team, in collaboration with AI/AN advisors, developed the Healthy Native Youth website (www.healthynativeyouth.org) to increase access to these culturally-relevant EBPs (15). The portal allows users

to filter and compare curricula on multiple dimensions to determine best-fit and includes implementation materials free-of-charge. Yet, solely increasing access to culturally-relevant EBPs may be insufficient to increase their use (7). Multiple barriers exist and AI/AN health educators often lack the resources to navigate the adoption and implementation process. Adolescent sexual health is a sensitive topic, and many Native communities lack the community readiness and resources to broach the issue. Varying Tribal review and school board approval processes may create delays in program adoption and implementation (16). Pervasive poverty often results in personnel turnover or temporary closures for AI/AN youth-serving agencies, which may compromise implementation fidelity and program sustainability (7). Geographic challenges, including remote villages and reservations, may impact program implementation and access to resources (1, 7). Finally, as in other locations, AI/AN communities may face competing priorities, perceived lack of administrative or parental support, and lack of specialized training in sexual health, including limited knowledge of where to find culturally-relevant EBPs or limited self-efficacy to implement them (17, 18). Innovative strategies that facilitate the adoption and implementation of sexual health EBPs in Native communities are needed to reduce these health disparities.

iCHAMPSS (CHoosing And Maintaining Effective Programs for Sex Education in Schools) is a theory-based online decision support system designed to address barriers to the dissemination and implementation (D&I) of sexual health EBPs in Texas schools (17, 19). Decision support systems are computer-based systems designed to facilitate a wide variety of decision tasks, including information gathering and analysis, alternative evaluation, and decision implementation (20). Grounded in D&I theories (21–23), iCHAMPSS comprises 60+ tools to provide step-by-step guidance to overcome D&I barriers for sexual education (www.ichampss.org). Demonstrated to impact critical determinants for adopting and implementing a sexual health EBP in Texas schools (24), iCHAMPSS serves as a promising implementation strategy to adapt for AI/AN communities.

To explore the potential of adapting iCHAMPSS, we conducted usability testing with AI/AN practitioners ($n = 36$) across the U.S. Overall, participants rated iCHAMPSS as acceptable, easy to use, credible, appealing, more helpful than current resources, and impactful of EBP adoption, implementation, and sustainability (25). However, using iCHAMPSS also significantly increased participants' perceived barriers to adopting an EBP. Some participants found the amount of information overwhelming and certain steps and tools, such as presenting a School Health Advisory Council (SHAC) recommendation letter to the School Board, were unfamiliar for Native communities. Sexual health education occurs in diverse settings in AI/AN communities, including schools, after-school programs, clinics, and community centers. Thus, the steps involved in the adoption and implementation of sexual health EBPs in Texas schools may not adequately reflect the steps involved in Native communities. Qualitative feedback from the usability testing provided tangible adaptation recommendations such as inclusion of culturally-relevant EBPs, provision of culturally appropriate assessment tools, integration of Tribal review and approval processes, and resources to adapt EBPs (25). Previous studies in AI/AN communities also suggest that embedding implementation within a consortium or learning community may enhance sustainability (26). Overall, findings indicated the potential for an adapted iCHAMPSS to address D&I barriers for sexual health EBPs in AI/AN communities.

In this “Methods” paper we describe how we applied Implementation Mapping to adapt iCHAMPSS to facilitate the adoption and implementation of sexual health EBPs in AI/AN communities. Implementation Mapping is a systematic approach for developing or adapting strategies to increase the adoption, implementation, and maintenance of evidence-based interventions, practices, or policies (27). It provides a step-by-step process, based in theory, empirical evidence, and community input, to identify the relevant determinants, mechanisms, and strategies for effecting change. The resulting *Healthy Native Youth Implementation Toolbox*

(www.healthynativeyouth.org/implementation-toolbox/) is an online implementation strategy to increase the adoption and implementation of culturally-relevant, age-appropriate sexual health EBPs in Native communities with the ultimate goal of improving sexual health equity among AI/AN youth.

Methods

iCHAMPSS decision support system

iCHAMPSS is a web-based, interactive, self-paced decision support system that guides individuals through the process of adopting, implementing, and maintaining sexual health EBPs in Texas schools (Figure 1). iCHAMPSS comprises: (1) a “staging tool” to provide tailored guidance based on a community’s level of readiness to implement a sexual health EBP, and (2) a “resource tools library” comprising 60+ support tools to enable successful completion of tasks within each implementation step. Tools include: step overviews, success stories (video testimonials from individuals who have adopted, implemented, or maintained a sexual health education EBP), facts and tips (e.g., a selection guide to identify EBPs), helpful links to online resources outside of iCHAMPSS, and templates that can be tailored to fit a school’s or community’s needs (19).

iCHAMPSS was developed using the original Intervention Mapping process (28). Guided by Diffusion of Innovation (21), Organizational Stage Theory (22), and Social Cognitive Theory (23), literature review findings on individual- and organizational-level factors that influence the adoption and implementation of sexual health EBPs in schools, and in-depth interviews with school district personnel, the research team developed adoption, implementation, and maintenance outcomes and performance objectives to delineate the specific actions needed to support sexual health EBPs in Texas schools. The resulting conceptual model, CHAMPSS (CHoosing And Maintaining Effective Programs for Sex Education in Schools), provides the theoretical foundation for the web-based iCHAMPSS, and includes three phases: “adoption,” “implementation,” and “maintenance,” which are further divided into seven steps: (1) prioritize, (2) assess, (3) select, (4) approve, (5) prepare, (6) implement, and (7) maintain EBPs. A core element, “Generate support” (i.e., connecting with other supporters of EBPs and adolescent sexual health), extends across all seven steps. Each step comprises two to six sub-steps or critical tasks to move program planners through the process (Figure 2) (17). The model is circular (Figure 3), reflecting that planners may enter the model at any step, depending on their level of readiness. They may also complete one step but then realize they need to revisit a previous step.

iCHAMPSS incorporates theory-based methods and implementation strategies as step-specific tools to influence

The image shows the homepage of the iCHAMPSS website. At the top, there is a navigation bar with links for HOME, GET-STARTED, TOOLS, CONNECT, ABOUT, and GLOSSARY. There is also a search bar with a 'SEARCH' button. Below the navigation bar, the text 'CHOOSING AND MAINTAINING EFFECTIVE PROGRAMS FOR SEX EDUCATION IN SCHOOLS' is displayed. The main visual is a photograph of a young woman with long brown hair, smiling, with a classroom in the background. To the right of the photo is a vertical column of seven orange boxes, each containing a step: PRIORITY, ASSESS, SELECT, APPROVE, PREPARE, IMPLEMENT, and MAINTAIN. Below the photo are four buttons: 'iCHAMPSS Process', 'Stage Your District', 'Resource Library', and 'Connect With Others'. Each button has a corresponding description and a 'GET STARTED!' button. The 'iCHAMPSS Process' button has a circular diagram with 'Adoption' at the bottom, 'Implementation' on the left, and 'Maintenance' on the right. The center of the diagram says 'Engage others on Adoption'.

PRIORITY

ASSESS

SELECT

APPROVE

PREPARE

IMPLEMENT

MAINTAIN

iCHAMPSS Process

Stage Your District

Resource Library

Connect With Others

Learn about how to navigate adopting, implementing, and maintaining effective sexual health education curricula in your district through a 7-step model:

The iCHAMPSS Stage Your District tool can help determine your district's level of readiness for adopting, implementing, and maintaining evidence-based programs.

GET STARTED!

Access over 60 tools to help you adopt, implement, and maintain effective sexual health education curricula in your district:

- Step Overview Videos
- Success Stories
- Fact & Tip Sheets
- Helpful Links
- Templates

[Visit our Resource Library](#)

Share stories and strategies with other champions just like you and interact on this online message board:

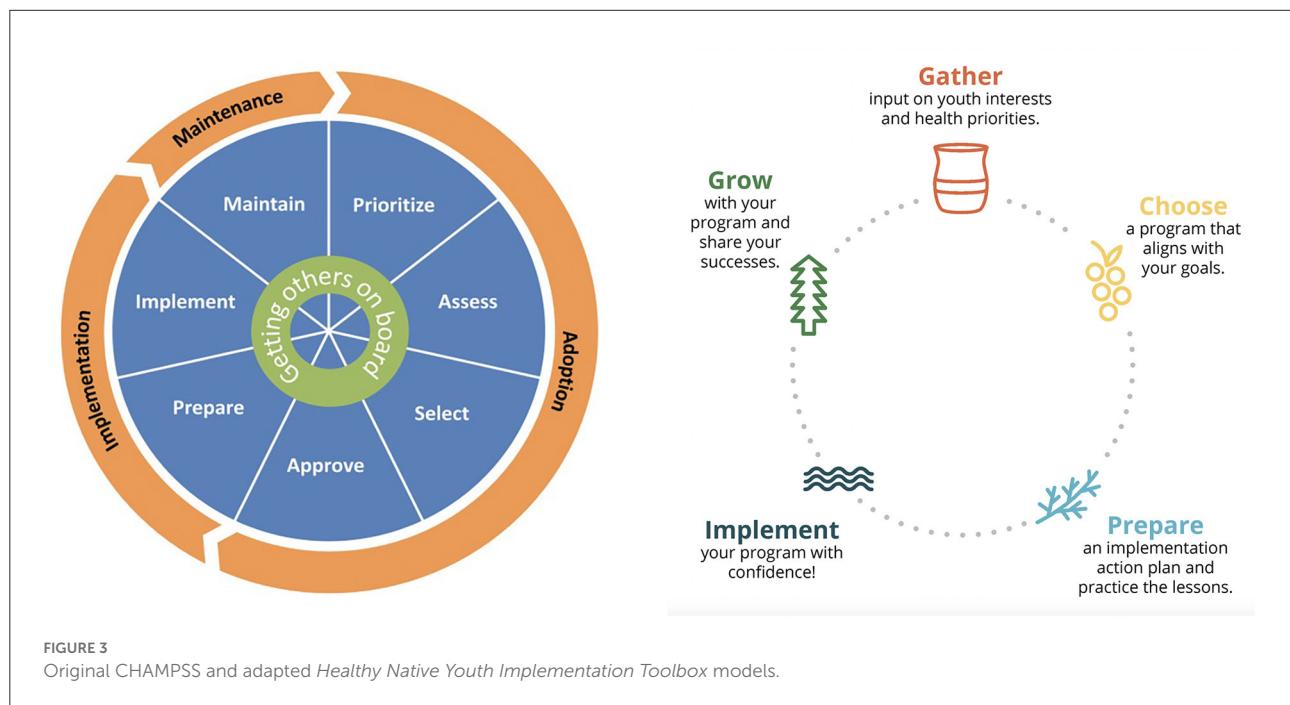
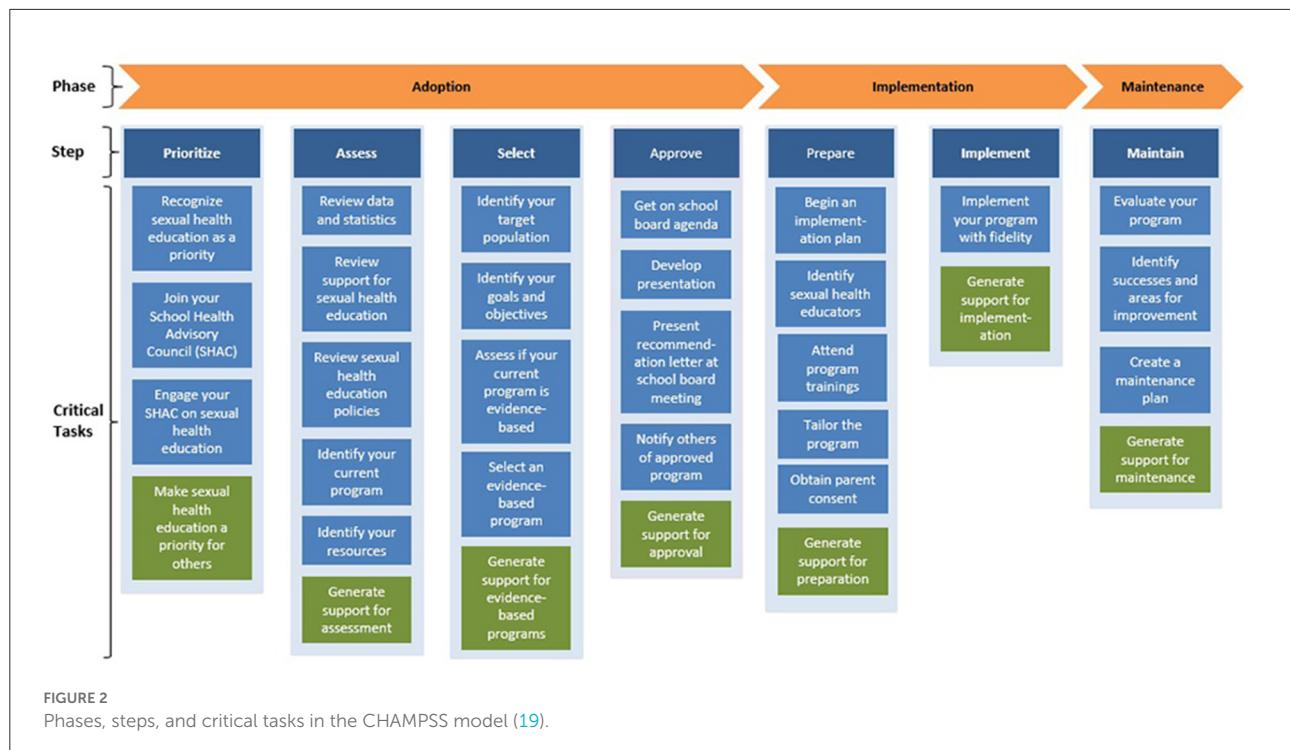
FIGURE 1
The iCHoosing And Maintaining Effective Programs for Sex Education in Schools (iCHAMPSS) online decision support system.

the determinants of adoption and implementation. For example, our success story video testimonials use modeling to influence planners' knowledge, skills, and self-efficacy to adopt, implement, or maintain a sexual health EBP. A detailed description of the development process is described elsewhere (17, 19).

The CHAMPSS model extends previous dissemination pragmatic models and frameworks (29–34) by providing greater focus on individual- and organizational-level determinants for the adoption, implementation, and maintenance of sexual health EBPs, and greater detail by operationalizing the steps needed to adopt, implement, and maintain sexual health EBPs in schools. The result is a pragmatic model with greater utility for practitioners, which is a recognized "model practice" by the National Association of County and City Health Officials (35).

Participatory planning approach

Community-based Participatory Research Planning (CBPR) is an important component of Implementation Mapping. CBPR principles involve engaging with community partners to better understand the complex intervention context and to facilitate integration of real-world and academic knowledge to increase the potential effectiveness of interventions and implementation strategies (27, 36). Participatory planning is especially important in partnering with AI/AN communities to ensure the integration of Native-informed practice models and conceptual frameworks (37–39). The core planning group for the adaptation process comprised adolescent health educators and researchers at the Northwest Portland Area Indian Health Board (NPAIHB), the Alaska Native Tribal Health Consortium (ANTHC), the Inter Tribal Council of Arizona, Inc. (ITCA), and the University of



Texas Health Science Center (UTHealth); hereafter, referred to as “we”. This group has collaborated for over a decade to adapt and develop online interventions and resources to promote adolescent sexual health in Native communities (11, 40, 41), including the Healthy Native Youth website

(www.healthynativeyouth.org), which provides a “one-stop-shop” for Tribal youth advocates to access culturally-relevant curricula and resources (15). The Healthy Native Youth team also hosts monthly Community of Practice virtual gatherings to share resources with Native practitioners.

We used an iterative design process incorporating input from Native practitioners and academicians, to ensure that the adapted decision support system reflects cultural identification, community values, and experiences. During the planning phase (Implementation Mapping Tasks 1 and 2), we convened an Expert Advisory Group to provide high-level guidance on adaptation of the conceptual model and parameters for use for the adapted system. The group comprised researchers in Native adolescent health and representatives from Tribal Epidemiology Centers, the National Indian Health Board, the State of Alaska Adolescent Health Program, and other Native community-based organizations. During the design phase (Implementation Mapping Tasks 3 and 4), we conducted formative feedback sessions with our Healthy Native Youth AI/AN Adolescent Sexual Health Workgroup to obtain input on the adapted model, proposed tools, and website design mock-ups. The workgroup comprises Tribal health educators, advocates, teachers, counselors, academics, and representatives from additional national organizations including the United National Indian Tribal Youth, Inc. (UNITY), Big Brothers, Big Sisters, and Boys & Girls Club of America Native Services. As we began feasibility testing (Implementation Mapping Task 5), we solicited feedback on features and tools from each *Toolbox* phase during consecutive Healthy Native Youth Community of Practice sessions. Participants included Tribal health educators, teachers, parents, and prevention specialists. Overall, these groups met virtually online using Zoom software eight times between November 2020 and June 2022. We used interactive activities (e.g., Jamboard), chat feed discussions, and polling to obtain feedback on the adapted model, tools, and the website's features, tone, and feel.

Implementation Mapping

Informed by the Intervention Mapping process and implementation science, Implementation Mapping provides step-by-step guidance for selecting, designing, or adapting implementation strategies to guide implementation efforts (27, 28). Implementation Mapping has been applied to improve the adoption, implementation, and sustainability of evidence-based programs, practices, and policies in real-world settings, including clinics, schools, and community-based service agencies (27, 42, 43). Implementation Mapping involves five specific tasks: (1) conduct a needs assessment and identify program adopters and implementers; (2) state adoption and implementation outcomes and performance objectives, identify determinants, and create matrices of change objectives; (3) choose theoretical methods and select or design implementation strategies; (4) produce implementation protocols and materials; and (5) evaluate implementation outcomes. These five tasks are iterative with the planning group circling back to previous tasks throughout to ensure all adopters and implementers, outcomes,

determinants, and objectives are addressed (27). In this project, we applied Implementation Mapping (IM) to adapt iCHAMPSS to facilitate the adoption and implementation of culturally-relevant sexual health EBPs in AI/AN communities.

Results

IM Task 1. Conduct an implementation needs assessment

In IM Task 1, planners conduct a needs and assets assessment to identify barriers and facilitators of implementation. It is important to involve all agents including adopters, implementers, and those responsible for maintaining the evidence-based interventions to identify actions needed to implement the program and determinants (barriers and facilitators) of implementation (27).

To inform the adaptation process, we conducted a needs and asset assessment to identify barriers and facilitators for the adoption, implementation, and maintenance of sexual health EBPs in AI/AN communities. Given limited D&I research within Native communities, we conducted: (1) a broad scoping review to identify common barriers and effective implementation strategies to disseminate and implement health promotion EBPs in AI/AN, Native Hawaiian/Pacific Islander (NH/PI), and Canadian Indigenous communities, and (2) key informant interviews with experienced sexual health educators to identify factors specific to the D&I of sexual health EBPs in AI/AN communities.

Scoping review

Partnering with a research librarian, we identified research questions (What are the main barriers encountered in the D&I of EBPs in Indigenous communities? What implementation strategies have been used in Indigenous communities for EBP adoption, implementation and/or maintenance?), relevant electronic publication databases of PubMed, EMBASE, and Medline, formulated database search strategies, and developed a data abstraction form. To encompass a broad range of studies, EBPs were defined as any evidence-based or evidence-informed intervention or program disseminated or implemented in AI/AN, NH/PI, and/or Canadian Indigenous communities to improve health or behavioral outcomes for any age range. "Dissemination" and "Implementation" were defined in accordance with the 2016 National Institute of Health definitions (44). Barriers were classified into nine barrier categories within a broader socio-ecological framework (45). For comparability with D&I research in non-Indigenous communities, we categorized and coded implementation strategies according to the SISTER (School Implementation Strategies, Translating ERIC Resources) taxonomy of implementation strategies

developed to facilitate the adoption, use, and maintenance of EBPs in school-based settings (46, 47). A detailed description of our scoping review methodology is described elsewhere (48).

Twenty-one studies met our inclusion criteria, representing community-based programs in diverse Tribal communities and settings. The programs encompassed a variety of health domains, including chronic disease and injury, substance misuse, wellness and illness prevention, and historical trauma, delivered among adults and/or children and youth. Key entities who were crucial to planning program implementation included decision makers in healthcare, school, community, organizations, academics, and government. Most cited barriers ($n = 38$) sorted into the category of “Social determinants of health,” which included barriers related to socioeconomic, geographic, and structural challenges, and the impact of historical oppression and trauma. Specific barriers related to program adoption included limited funding, competing demands, and lack of program integration with cultural values. These barriers created challenges in obtaining buy-in and support from key decision makers and community members. Barriers related to program implementation and maintenance included high attrition among program participants, high personnel turnover, limited evaluation skills among program implementers, and lack of technical assistance. These barriers have implications for ensuring implementation fidelity and sustaining community participation and support.

The most commonly reported SISTER implementation strategy (identified in 86% of studies) was: “Build partnerships (i.e., coalitions) to support implementation,” followed by “Capture and share local knowledge” (81%), “Tailor strategies” (71%), and “Conduct local consensus discussion” (52%). Four SISTER strategies, previously recognized as being *highly important* for D&I success in non-Indigenous settings were represented in the top 10 strategies (47). These were, “Conduct ongoing training,” “Monitor the progress of the implementation effort,” “Provide ongoing consultation/coaching,” and “Make training dynamic.” Four SISTER strategies previously described as *most feasible* for successful D&I in non-Indigenous settings were also represented in the top 10 (47). These were: “Capture and share local knowledge,” “Make training dynamic,” “Distribute educational materials,” and “Facilitation/Problem solving” (48).

Key informant interviews

NPAIHB, ANTHC, and ITCA team members invited five sexual health educators from their respective regions to share their experience adopting, implementing and maintaining sexual health education EBPs with AI/AN youth. The interviews were conducted *via* Zoom; they lasted about 45 min, and were audio-recorded for transcription. Participant characteristics were collected in a brief post-interview survey. Participants received a \$20 e-gift certificate in appreciation of their

time. We developed an interview guide based on the adoption, implementation, and maintenance steps outlined in the CHAMPSS model. Closing questions focused on recommendations to adapt iCHAMPSS for use in Native communities (see interview guide in [Supplementary materials](#)). For data analysis, we developed a codebook based on the interview guide to categorize each step in the adoption, implementation, and maintenance process as an analytic unit. We used ATLAS.ti to code the 15 key informant interviews according to the codebook. New codes were created based on emerging themes in each category and further broken down into subthemes.

Our key informants comprised nine women, three men, and one gender non-conforming individual. Two did not disclose their gender. The majority self-identified as AI/AN, with two also selecting Asian/Pacific Islander; four participants self-identified as non-Hispanic White. Five participants listed their primary role as a health educator; others included community representatives, clinical staff, a school administrator, youth mentor, and parent. Combined, participants had over 32 years’ involvement in decision-making around or implementing sexual health education.

High rates of teen pregnancy and STIs were cited as key factors for prioritizing sexual health education in Native communities. Participants recommended engaging community partners, including community and Tribal leaders, elders, representatives from youth-serving agencies, parents, and youth throughout the planning process to build community support and reduce individual burden. Framing sexual health from a holistic health perspective and integrating culture as a protective factor helped to increase comfort and support for sexual health education. Compiling and sharing local data on adolescent health priorities and resources helped to generate support and guide program selection. Effective communication with key decision-makers, including Tribal Council and/or school board members, engaging youth voice, and preparing required paperwork, such as a memorandum of agreement, facilitated program approval.

Successful implementation of an approved program was influenced by the facilitator’s community presence, visibility, and relationship with schools and community-based programs. Participants emphasized the need for pre-planning and effective communication with site leadership regarding program logistics (e.g., supplies, space, and co-facilitators) to avoid potential barriers. Integrating digital resources helped overcome geographic challenges. Effective teaching strategies included becoming comfortable with sexual health topics, being flexible, open-minded, culturally aware, and receptive to community and youth needs. Acknowledgment of diverse backgrounds and values within the classroom, encouraging youth voice, developing and enforcing classroom rules, and integrating self-care were identified as key factors for creating a supportive environment for facilitators and youth. Engaging youth as peer

educators, providing incentives, and tailoring activities, such as inviting Tribal elders and clinicians as guest speakers, helped sustain youth involvement. Participants recommended engaging youth in reflecting on what worked well and what could be improved, and celebrating program successes with youth.

Successful maintenance of a sexual health program relied on ongoing, open communication with community members throughout the year. Sharing successes and lessons learned helped sustain interest and support. Seeking opportunities for community collaboration and input helped tailor programs to better reflect community-specific needs. Ongoing engagement with youth through cultural activities and events helped to maintain the excitement and “buy-in.” Given high personnel turnover, participants emphasized the need for ongoing training, technical assistance, and peer support to sustain and grow their program.

Recommendations for adapting iCHAMPSS for Native educators included greater representation of Native cultures and people through graphics, imagery, color schemes, and art. Participants appreciated the inclusion of videos to convey information, and recommended easy access to technical assistance or a program point of contact for implementation support. Overall, participants recommended simplifying the CHAMPSS model, and adapting the tools to reflect relevant processes in Native communities.

Prioritizing barriers and facilitators

With input from our Expert Advisory Group, the planning group synthesized findings from the needs and asset assessment to prioritize important and changeable barriers and facilitators for implementing culturally-relevant sexual health EBPs in AI/AN communities. Importance relates to how causally related a given barrier or facilitator is to implementation; changeability relates to the ease or difficulty of changing that factor (49). We chose to frame the prioritized list in the positive—that is, even when a barrier was identified, we stated it in terms of the change that needed to happen to improve implementation outcomes. We used these key recommendations to inform planning for IM Task 2 (Table 1).

IM Task 2. Identify adoption and implementation outcomes, performance objectives, determinants, and change objectives

In IM Task 2, implementation planners state adoption and implementation outcomes and performance objectives, identify determinants, and develop matrices of change objectives. Adoption and implementation outcomes are statements that describe the goal of program adoption, implementation, and

maintenance. Performance objectives describe the specific steps, or sub-behaviors, that adopters and implementers must perform to meet that overall adoption or implementation goal. Performance objectives make clear “*who has to do what*” for the program to be adopted, implemented, and maintained. For example, for adopters, one question is: “*What do [adopters] have to do to make the decision to use [the program]?*” (27).

The planning group used findings from our needs and asset assessment and Expert Advisory Group feedback to adapt the adoption and implementation outcomes and performance objectives from the CHAMPSS model to better reflect the values and experiences of AI/AN communities. Table 2 lists the adoption and implementation outcomes and performance objectives for the *Healthy Native Youth Implementation Toolbox*.

Findings from Task 1 emphasized the importance of building partnerships, as well as capturing and sharing local knowledge, to support EBPs in AI/AN communities. Feedback from our Expert Advisory Group and key informant interviews reiterated the importance of collaborative processes, community involvement, and inclusion of youth voice throughout the planning process. Recommendations were to simplify the model, with a focus on community capacity-building and collective decision-making with the community and youth. Recognizing the diverse settings in which sexual health programs are implemented in AI/AN communities and the diverse profiles of Tribal health educators, we expanded key partners beyond the school system, and identified AI/AN youth advocate(s) (e.g., representatives from school, afterschool, community-based, health, or clinic organizations) and community members, including community and Tribal leaders, elders, representatives from youth-serving agencies, parents, and youth as key actors for program adoption, implementation, and maintenance. Additional actors for implementation include Tribal health educators and peer advocates for specific program delivery.

To simplify the tasks involved in program adoption, we combined two CHAMPSS’ steps, “Prioritize” and “Assess,” into a single phase, titled “GATHER,” and two CHAMPSS’ steps, “Select” and “Approve,” into a single phase, titled “CHOOSE.” GATHER recognizes the importance of community members coming together to share their learning, visionary wisdom, and perspectives. It recognizes Tribal communities as experts and engages with them as partners to gather input on adolescent health priorities and desired health skills. Taking a strengths-based, holistic approach, the model recognizes that adolescent sexual health represents one aspect of overall physical, mental, emotional, social, and spiritual health (50, 51). The GATHER phase performance objectives describe the specific steps that program adopters must take to identify youth interests and health priorities in their community.

“CHOOSE” recognizes the role of shared decision-making in selecting a health program that best aligns with these interests and health priorities. The CHOOSE phase performance objectives describe the steps that program adopters must take

TABLE 1 Implementation Mapping Task 1: Identified barriers and facilitators for adopting, implementing, and maintaining culturally-relevant, evidence-based sexual health education programs in AI/AN communities.

| Factors identified in the needs and asset assessment | Barrier | Facilitator | Source | | Key recommendations |
|--|---------|-------------|----------------|--------------------------|---|
| | | | Scoping review | Key informant interviews | |
| Adoption | | | | | |
| Funding | ✓ | | ✓ | | <ul style="list-style-type: none"> Engage community members, Tribal leaders, parents and youth in planning process |
| Competing demands | ✓ | | ✓ | ✓ | <ul style="list-style-type: none"> Obtain community input on adolescent health priorities and resources |
| Community partnerships | | ✓ | ✓ | ✓ | <ul style="list-style-type: none"> Alleviate sensitivity by applying a holistic framework |
| Local knowledge | | ✓ | ✓ | ✓ | <ul style="list-style-type: none"> Ensure cultural relevancy (in available EBPs and implementation support) |
| Sensitivity of sexual health | ✓ | | | ✓ | <ul style="list-style-type: none"> Communicate with key decision-makers |
| Holistic health perspective | | ✓ | | ✓ | |
| Cultural values | | ✓ | | ✓ | |
| Tribal council and school board approval processes | ✓ | | | ✓ | |
| Implementation | | | | | |
| Socioeconomic, geographic, and structural challenges | ✓ | | ✓ | ✓ | <ul style="list-style-type: none"> Communicate with key decision-makers to overcome logistical challenges |
| Impact of historical oppression and trauma | ✓ | | ✓ | ✓ | <ul style="list-style-type: none"> Include digital channels to address geographic barriers Provide appropriate training |
| Level of comfort with sexual health topics | ✓ | | | ✓ | <ul style="list-style-type: none"> Adapt program to fit local context and need Engage youth in programming |
| Participant attrition | ✓ | | ✓ | ✓ | <ul style="list-style-type: none"> Increase staff capacity to document implementation |
| Responsiveness to youth and community needs | | ✓ | | ✓ | |
| Tailored strategies | | ✓ | ✓ | ✓ | |
| Evaluation skills | ✓ | | ✓ | | |
| Maintenance | | | | | |
| Interest in program | ✓ | | ✓ | | <ul style="list-style-type: none"> Communicate with community members |
| Personnel turnover | ✓ | | ✓ | ✓ | <ul style="list-style-type: none"> Collaborate with other youth programs |
| Community communication | | ✓ | | ✓ | <ul style="list-style-type: none"> Provide ongoing training, technical assistance and peer support |
| Continued youth engagement | | ✓ | | ✓ | |
| Training and technical assistance | ✓ | | ✓ | ✓ | |

to select a culturally-relevant, age-appropriate, evidence-based health promotion program, and get approval from key decision-makers in a school or community setting, such as the school principal, clinic director, school board, health committee or Tribal council. Given varying tribal review and school board approval processes, these steps engage partners with decision-makers early in the planning process to better understand program constraints and requirements from their perspective.

For program implementation, we modified the CHAMPSS steps, “Prepare” and “Implement,” to help implementers plan and deliver a culturally-relevant program. The “PREPARE” phase performance objectives describe the steps needed to plan program implementation and gain support from key decision-makers. Inviting guest speakers, for example Tribal elders, recruiting peer educators, and integrating cultural

activities, help to engage youth and community members, and increase program transparency. Integrating self-care planning for implementers and youth helps to reduce personnel burnout and create a supportive learning environment. “IMPLEMENT” focuses on program delivery with a shift from traditional fidelity and assessment to an emphasis on reflection, listening, and feedback. The IMPLEMENT phase performance objectives describe the steps needed to implement the program successfully and collect feedback to guide future program adjustments.

For program maintenance, we modified the CHAMPSS step, “Maintain,” to inform our “GROW” phase. “GROW” recognizes the importance of reflection and collaboration to nourish and sustain your program. The GROW phase performance objectives describe the steps that planners must take to grow and sustain their program by sharing successes with community

TABLE 2 Implementation Mapping Task 2: Adapted adoption, implementation, and maintenance outcomes, actors, and performance objectives.

| Original iCHAMPSS phases | Adoption, implementation, and maintenance outcomes, and actors ^a | Performance objectives |
|--------------------------|---|--|
| Adoption | <p>GATHER community members to get guidance and feedback</p> <ul style="list-style-type: none"> • AI/AN youth advocate(s) • Community partners <p>CHOOSE a culturally relevant health program and get approval if needed</p> <ul style="list-style-type: none"> • AI/AN youth advocate(s) • Community partners | <ol style="list-style-type: none"> 1. Connect with community members for guidance and feedback 2. Gather input on youth interests and health priorities 3. Identify your community's needs and resources 4. Select your program setting 5. Gather input from youth and program participants <ol style="list-style-type: none"> 1. Identify decision-makers 2. Choose which criteria (e.g., participant age, setting, duration, and cost) are most critical 3. Select a program that aligns with your goals 4. Get approval, if needed 5. Seek input from youth and community |
| Implementation | <p>PREPARE to implement a culturally relevant health program in your school or community setting</p> <ul style="list-style-type: none"> • AI/AN youth advocate/s • Health educators • Peer educators • Community partners <p>IMPLEMENT your program and celebrate the journey</p> <ul style="list-style-type: none"> • AI/AN youth advocate(s) • Health educators • Peer educators • Community partners | <ol style="list-style-type: none"> 1. Invite guest speakers 2. Attend Community of Practice sessions 3. Prepare an implementation action plan that includes self-care 4. Order supplies, teaching tools, and incentives 5. Practice going through the program and activities 6. Recruit caregivers, youth, and allies <ol style="list-style-type: none"> 1. Explore technical assistance and resource supports 2. Implement your program with confidence 3. Track your implementation journey 4. Assess student learning and experiences 5. Celebrate the youth |
| Maintenance | <p>GROW and sustain your program</p> <ul style="list-style-type: none"> • AI/AN youth advocate(s) • Health educators • Peer educators • Community partners | <ol style="list-style-type: none"> 1. Collaborate with other youth programs 2. Grow with your program 3. Share successes and lessons learned 4. Keep the momentum going 5. Stay connected with youth beyond programming |

^aAI/AN youth advocates are typically representatives from school, afterschool, community-based, health, or clinic organizations; community partners include community and Tribal leaders, elders, representatives from other youth-serving agencies, parents, and youth.

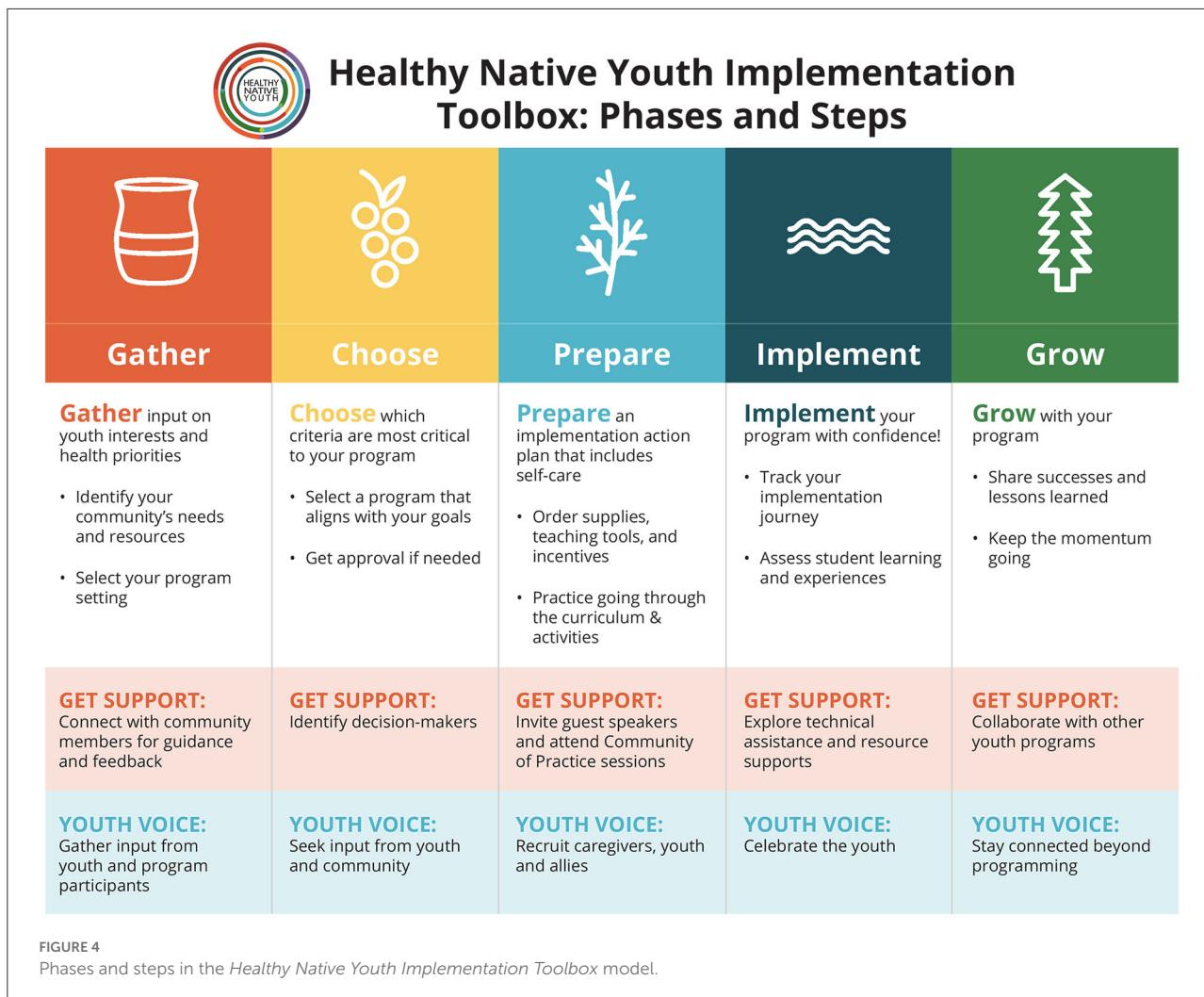
members, and cultivating relationships across other youth programs and services to keep youth engaged.

The critical elements, “Get support” (i.e., connecting with other supporters of EBPs and adolescent health) and “Youth Voice” are integrated throughout the planning process in the first and final performance objectives of each phase. These elements underscore the importance and value placed in Native communities on building partnerships, capturing and sharing local knowledge, and ensuring inclusive participation throughout the adoption, implementation, and maintenance process.

As in the original CHAMPSS model, the *Toolbox* conceptual model is circular (Figure 3), indicating that partners may enter the model at any phase depending on their community's readiness or experience implementing sexual health EBPs, or they may enter the planning process at the beginning to adopt

a new sexual health program. Figure 4 presents the “rolled-out” version of the model, illustrating the five phases (Gather, Choose, Prepare, Implement, and Grow) and phase-specific steps in the adapted *Healthy Native Youth Implementation Toolbox* model.

After we identified the performance objectives for each phase, we reviewed findings from Task 1 and the original CHAMPSS planning documents to identify important and changeable personal determinants for adopters and implementers. Determinants answer the question of “why?” For example, “*Why would an implementer deliver the program as planned?*” These may be constructs from health promotion theories, such as Social Cognitive Theory (23) or Theory of Planned Behavior/Reasoned Action Approach (52), or from implementation science frameworks. They are modifiable factors internal to the adopters and implementers that influence their adoption and implementation behavior (27). In developing



the CHAMPSS model, we identified awareness/knowledge, attitudes, skills and self-efficacy, outcome expectations, and perceived norms as important and changeable determinants for sexual health EBP adopters and implementers (17, 19). The planning group agreed that these determinants were also relevant for adopters and implementers in AI/AN communities. Thus, we used these determinants to complete the final step in IM Task 2, develop matrices of change objectives.

Matrices cross performance objectives with personal determinants to produce change objectives. They answer the question: “What has to change in this determinant to bring about this performance objective?” Change objectives are the discrete changes required in each relevant determinant to influence achievement of the performance objective (27). Table 3 presents the matrix of change objectives for the Toolbox adoption phase, GATHER. The first performance objective is for the AI/AN youth advocate and community partners to “PO1: Connect with community members for guidance and feedback” and the corresponding change objective for the determinant,

Awareness/Knowledge, is “List venues and organizations from which to engage youth and adult community members who understand and care about adolescent health priorities.” These matrices of change objectives formed the blueprints for adapting or developing new implementation methods and strategies in IM Task 3.

IM Task 3. Select theoretical methods and design implementation strategies

In IM Task 3, planners choose theory- or evidence-based methods to influence the determinants identified in Task 2. They also select or design implementation strategies to operationalize those methods. Theory-based methods are techniques to influence determinants of implementation (27, 28). These methods can focus either at the individual level (the knowledge, attitudes, and skills of the implementer), or at the organizational level aimed at influencing organizational change directly

(e.g., creating strong organizational leadership). Methods are important as they represent the underlying mechanism for change for an implementation strategy. Methods originate from behavioral, organizational, and community change theories, such as Social Cognitive Theory (23), the Elaboration Likelihood Model (53), Organizational Development Theory (54), and Models of Community Organization (55). These theories also specify “parameters” or situations under which a method is used appropriately. Implementation strategies refer to the ways in which program planners operationalize methods to influence determinants and change objectives for a specific adopter and task (small-scale strategies) or to the overall package of strategies influencing adoption, implementation, and maintenance (27).

In IM Task 3, we reviewed the theory-based methods and implementation strategies used in iCHAMPSS to guide decisions regarding the adaptation or development of culturally-relevant implementation strategies for the *Healthy Native Youth Implementation Toolbox*. During formative feedback sessions, our Healthy Native Youth AI/AN Adolescent Sexual Health Workgroup provided input on the acceptability and feasibility of specific implementation strategies to promote sexual health EBPs in Native communities.

In iCHAMPSS, we used multiple methods, including elaboration, persuasive communication, modeling, shifting perspective, goal-setting, and technical assistance to influence change objectives for the adoption, implementation, and maintenance of sexual health EBPs. The corresponding implementation strategies included step overviews, success stories, facts and tip sheets, ready-to-use templates, and helpful links (19). Reviewing these strategies, as well as existing culturally-relevant strategies developed by the planning group, such as the NPAIHB’s Adolescent Health Tribal Action Plan (50), the *Healthy Native Youth: Virtual Adaptation Guide* (56), and strategies from the Native STAND Dissemination, Implementation and Evaluation project, we developed a list of possible methods and implementation strategies for the Toolbox. Table 4 provides examples of methods, parameters, and implementation strategies for steps in the GATHER phase. For example, in “PO.1. Get support: Connect with community members for guidance and feedback,” we used the methods of active learning (from the Elaboration Likelihood Model) (53) and enhancing network linkages (from Theories of Social Networks and Social Support) (57) to influence awareness/knowledge, skills, and self-efficacy related to connecting with community members. The associated implementation strategy was a customizable worksheet template to identify youth advocates and community partners.

After reviewing possible methods and implementation strategies for all five Toolbox phases with our Healthy Native Youth AI/AN Adolescent Sexual Health Workgroup, we identified a common set of implementation strategies or “tool types.” These included phase overviews, templates, examples, activity guides, helpful links to resources (including Healthy

Native Youth Community of Practice recorded sessions), tips, and stories from the field (video testimonials from experienced AI/AN sexual health educators). Healthy Native Youth’s Curriculum Portal and Request Technical Assistance feature were also identified as important implementation strategies. Table 5 provides a description of each “tool type,” including its related determinants, methods, purpose, and delivery mode.

IM Task 4. Produce implementation protocols and materials

In IM Task 4, planners produce implementation protocols, activities and/or materials. Similar to Step 4 in Intervention Mapping, this requires planners to create design documents, draft content, pretest and refine content, and produce final materials. Design documents are shared between planners and production teams, and they are created for each document or other materials that are a part of the implementation strategy (27).

In Task 4, the planning group developed design documents and drafted content to guide production of the *Healthy Native Youth Implementation Toolbox* and its supporting tools. The design documents provided detailed instructions for program designers to produce the Toolbox, including specific content, messages, and tools for each Toolbox phase. We shared proposed tools and website design mock-ups with our Healthy Native Youth AI/AN Adolescent Sexual Health Workgroup to obtain feedback prior to final production.

Website development

We partnered with the original Healthy Native Youth website design team to develop and integrate the *Toolbox* into the existing website. Utilizing an user-centered design process, the website designers created “use cases” to determine different user experiences interacting with the *Toolbox*, and wire frames to guide feedback with the planning group during website development. To increase accessibility, the *Toolbox* is designed to be viewed on desktop, laptop, tablet, and mobile devices.

The *Implementation Toolbox* is accessed via the Healthy Native Youth website (www.healthy-native-youth.org; Figure 5). The home page includes links to an Introduction, which orients users to the purpose of the *Toolbox*, and two features, “Where Do I Start?” and “The Big Picture,” which are tailored to the user’s experience or need. The “Where do I start?” feature is tailored for users who have already started the process of implementing youth programs and may have specific goals. The user can select from a list of nine activities, each relating to one of the five phases, such as, “I want to engage youth in the planning process,” “I want to do a community needs

TABLE 3 Implementation Mapping Task 2: Example matrix of change objectives for adoption outcome, "GATHER community members to get guidance and feedback."

| Performance objectives (PO) AI/AN youth advocate and community partners ^a will: | Determinants | | | | |
|---|---|---|--|--|--|
| | Awareness/knowledge (A/K) | Attitudes (A) | Skills and self-efficacy (SSE) | Outcome expectations (OE) | Perceived norms (PN) |
| PO.1. Connect with community members for guidance and feedback | A/K.1.a. List venues and organizations from which to engage youth and adult community members who understand and care about adolescent health priorities | A.1.a. Recognize the value of integrating community voice, expertise, and resources throughout the planning process | SSE.1.a. Demonstrate ability to engage youth and adult community members in the planning process SSE1.b. Express confidence in building partnerships to help your program succeed | OE.1.a. Expect that obtaining guidance and feedback from youth and adult community members will help prioritize adolescent health issues in your community, and support implementation of your program | PN.1.a. Recognize that other youth advocates engage youth and adult community members in planning adolescent health programs |
| PO.2. Gather input on youth interests and health priorities | A/K.2.a. Describe different methods (surveys, social media poll, in-person interviews, Zoom breakout rooms, Poll feature) to assess adolescent health priorities and desired health skills | A.2.a. Feel positive about engaging youth and adult community members to identify youth interests and health priorities | SSE.2.a. Demonstrate ability to gather feedback from youth and adult community members SSE2.b. Express confidence to collectively identify youth interests and health priorities | OE.2.a. Expect that gathering input from different perspectives will help identify adolescent health priorities and desired health skills | PN.2.a. Recognize that other youth advocates and partners gather input to prioritize adolescent health topics |
| PO.3. Identify your community's needs and resources | A/K.3.a. Describe strategies to assess what youth, their families, and the broader community want to see in youth programming A/K.3.b. List available resources (staffing, program materials, teaching tools, funding) to implement an adolescent health program A/K.3.c. List constraints or challenges to be addressed A/K.3.d. List strategies to assess community readiness to inclusively address adolescent health, including needs of 2SLGBTQ youth | A.3.a. Feel positive about partnering with community members to identify needs and resources | SSE.3.a. Demonstrate ability to identify needs and resources for adolescent health programs SSE3.b. Express confidence in assessing community readiness to inclusively address youth's health needs SSE.3.c. Express confidence in aligning adolescent health programs with community's cultural values and traditions | OE.3.a. State that identifying needs and resources for adolescent health will lead to adopting a program that is feasible, acceptable, and culturally relevant for youth in the community | PN.3.a. Recognize that youth advocates and partners in other communities assess needs and resources for adolescent health programs |

(Continued)

TABLE 3 (Continued)

| Performance objectives (PO) AI/AN youth advocate and community partners ^a will: | Determinants | | | | |
|---|---|--|---|---|---|
| | Awareness/knowledge (A/K) | Attitudes (A) | Skills and self-efficacy (SSE) | Outcome expectations (OE) | Perceived norms (PN) |
| PO.4. Select your program setting | A/K.4.a. List potential settings (e.g., school, afterschool, community, and clinic) to implement an adolescent health program A/K.4.b. List possible delivery modes (in-person, virtual, and hybrid) for adolescent health program A/K.4.c. Describe challenges or limitations (limited time, shared space, and few trained facilitators) | | SSE.4.a. Express confidence in identifying potential settings and delivery modes for program implementation | OE.4.a. Describe how selection of potential settings and delivery modes by community partners will increase likelihood of successful program implementation | PN.4.a. Recognize that youth advocates and partners in other communities successfully implement adolescent health programs implementation |
| PO.5. Gather input from youth and program participants | A/K.5.a. Describe how programs and services aimed at adolescents are likely to have a more significant impact if they are developed with the involvement of youth A/K.5.b. Describe ways to gather input from different youth audiences (rural, reservation, and urban) and age groups | A.5.a. Express that youth are experts on their own beliefs, values, and behaviors, as well as those of their peers | SSE.5.a. Demonstrate ability to gather youth input regarding program selection SSE.5.b. Express confidence in obtaining youth input in program selection | OE.5.a. State that obtaining youth input in the planning process will help ensure that selected program(s) are relevant to youth needs | PN.5.a. Recognize that youth advocates and partners in other communities value the inclusion of youth voice in decision-making |

^aAI/AN youth advocates are typically representatives from school, afterschool, community-based, health, or clinic organizations; community partners include community and Tribal leaders, elders, representatives from other youth-serving agencies, parents, and youth.

TABLE 4 Partial Implementation Mapping Tasks 3 and 4: Steps, determinants, methods, parameters, implementation strategies, and example messages from the *Healthy Native Youth Implementation Toolbox* GATHER phase.

| GATHER steps ^a | Determinants and change objectives ^b | Methods ^c | Parameters ^c | Implementation strategies ^c | Example messages in the implementation strategy |
|--|--|---|--|---|---|
| Get Support: Connect with community members for guidance and feedback | Awareness/knowledge A/K.1.a. Skills/self-efficacy SSE.1.a., 1.b. Attitudes, outcome expectations, and perceived norms A.1.a, OE.1.a PN.1.a. | Active learning Enhancing network linkages Persuasive communication Modeling | Requires time, information, and skills Requires available network Messages must be relevant, not too dissimilar from individual's beliefs Model must be relatable, describe specific steps or skills, receive reinforcement | Template: Customizable worksheet to identify youth advocates and community partners Phase overview: Supportive, friendly introduction to phase goal and steps Stories from the field: Video testimonial from a Native trusted advisor to inspire caring adults to support Native youth by selecting and implementing culturally-relevant programs | Teamwork makes the dream work! In the GATHER phase of the process, connect with community members to identify the health priorities and interests of youth in your program As you begin the planning process, it's a good idea to identify community partners that can support the delivery and implementation of your program |
| Gather input on youth interests and health priorities | Awareness/knowledge A/K.2.a. Skills/self-efficacy SSE.2.a., SSE.2.b. Attitudes, outcome expectations, and perceived norms A.2.a, OE.2.a PN.2.a. | Technical assistance Modeling | Must fit user's need, culture, and resources Model must be relatable, describe specific steps or skills, receive reinforcement | Helpful links: Links to example adolescent health action plans that incorporate adolescent health and wellness models Stories from the field: Video testimonial from an educator on the skills that Native youth learn from culturally-relevant programs | Engage diverse community partners to gather feedback from different perspectives to identify adolescent health priorities and desired health skills An educator shares her observation of Native youth learning accurate adolescent health information in their Native STAND class and paying it forward as peer educators |
| Identify your community's needs and resources | Awareness/knowledge A/K.3.a., A/K.3.b., A/K.3.c., A/K.3.d. Skills/self-efficacy SSE.3.a., SSE.3.b., SSE.3.c. Attitudes, outcome expectations, and perceived norms A.1.a OE.1.a PN.1.a. | Community assessment Community development | Requires assistance and possibilities for feedback Starting where the community is; may be grassroots or professional driven | Template: Customizable guide to conduct a community needs and resource assessment (who to engage, how to reach them, how and where to gather input, sample questions, how to share findings) | It is helpful to complete a community needs and resource assessment early in the planning process... This phase shouldn't be a major research effort! By gathering feedback or asking questions, you will be collecting valuable information and building partnerships that will help your program succeed. |

(Continued)

TABLE 4 (Continued)

| GATHER steps ^a | Determinants and change objectives ^b | Methods ^c | Parameters ^c | Implementation strategies ^c | Example messages in the implementation strategy |
|--|---|----------------------------------|--|---|---|
| Select your program setting | Awareness/knowledge A/K.4.a., A/K.4.b., A/K.4.c., Skills/self-efficacy SSE.4.a. Outcome expectations OE.4.a. | Active learning | Requires time, information, and skills | Template: Customizable worksheet | Now, it's time to choose when and where to identify strengths and deliver the program... Think through each of limitations of program settings and your options: Will you implement the virtual platform options for adolescent health programs |
| Youth Voice: Gather youth input | Awareness/knowledge A/K.5.a., Skills/self-efficacy SSE.5.a., SSE.5.b. Attitudes, outcome expectations, and perceived norms A.5.a., OE.5.a., PN.5.a. | Active learning Participation | Requires time, information, and skills Requires willingness by the health promoter or convener to accept the participants as having a high level of influence | Activity guide: Interactive Bingo activity to make ensure programs reflect youth needs and concerns | Young people are experts on their own beliefs, values, and behaviors, as well as those of their peers. Consult with your Tribe's Youth Delegates, talk with your current students, or host a youth gathering and moderate the "Bingo Data Collection" activity to make sure your programs reflect their needs and concerns. |

^aPerformance objectives from adoption outcome matrix for GATHER in [Table 3](#).

^bDeterminants and change objectives from adoption outcome matrix for GATHER in [Table 3](#).

^cA theory-based method "is a general technique to influence determinants of implementation;" parameters are guidelines or conditions needed for a method to be effective; implementation strategies are strategies to influence specific determinants and change objectives of an adopter or implementer ([27, 28](#)).

TABLE 5 Implementation Mapping Tasks 3 and 4: *Healthy Native Youth Implementation Toolbox* tool types: Determinants, methods, delivery mode, purpose, and description.

| Tool types | Determinants | Methods | Delivery Mode | Purpose | Description and number of tools |
|--|---|---|--------------------------|---|--|
| Phase overviews | Awareness/knowledge, attitudes, skills and self-efficacy, outcome expectations, and perceived norms | Persuasive communication | Text on screen | Introduction to the goal and steps of each phase | Supportive, friendly introductions to each phase's goal and steps ($n = 5$) |
| Templates | Awareness/knowledge, attitudes, skills and self-efficacy | Active learning | Customizable documents | Ready-to-use formatted examples of deliverables (e.g., community needs and resource assessment, letter of support, implementation action plan, attendance sheets) | Ready-made, easily modifiable documents that take the burden off the user ($n = 17$) |
| Examples | Awareness/knowledge, skills and self-efficacy, perceived norms | Modeling | Print materials | Sample models of deliverables (e.g., program budget, student surveys, certificate of completion, newspaper article) | Culturally-relevant, easy-to-replicate examples of print deliverables ($n = 12$) |
| Activity guides | Awareness/knowledge, attitudes, skills and self-efficacy | Active learning Participation | Print material | Guide for interactive feedback activity | Step-by-step guide for conducting interactive Bingo data collection activity ($n = 1$) |
| Helpful links | Awareness/knowledge, attitudes, skills and self-efficacy, outcome expectations, and perceived norms | Facilitation | Additional web resources | Credible / trustworthy outside resources for more information on particular topics | Easy-to-navigate links to resources including links to Community of Practice recorded session on HNY You Tube ($n = 9$) |
| Tips | Awareness/knowledge, skills and self-efficacy | Facilitation Persuasive communication | Text on screen | Encouraging advice for completing a particular phase | Tips and lessons from the field to assist with program selection, implementation, and growth ($n = 7$) |
| Stories from the field | Awareness/knowledge, attitudes, skills and self-efficacy, outcome expectations, and perceived norms | Modeling | Video | Stakeholder role models who validate the user's readiness and demonstrate how they successfully implemented a culturally-relevant adolescent health program | Stories from real practitioners who can relate their experience of changing attitudes and capabilities as they navigated barriers and achieved success ($n = 7$) |
| Healthy Native Youth curriculum portal | Awareness/knowledge, outcome expectations, skills and self-efficacy | Facilitation Technical assistance Active learning | Web-based resource | Preview and compare culturally-relevant, age-appropriate adolescent health curricula Access curricular materials and training | Culturally-relevant, evidence-based, age-appropriate adolescent health curricula on sexual health ($n = 9$), suicide prevention ($n = 4$), healthy coping ($n = 1$), and positive parenting ($n = 1$) <i>Curriculum-specific program pages</i> provide information on training, lesson plans, supporting materials, cultural relevance, and evaluation findings ($n = 15$) <i>Curriculum comparison chart</i> allows user to compare curricula by criteria (e.g., age, setting, duration, cost, and evidence of effectiveness; $n = 1$) |

(Continued)

TABLE 5 (Continued)

| Tool types | Determinants | Methods | Delivery Mode | Purpose | Description and number of tools |
|--|---|---|---------------|--|---|
| Healthy Native Youth Community of Practice and recorded sessions | Awareness/knowledge, attitudes, skills and self-efficacy, outcome expectations, and perceived norms | Modding Facilitation Technical assistance | Video | Online learning community to share experiences with AI/AN youth advocates. Users may review previously recorded Community of Practice sessions and download supporting documents | Community of Practice online sessions provide resources and opportunities to engage with Native professionals in AI/AN adolescent health ($n = 42$) |
| Healthy Native Youth request technical assistance form | Awareness/knowledge, attitudes, skills, and self-efficacy | Facilitation Technical assistance | In-person | Allows user to submit an online request for technical assistance or training to select or implementing a culturally-relevant program or address other youth topics | Online form to submit technical assistance request |

assessment,” or “I want to select a health curriculum,” and be directed to the relevant phase and tools. “The Big Picture” feature provides a concertina-style overview of the five phases and their respective steps and tools, so that users may select their own entry point into the *Toolbox*. The “ulu” icon (an all-purpose knife traditionally used by Inuit, Iñupiat, Yupik, and Aleut women) indicates links to relevant tools. “The Big Picture” feature was designed for easy viewing on mobile devices (Figure 6).

Within the *Toolbox*, each phase has its own Phase Overview page that orients the user to the goal and steps for that phase, including steps for Get Support and Youth Voice. Each overview page leads to step-specific pages with links to relevant tools (templates, examples, activity guide, tips, helpful links, or success stories) to successfully complete the phase. A radio button panel across the top of each page indicates the user’s overall progress through the phases and steps (Figure 7).

Tools development

The planning group developed design documents for each tool that specified its purpose, delivery mode, content, and messages. The tone of the messages is user-friendly, strength-based, and supportive. Table 3 (sixth column) provides example of specific messages for tools in the GATHER phase. The NPAIHB graphic design team developed Indigi-icons, reflective of Native values, to represent each phase in the planning process (Figure 4). Each tool includes the Indigi-icon for its respective phase and simple instructions on how to use the tool. Figure 8 presents the customizable template from the GATHER phase to create a youth advocates and community partners map.

Healthy Native Youth’s *Curriculum Portal* is an important tool for the CHOOSE phase as it provides free access to culturally-relevant, age-appropriate evidence-based curricula designed or adapted for AI/AN youth. The portal currently includes nine curricula related to sexual health, four related to suicide prevention, and two related to healthy coping and positive. *Curriculum-specific program pages* provide information on training, lesson plans, supporting materials, cultural relevance, and evaluation findings. The *Curriculum Comparison Chart* allows users to compare curricula by criteria (e.g., age, setting, duration, cost, and evidence of effectiveness) to select a curriculum that best aligns with their community’s goals. Evidence of effectiveness follows the Center for Disease Control and Prevention’s (CDC) classification of evidence-based practices: emerging practice, promising practice, leading practice, best practice, and/or tribal best practice (8) (Figure 9).

Finally, the Healthy Native Youth Community of Practice and Request Technical Assistance features provide peer and technical support from the Healthy Native Youth Collective Partnership to help AI/AN youth advocates adopt and implement culturally-relevant health programs. The Healthy Native Youth SMS text messaging series provides additional

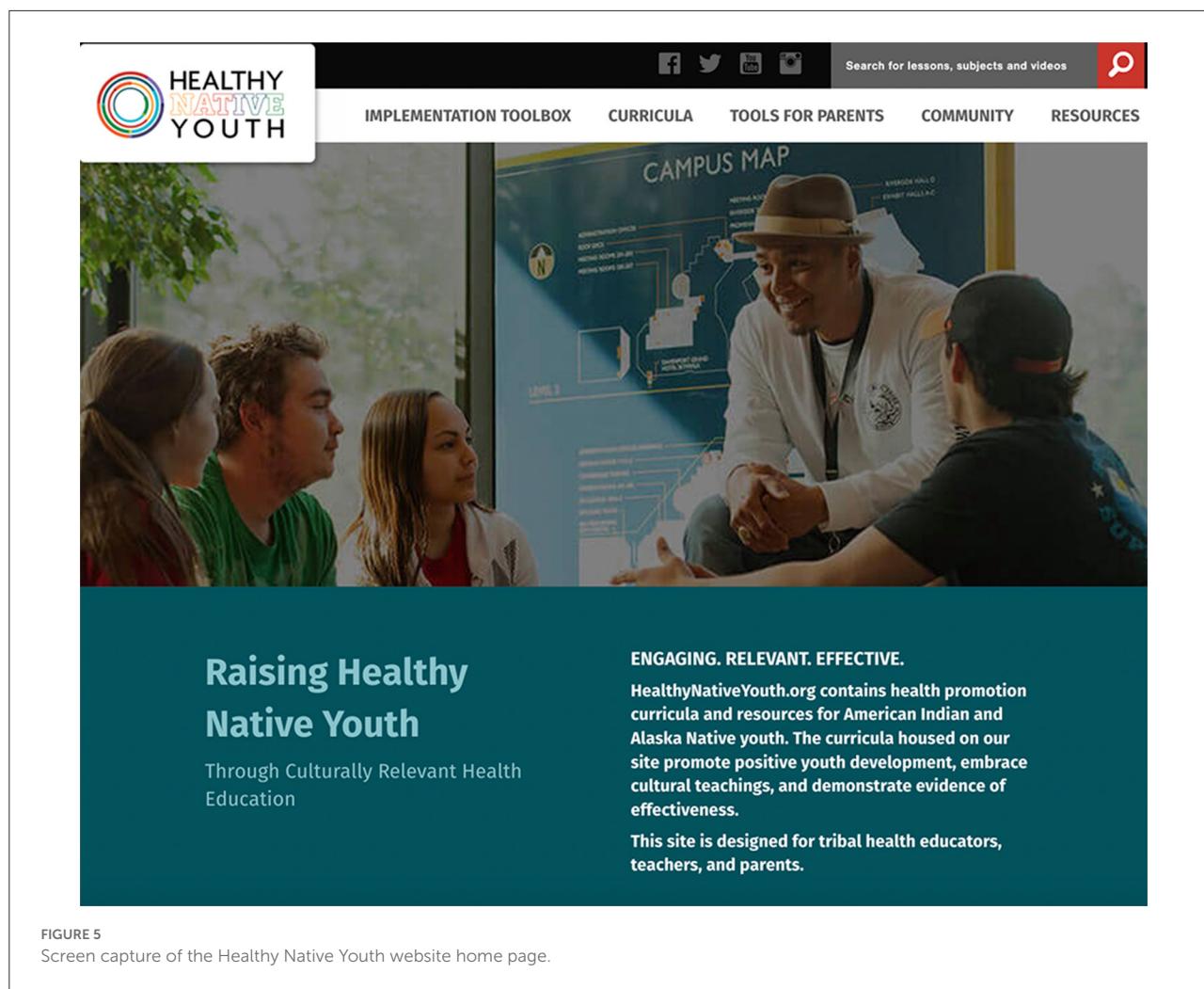


FIGURE 5
Screen capture of the Healthy Native Youth website home page.

resources for directly for youth and trusted adults. See [Supplementary material](#) for a comprehensive list of current *Toolbox* tools by phase. [Table 6](#) provides a side-by-side summary of adaptations by Implementation Mapping task from the original iCHAMPSS decision support system to the adapted *Healthy Native Youth Implementation Toolbox*.

We launched the *Healthy Native Youth Implementation Toolbox* in December, 2021. We have sequentially shared the GATHER, CHOOSE, PREPARE and IMPLEMENT, and GROW phase tools with AI/AN youth advocates at four, online Community of Practice sessions. The feedback from practitioners has been positive, with comments including: “very user friendly,” “helpful, easy to understand,” “concretely helpful tools,” “visually great,” “ease of access.” We also received feedback that, “Downloadable tools and templates in the Big Picture were hard to find.” We are also actively disseminating the *Toolbox* via Healthy Native Youth’s e-newsletter, Twitter, and Facebook page and Indiancountryecho.org. Based on feedback, we are compiling a list of features for the *Healthy*

Native Youth Implementation Toolbox version 2.0, which will include a searchable “tools library” to help users locate the tools they need.

IM Task 5. Evaluate implementation outcomes

In IM Task 5, planners develop an evaluation plan that describes expected implementation outcomes for adoption, implementation, and/or maintenance (27). To inform evaluation planning, we are conducting a feasibility study to obtain feedback from AI/AN youth advocates on their experience using the *Toolbox*, and to assess its preliminary impact on individual and community-level determinants for implementing culturally-relevant sexual health EBPs in AI/AN communities. Using a convenience sample, pre/post-test design, we have recruited 29 individuals

THE BIG PICTURE

GIVE US FEEDBACK 

Where do I start?

 **Gather**

Get support: Connect with community members for guidance and feedback. [Learn more](#) 

Gather input on youth interests and health priorities. [Learn more](#) 

Identify your community needs and resources. [Learn more](#) 

Select your program setting. [Learn more](#) 

Youth voice: Gather input from youth and program participants. [Learn more](#) 

 **Choose** 

 **Prepare** 

 **Implement** 

 **Grow** 

FIGURE 6
Screen capture of the *Healthy Native Youth Implementation Toolbox*: The Big Picture feature.

from AI/AN youth-serving organizations across the U.S. to trial the *Toolbox* for a 6-month period. We will use pre- and post-test survey data to assess changes in stage of community readiness to adopt/implement/maintain a sexual health EBP; individual knowledge and attitudes toward culturally-relevant sexual health EBPs; perceived support of an EBP by various groups (e.g., parents and Tribal leaders); self-efficacy to complete each *Toolbox* step, and network connections to advocate for culturally-relevant sexual health EBPs. Post-test survey items adapted from previous usability instruments will assess acceptability, ease of use, utility, credibility, motivational appeal, and perceived helpfulness (24, 25, 58, 59). Additional items request recommendations for future enhancements. Findings will inform the development of *Toolbox Version 2.0* and provide preliminary data for a future multisite effectiveness-implementation trial.

Discussion

Limited tools exist to help AI/AN communities adopt, implement, and maintain culturally-relevant, age-appropriate, evidence-based adolescent sexual health education programs. We used the systematic planning approach, Implementation Mapping, to adapt an existing online decision support system, iCHAMPSS, to better support sexual health education D&I processes in Native communities. The resulting conceptual model that underlies the *Healthy Native Youth Implementation Toolbox* is reflective of the values and experiences of AI/AN communities. More importantly, the *Toolbox* provides guidance and decision support to Tribal health advocates on each phase of the process, sharing adaptable ready-to-use templates, relatable examples, and stories from the field. Many health educators tasked with selecting and implementing a culturally-relevant, age-appropriate sexual health program do not have formal

GROW

OVERVIEW: Sustain and grow your program

Goal: Reflect on what works, what can change, and what you are learning as you go on this journey. Use this knowledge to grow and to keep the momentum going.

Congratulations! You have implemented your program and you have learned quite a bit on the journey. You are now in the GROW phase. Take some time to think about how you will grow with the program and how you want to keep the momentum going. Reach out and collaborate with other youth programs. Document your experiences and plan to build upon them in the next round of implementation. Share the lessons you learned with your youth and your community. Celebrate the wins! Above all, keep cultivating relationships and find ways to stay connected beyond programming.

Grow Phase Steps

Get support: Collaborate with other youth programs

1. Grow with your program
2. Share successes and lessons learned
3. Keep the momentum going

Youth voice: Stay connected beyond programming

FIGURE 7
Screen capture of the *Healthy Native Youth Implementation Toolbox*: GROW phase overview.

training in public health or research methods. Developing approachable language and visuals, offered in phased bite-size pieces, is critical to meet the needs of diverse program champions, who in turn must navigate diverse delivery settings. Many of the tools and templates now featured in the *Toolbox* had already been used in the field by Tribal health educators, but were not logically sequenced or offered with accompanying tips or examples. Consolidating these tools and resources into a comprehensive *Toolbox* was a critical next-step to support AI/AN health advocates and community partners to navigate the planning process.

Using Implementation Mapping to guide the adaptation process had multiple advantages and helped address several challenges previously identified in the implementation science literature. Prior research has highlighted the need for methods

that improve the selection and tailoring of implementation strategies for a given setting (60), and that articulate the causal pathways through which implementation strategies are effective (61). Implementation Mapping provided a systematic approach to select, adapt, and create implementation strategies that are tailored to the cultural values and realistic experiences of Native communities. In Tasks 1 and 2, we identified barriers and facilitators unique to the D&I process of sexual health EBPs in Native communities, and developed culturally-relevant behavioral outcomes and performance objectives to guide the adaptation process. In Tasks 3 and 4, we selected theory-based methods that would influence the personal determinants of Native adopters and implementers, and designed culturally-relevant tools and messages to facilitate the D&I process. The explicit linkage of determinants to methods to tools



FIGURE 8
Template for GATHER phase: Youth advocates and community partners map.

articulates the proposed mechanism of change that underlies the *Toolbox*.

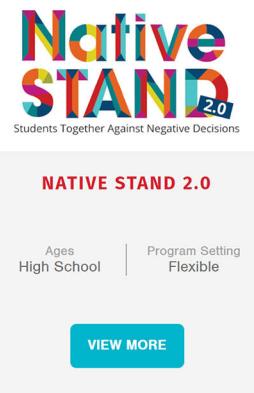
Prior research has also highlighted the critical role of community engagement to accelerate and improve the implementation of EBPs. Community-engaged D&I research can help improve health inequities through incorporating unique perspectives from communities, that have been historically left out of the research process (62, 63). Collaborative planning is a fundamental principle of Implementation Mapping (27). Our adaption process involved a multi-disciplinary research team together with input from diverse partners ranging from national experts to educators on the ground to capture the unique experience of implementing sexual heath EBPs in Native communities. We are continuing to collect feedback from users to guide further development of the *Toolbox* to ensure higher reach, satisfaction, and sustained implementation outcomes. Continued training and technical assistance will be also critical to successfully support uptake and use.

Developing culturally-relevant implementation strategies requires collaboration with AI/AN practitioners and academicians, as well as responsiveness to Native-informed practice models and conceptual frameworks (37, 38). Interventions must also align with organizational capacity and community readiness to be sustainably implemented (39).

Our adaptation process was informed by cultural sensitivity adaptation frameworks and principles (37, 64–68), and included changes to surface and deep structures (65). Surface structure adaptations involved matching materials and messages to observable characteristics of AI/AN communities (e.g., images, people, and locations), while deep structure involved incorporating cultural, social, environmental, and psychological processes unique to the dissemination and implementation of sexual health EBPs in Native communities. We used an iterative design process, incorporating input from diverse Native partners, to ensure that the final product reflects cultural identification, community values, and needs.

Although using Implementation Mapping had multiple advantages, it was not without its challenges. These included the time required to identify relevant outcomes and performance objectives that reflected the values and processes involved in adopting, implementing, and maintaining sexual health educations programs in Native communities. This process took over a year to complete, with iterative feedback from our advisory groups and community members. It then took 6 months to translate these objectives into supportive, accessible messaging and tools that would resonate with our intended audience. Lessons learned along the way included the critical role that NPAIHB, ANTHC, and ITCA's collective experience partnering with AI/AN communities played in grounding the

| Program Name | Native STAND 2.0 | Native It's Your Game 2.0 | Respecting the Circle of Life |
|---------------------------|---|---|--|
| Age | High School | Middle School | Middle School High School |
| Program Setting | Flexible | Flexible | Flexible |
| LGBT Inclusive | Yes | Yes | Yes |
| Trauma Informed | Yes | Yes | Yes |
| Health Topics Covered | Healthy Relationships Other Healthy Life-Skills Sexual Health | Healthy Relationships Other Healthy Life-Skills Sexual Health | Healthy Relationships Sexual Health |
| Evidence of Effectiveness | Promising Practice | Promising Practice | Best Practice |
| Duration | 18 sessions (50 minutes each) | 13 lessons (30-50 minutes each) | Available in 50, 60, 80, or 120-minute lessons. Entire program duration from 9-13 lessons. Total time is 16 hours. Download schedule for more details. |
| Certification Required | No | No | No |



NATIVE STAND 2.0
Students Together Against Negative Decisions

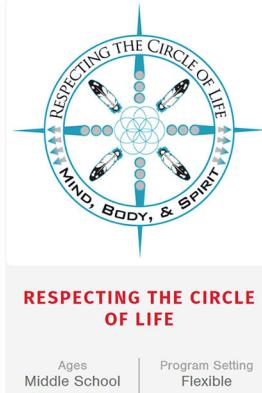
Ages: High School | Program Setting: Flexible

[VIEW MORE](#)



NATIVE IT'S YOUR GAME 2.0
NIYG 2.0 CURRICULUM

Native IYG is new & improved!



RESPECTING THE CIRCLE OF LIFE

Ages: Middle School
High School | Program Setting: Flexible

FIGURE 9
Healthy Native Youth curriculum portal resources, including curriculum comparison chart and example curricula.

adaptation process from a holistic, strengths-based perspective, and the importance of collaborating with experienced AI/AN creatives for website development and graphic design to ensure that *Toolbox* features, language, and imagery were relevant and engaging for Native practitioners.

Alongside these lessons learned, several limitations should be noted. First, the *Toolbox* represents an adaption of an existing online decision support system rather than the development of a new program using ethnographic and grounded theory approaches. Thus, it does not meet the ideal of a culturally-based, culturally congruent, and culturally grounded practice emerging from AI/AN world views (37). Second, for our scoping review, although the similarity with findings from previous studies indicates some validity across cultural settings, our coding, or limited D&I research in these settings, may have failed to identify implementation strategies that are unique to Native

communities. Third, the limited practitioner sample for our key informant interviews and feedback during the adaptation process means that the generalizability of the conceptual model and implementation strategies are unknown. Finally, the feasibility and efficacy of the *Toolbox* are yet to be established. Findings from our feasibility study will provide feedback to further refine the *Toolbox*, and future studies should focus on a rigorous evaluation to assess its impact on the adoption, implementation, and maintenance of sexual health EBPs in Native communities.

Conclusion

There is a continued need to design, test, and evaluate D&I strategies that are relevant to Native communities. The

TABLE 6 Summary of Adaptations from iCHAMPSS to the *Healthy Native Youth Implementation Toolbox* by Implementation Mapping Task.

| Original iCHAMPSS | Adapted Healthy Native Youth (HNY) Implementation Toolbox |
|--|---|
| IM Task 1. Conduct an implementation needs assessment | |
| Priority population | <ul style="list-style-type: none"> • Texas school districts |
| Innovation being disseminated | <ul style="list-style-type: none"> • US DHHS recognized evidence-based sexual health education programs |
| Stakeholder feedback groups | <ul style="list-style-type: none"> • School-based community stakeholder group (district level School Health Advisory Council [SHAC] members, district curriculum coordinators, school nurses, and parents) |
| Adopters | <ul style="list-style-type: none"> • School district level personnel (Board of Trustees and SHAC members), school principals |
| Implementers | <ul style="list-style-type: none"> • District curriculum coordinator, school principals, school curriculum coordinator, and teachers |
| Maintainers | <ul style="list-style-type: none"> • District and school curriculum coordinators, principals, and teachers |
| IM Task 2. Identify adoption and implementation outcomes and performance objectives | |
| Conceptual model based on implementation outcomes and performance objectives |  |
|  | |
| IM Task 3. Select theoretical methods and design implementation strategies | |
| Theoretical methods | <ul style="list-style-type: none"> • Persuasive communication: Step overview videos |
| Implementation strategies (examples) | <ul style="list-style-type: none"> • Modeling: Success story testimonial videos • Active learning: Templates • Technical assistance: Facts and tips • Technical assistance: Helpful links • Enhancing network linkages: Online message board |
| IM Task 4. Produce implementation protocols and materials | |
| Website url | <ul style="list-style-type: none"> • www.ichampss.org |
| Delivery vehicle | <ul style="list-style-type: none"> • Desktop, laptop |
| Point(s) of entry | <ul style="list-style-type: none"> • Get Started feature; Stage Your District tool |

(Continued)

TABLE 6 (Continued)

| | Original iCHAMPSS | Adapted Healthy Native Youth (HNY) Implementation Toolbox |
|--|--|--|
| Curriculum selection tools | <ul style="list-style-type: none"> EBP Selection guide (pdf) lists US DHSS reviewed evidence-based sexual health education curricula ($n = 26$) by curriculum characteristics (e.g., age, gender, race/ethnicity, and outcomes of evaluation study, cost, training requirements) | <ul style="list-style-type: none"> Curriculum portal provides access to culturally-relevant, evidence-based sexual health, substance use, suicide prevention, healthy coping, and positive parenting curricula ($n = 15$) Curriculum Comparison Chart allows users to compare curricula by criteria (e.g., age, setting, duration, cost, and evidence of effectiveness) |
| Testimonial videos | <ul style="list-style-type: none"> Success Stories from experienced Texas school district personnel | <ul style="list-style-type: none"> Stories from the Field from experienced AI/AN sexual health educators |
| Tools library | <ul style="list-style-type: none"> 60+ tools | <ul style="list-style-type: none"> 20+ tools |
| Images | <ul style="list-style-type: none"> School district and school settings, diverse youth and adults | <ul style="list-style-type: none"> AI/AN communities, youth, adults, and elders Indigi-icons |
| Communication and networking | <ul style="list-style-type: none"> Online message board | <ul style="list-style-type: none"> HN Community of Practice online sessions |
| Technical assistance | <ul style="list-style-type: none"> Contact us feature | <ul style="list-style-type: none"> Request technical assistance feature Recorded HNY Community of Practice sessions |
| IM Task 5. Evaluate implementation outcomes | | |
| Preliminary evaluation | <ul style="list-style-type: none"> Usability and pilot study with Texas school personnel | <ul style="list-style-type: none"> Feasibility study with AI/AN youth advocates |

Healthy Native Youth Implementation Toolbox contributes to the dissemination and implementation of evidence-based, culturally-relevant sexual health education programs in diverse Native communities. The *Toolbox* moves beyond simply providing access to EBPs to help Native communities successfully navigate the adoption and implementation process. Implementation Mapping provided a systematic approach to guide the adaptation process and integrate community voice with the ultimate goal of improving sexual health equity among AI/AN youth.

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 the Institutional Review Board at the University of Texas Health Science Center at Houston, Committee for the Protection of Human Subjects (CPHS), and the Alaska Area Institutional Review Board. Appropriate tribal approval was obtained in Alaska through the Alaska Native Tribal Health Consortium. Written informed consent for participation was not required for this

study in accordance with the national legislation and the institutional requirements.

Author contributions

All authors made substantial contributions to the conception, design of the work, acquisition, analysis, interpretation of the data, and drafted the work or critically revised it for important intellectual content, provided final approval of the manuscript, and agreed to be accountable to all aspects of the work.

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Conflict of interest

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

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Supplementary material

The Supplementary Material for this article can be found online at: <https://www.frontiersin.org/articles/10.3389/fpubh.2022.889924/full#supplementary-material>

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Using implementation mapping for the adoption and implementation of *Target:BP* in community health centers

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Background: Despite the availability of multilevel evidence-based interventions for blood pressure management, poor hypertension control is common among community health center patient populations across the state of Texas and the United States. *Target:BP*TM is a national initiative from the American Heart Association and the American Medical Association to assist healthcare organizations and care teams in improving blood pressure control rates using evidence-based approaches and recognition of organizations who have successfully integrated the program in their practice. Using the Implementation Mapping approach, we identified determinants of *Target:BP*TM adoption and use and developed implementation strategies to improve program uptake and implementation in Community Health Centers in Texas.

Methods: We used Implementation Mapping (IM) to identify barriers and facilitators influencing the adoption and implementation of the *Target:BP*TM program and develop strategies to increase program adoption and use. We recruited four clinics across four counties in Texas and assessed barriers and facilitators at the organizational level, including electronic health records and data use. We used this data to inform clinic-specific implementation strategies based on the organization capacity and priorities feedback. We developed an implementation plan and timeline designed to improve the implementation and maintenance of *Target:BP*TM.

Results: As part of the needs and capacity assessment, we collected data through interviews with CHC staff, examining gaps in needs and services (e.g., what do clinics need to implement *Target:BP*TM?), and assets to leverage. We worked with Community Health Centers to a) identify individuals who would be involved in the adoption, implementation, and maintenance of *Target:BP*TM, b) describe adoption and implementation actions, and c) identify barriers and facilitators influencing adoption and implementation. Together with partners from Community Health Center, we used the IM

approach to identify and develop program goals, identify methods and strategies to address barriers, and create an implementation plan. Our strategies included monthly or biweekly meetings to provide technical support, reviewing program goals and timeline to ensure program implementation, progress toward reaching goals, and address quality improvement needs at each clinic site. We developed a *Target:BPTM* implementation protocol for each clinic based on the needs and capacity assessment, identification of technology use and capacity, and gap analysis. We reviewed *Target:BPTM* program strategies and self-measured blood pressure protocols tailored to the clinic patient population. We developed a collaborative plan, reviewed funding and capacity for implementation, and provided continuous quality improvement guidance. Ongoing process and impact evaluations using the Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) framework are underway.

Discussion: This paper provides an example of using Implementation Mapping to develop strategies to increase the adoption and implementation of evidence-based cardiovascular risk reduction interventions in Community Health Centers. The use of implementation strategies can increase the use of *Target:BPTM* in Community Health Centers and improve hypertension control.

KEYWORDS

implementation mapping, *Target:BP*, hypertension, community health centers, evidence-based interventions, hypertension management

Introduction

Despite the availability of multilevel evidence-based interventions (EBI's) for blood pressure (BP) management, poor hypertension control is common among community health center (CHC) patient populations across the United States. It is estimated that almost 46.6% of the U.S. adult population aged 20 and over have high BP (i.e., systolic BP greater than 130 mmHg or diastolic BP greater than 80 mmHg) and/or are taking antihypertensive medications (1). Unscheduled physician and emergency room visits with hypertension as the primary diagnosis is of critical concern, with over 33.6 million health care and 1.1 million emergency room visits annually, costing over \$131 billion each year (2). Moreover, half of all adults diagnosed with hypertension have uncontrolled hypertension and accounts for more than half a million deaths (12.7 deaths per 100,000 population) in the United States each year (3).

Considerable racial/ethnic, sex, and socio-economic disparities exist in hypertension diagnosis, treatment, and control. For example, Hispanic and Black males are disproportionately more likely to have hypertension than their female counterparts (4). Among adults with a diagnosis of hypertension, BP control is higher among non-Hispanic Whites (32%) compared with non-Hispanic Blacks (25%), non-Hispanic Asians (19%), and Hispanics (25%) (5). Further disparities are found by geographic regions, with Texas having a 32% prevalence of self-reported hypertension among adults

compared to lower rates across the U.S. This reported prevalence may be an underestimation for Texas given the large uninsured and underinsured population; 18.4 percent of Texans were uninsured in 2019, double the national average, and numbers have risen due to the economic impact of COVID-19 and job losses (6).

Given these continuing health disparities, evidence based interventions addressing patient and organization level strategies to control BP in patients are highly needed. The *Target:BPTM* program is a national initiative from the American Heart Association (AHA) and the American Medical Association (AMA) to assist healthcare organizations and care teams improve BP control rates through the implementation of evidence-based programming and recognition of organizations with successful integration. The unique aspect of *Target:BP* is the focus on building community clinic capacity to implement and maintain guideline-based care and promote accurate hypertension monitoring to improve patient-level outcomes. There are other EBIs that have been designed and implemented to address different aspects of hypertension control have been successfully implemented in community and clinic settings. For example, the *Million Hearts Collaboration* focuses on the alignment of cardiovascular disease prevention efforts through community linkages (7), the Healthy Heart Ambassador program supports community efforts through trained, certified ambassadors who provide one-on-one and group counseling to participants (8), and the WISEWOMAN

program provides tools and resources to clinics that help women understand and reduce their risk of heart disease and stroke (9). Using the Implementation Mapping approach, we identified determinants of *Target:BPTM* adoption and use them to develop implementation strategies to improve *Target:BPTM* uptake and implementation in Texas CHCs, primarily Federally Qualified Health Centers (FQHCs) and look-alikes.

Overview of *Target:BPTM*

The *Target:BPTM* program is a national initiative formed by the AHA and the AMA to aid health care organizations to improve BP control through evidence-based quality improvement and clinical redesign. The program achieves this goal by helping practices ensure accurate BP measurement, empowering providers to start or increase treatment when BP is high at 2 or more office visits (10), and promoting shared decision-making and a patient-provider partnership to support patients' BP self-management through self-measured BP (SMBP), lifestyle changes and/or medication adherence, as appropriate (11).

The program provides participating clinics patient-facing materials on BP control to raise awareness, along with tools and resources for systems and process changes at the practice and/or health system level to improve BP management (12). The program promotes the use of 6 evidence-based activities to ensure accurate BP measurement (13): 1) calibrating BP measurement devices per manufacturer recommendations, 2) ensuring semi- and fully automated BP measurement devices are validated for clinical accuracy, 3) using a structured curriculum of at least 30 min every 6–12 months to increase staff knowledge and skills related to BP measurement, 4) using an objective skills demonstration assessment to test staff skills every 6–12 months, 5) using a BP measurement protocol to obtain consistent, accurate BP measurements, and 6) posting an infographic displaying best practices for accurately measuring BP in all locations where BP is measured.

For program recognition, practices are required to submit evaluation data (14), including their total adult patient population and breakdown by age, sex, ethnicity (15), those with hypertension, and those with controlled hypertension. Instructional videos and a data collection worksheet are provided to assist practices with collecting and submitting the evaluation data. The program recognizes organizations committed to improving BP control utilizing a tier system of recognition (Table 1) (16). Practices that achieve these successes are acknowledged by the AHA and AMA via various platforms (e.g., website, AMA and AHA national meetings) and provided with both promotional digital assets (e.g., digital seal for emails, social media messaging) and office items (e.g., plaque) to indicate achievement. While several of the activities recommended as part of the *Target:BPTM* program can be considered implementation strategies themselves (training

TABLE 1 *Target:BP* recognition levels based on evidence-based blood pressure activities completed.

| Recognition status | Activities required | Controlled hypertension rate |
|----------------------|--|------------------------------|
| Participation status | Submit data for the first time to the AHA Commits to reducing uncontrolled hypertension | – |
| Silver status | Submit data to AHA Complete 4/6 activities | – |
| Gold status | Submit data to AHA Complete 4/6 activities | ≥70% |
| Gold+ status | Submit data to AHA Complete 4/6 activities | ≥70% |

This table was created using the *Target:BP* levels of recognition for blood pressure control rates from "Target:BP Recognition Program" <https://targetbp.org/recognition-program> (accessed February 4, 2021). AHA, American heart association; BP, blood pressure.

staff in BP measurement), the need to develop strategies to implement the *Target:BPTM* program as a whole remained. Thus, we used Implementation Mapping for this purpose.

Implementation mapping

Implementation Mapping, a systematic process for developing or choosing implementation strategies is based on the Intervention Mapping, a protocol to guide the development of multi-level interventions (17). Specifically, Implementation Mapping expands on step 5 of Intervention Mapping (development of an implementation plan) and integrates both implementation science and health promotion to increase understanding of factors influencing implementation within a specific setting, and to guide the development of implementation strategies to increase intervention adoption, use, and sustainment (18). Implementation Mapping includes five tasks: 1) conduct an implementation needs and assets assessment and identify program implementers, 2) identify adoption and implementation outcomes, determinants, performance objectives (this includes the specific tasks or sub-behaviors required to carry out program adoption, implementation, and maintenance objectives), and develop matrices of change objectives (defined as the changes required for each determinant that will influence success of each performance objective), 3) select theory-based methods and identify practical applications associated with these methods, 4) produce implementation protocols and materials, and 5) evaluate implementation outcomes (18). For this project, we used an iterative process to identify barriers and facilitators influencing the adoption and implementation of the *Target:BP* program within the partner CHCs, and to develop a comprehensive plan for program integration (Figure 1).

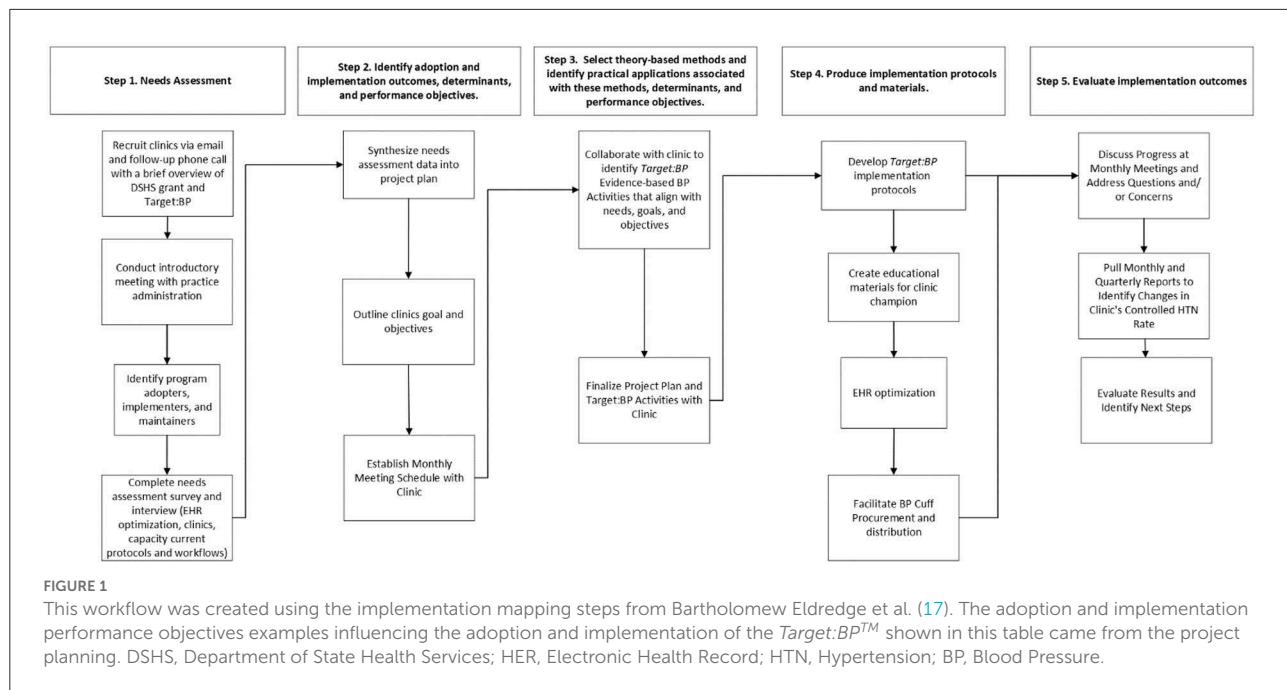


FIGURE 1

This workflow was created using the implementation mapping steps from Bartholomew Eldredge et al. (17). The adoption and implementation performance objectives examples influencing the adoption and implementation of the *Target:BP*™ shown in this table came from the project planning. DSHS, Department of State Health Services; HER, Electronic Health Record; HTN, Hypertension; BP, Blood Pressure.

Methods

Recruitment

We recruited four clinics from both rural and urban counties within Public Health Regions (PHR) 2/3 and 11, representing the greater Dallas-Fort Worth area and the Rio Grande Valley area of Texas, respectively. In collaboration with clinical leadership from the selected clinics and the research team, we used a team-based approach to promote and implement the *Target:BP* program. Our goal was to recruit a total of 5 clinics, a total of 20 clinics were contacted by email and telephone. Clinics were identified by location, previous history in partnership with the university, and by searching for Federally Qualified Health Centers serving the region. There were no financial incentives provided to the participating clinics.

As part of the recruitment, we completed discussions with the clinic office manager and or senior leadership to ensure decision making authority and need, priority, and interest in the program. The onboarding process differed at each clinic site. After the introductory meeting (i.e., within the following 2 weeks) the team and clinic partners completed the Needs Assessment survey and a program and organization capacity review. For each clinic, we first identified implementers and a program champion or primary contact to participate in the Implementation Mapping process to ensure each step was tailored to the clinic setting and the patient's needs. To recruit clinics, we followed a 4-step process: (1) identified clinics by email and follow-up phone call with a brief overview of the overall contract goals and *Target:BP*, (2) once agreed to

serve as a site, we held an introductory meeting with clinic administration to learn about current practices, (3) conducted a needs assessment, and (4) synthesized information from the needs assessment to present to our clinic partner as part of our adoption/implementation step.

Data collection

Electronic health record assessment

We began by assessing the clinic's EHR, hypertension practices, and collection of hypertension management data. Since utilization of EHR technology is an anchor for successful implementation of the *Target:BP* program, each clinic partner agreed to share EHR data and information with the UTHealth team. Thus, each clinic team collected data on-site and shared the data with the UTHealth team; the UTHealth team then reviewed and synthesized these data to inform discussions and assist each of the clinics with the EHR optimization needed to support and track the implementation of the *Target:BP* program.

Data collection and reporting

We used a standardized needs assessment instrument using both qualitative and quantitative measures to collect data at the start of the program. As part of this needs and capacity assessment, we conducted interviews with the staff at each clinic, examining gaps in needs and services (e.g., what do clinics need to implement *Target:BP*™), and assets to leverage. Additional data and reporting occurred during

the partner clinic's leadership and the research team monthly meetings to identify adoption and implementation outcomes while integrating strategies to enhance implementation of *Target:BPTM* per CHC goals.

Following the limited data sharing agreements, each of the clinics provided the UTHealth team with quarterly data reports. Each of the clinics extracted data from the EHR and shared with UTHealth *via* secure email. The data reports helped us estimate baseline control hypertension rates and assess improvements over time as well as were included in funder reports. Additionally, as part of the *Target:BP* recognition program, each site submits annual data on hypertension rates and the activities completed the year prior.

Results

For each CHC, we completed a needs assessment to determine organizational, patient, and capacity needs. We paid particular attention to barriers and facilitators at the organizational level to ensure the success and integration of changes within the CHC setting. We identified specific barriers and facilitators for adoption and implementation of *Target:BPTM* including action steps for adoption and implementation of *Target:BPTM* (e.g., who would complete what to implement) and determinants. Additionally, we developed and tailored clinic-specific implementation strategies which were informed by theory, empirical evidence, and organizational implementation team, including the program champion, leadership and others identified at the organization, feedback. Working in partnership with each of the four CHCs, we developed a tailored implementation plan and timeline designed to promote and enhance fidelity of implementation to promote maintenance of *Target:BPTM* at each clinic.

Task 1: Conduct a needs assessment to assess clinical capacity and identify program implementers

To guide the successful adoption of the *Target:BP* program, we had to understand each clinic's organizational capacity and identify program adopters, implementers, and maintainers. Thus, the first task involved conducting a thorough needs and capacity assessment. We initially contacted each of the selected CHC's leadership *via* email or telephone. During this initial contact, we provided the CHC with a general overview and scope of the *Target:BP* program as well as an introduction of the services our research team could provide to their clinics to facilitate the implementation of *Target:BP*. It is important to note that unlike many implementation

research studies where participating clinics have previously agreed to implement a program, the approach described here included clinics who had not yet agreed to adopt or implement *Target:BP*.

Once the CHC was engaged and interested, an introductory virtual (e.g., Zoom or Microsoft Teams) meeting with the clinic's leadership was scheduled to present an overview of the *Target:BP* program (e.g., program participation levels, *Target:BPTM* evidence-based activities for recognition, enrollment, and registration). During the virtual meeting, we also discussed clinical characteristics and practices and the patient population (e.g., type of organization, number of sites and providers, patient volume and sociodemographics, etc.). Clinics then identified and set goals for implementation of the program including EHR optimization, and hypertension management and prevention. We also used this opportunity to identify clinical staff and members of the clinical leadership team (i.e., Chief Operating Officer, IT/Data Analyst, Practice Administrator) who would be potential program adopters, implementers, and maintainers.

We then worked with the CHCs to identify their *Target:BPTM* team, that is, the individuals who would be involved in the adoption and implementation of the *Target:BPTM* program, to describe the adoption and implementation actions, and identify barriers and facilitators from the needs assessment. Strategies were collaboratively developed to identify patient needs and program goals for their unique setting, and to develop methods and strategies to inform the implementation of *Target:BPTM*. We developed a *Target:BPTM* implementation protocol based on the needs assessment for each clinic based on the needs and capacity assessment, identification of technology capacity and use, and gap analysis findings. We reviewed *Target:BPTM* program strategies and SMBP protocols tailored to the clinic patient population. Details on clinic characteristics and identified patients' needs were used to address the multi-level needs for dissemination and implementation of this evidence-based program (Table 2).

The next steps included completion of a Memorandum of Understanding (MOU), needs assessment, project plan development, and program delivery. After completion of the MOU between the designated CHC and UTHealth, a needs assessment survey was administered *via* Qualtrics to determine the CHC's hypertension workflow, the use of clinical decision support (CDS) tools for hypertension-related practices (i.e., patient identification, treatment, and management), recommendation of evidence-based activities (i.e., self-measured BP monitoring [SMBP]), patient portal usage, as well as hypertension outcomes related to BP control.

Identifying the CHC's implementation capacity was a critical step since many times, the CHC's staff may not have time to assess and identify all variables needed for the implementation of an EBI. These tasks were completed in collaboration with the CHC and the UTHealth team, which allowed for real-time data sharing to inform the tailoring of the *Target:BP*

TABLE 2 Results from community health centers needs assessment survey.

| Characteristics | Community health centers | | | |
|---|--------------------------|--------|--------|--------|
| | CHC A | CHC B | CHC C | CHC D |
| PHR region | 11 | 2/3 | 2/3 | 2/3 |
| Type of clinic | FQHC | FQHC | FQHC | CHC |
| Patient demographics | | | | |
| <i>Race and ethnicity</i> | | | | |
| Hispanic or latino | 73.00% | 40.80% | 73.83% | 0.00% |
| Non-hispanic or latino | 27.00% | 59.20% | 26.17% | 100% |
| Native american or alaskan native | 0.05% | 0.19% | 0.00% | 92.53% |
| Asian | 0.05% | 0.67% | 20.48% | 0.00% |
| Black | 0.38% | 17.77% | 41.65% | 0.00% |
| Native hawaiian/other pacific islander | 0.04% | 0.35% | 0.00% | 0.00% |
| White | 13.76% | 61.38% | 91.03% | |
| Other (not indicated) | 0.49% | 19.63% | 0.00% | 7.47% |
| <i>Type of insurance coverage</i> | | | | |
| Private insurance | 14.55% | 15.29% | 5.28% | 17.05% |
| Medicare | 7.70% | 9.25% | 1.99% | 11.12% |
| Medicaid | 23.92% | 23.46% | 20.73% | 3.73% |
| Uninsured/self-pay | 52.21% | 51.11% | 72.01% | 50.53% |
| Other (Not Indicated) | 0.34% | 0.89% | 0.48% | 0.00% |
| <i>Hypertension management qualitative indicators</i> | | | | |
| CHC awareness of <i>Target:BP</i> TM prior to implementation | Yes | Yes | Yes | Yes |
| CHC use of CDS tools in EHR to identify, treat, and manage patients with hypertension | Yes | Yes | Yes | No |
| CHC use of SMBP protocol for patients diagnosed with hypertension | Yes | Yes | No | Yes |

The data displayed in this table come from the Community Health Centers Needs Assessment Survey results completed as part of the Implementation Mapping process. PHR, Public Health Region; CHC, Community Health Center; CDS, Clinical Decision Support; HER, Electronic Health Record; SMBP, Self-Measured Blood Pressure; BP, Blood Pressure.

program implementation. Following these first steps, an in-depth interview was scheduled with clinical leadership to further assess current workflows and data reporting, and identify the CHC's barriers and facilitators for the implementation of *Target:BP*. After completion of the needs assessment, a follow-up meeting was scheduled with the CHC's stakeholders to discuss results, identify areas for improvement and initiate a project implementation plan.

As noted above, the initial meeting with each of the clinics and follow-up meetings were conducted by videoconference, and the scheduling and coordination were completed by email and based on the availability of the clinic sites. Communication with each of the clinics related to activities and goals between program implementation meetings was completed by email and phone calls. Specifically, UTHealth scheduled and provided support to each of the clinics and the program consultants to ensure coordination and facilitation of meetings and focus on activities, partnerships and goals. At each clinic site, attendance at meetings usually included the clinic's leadership, management team and implementers including medical directors, nurse team members, patient navigators, operation managers and information technology team members.

Task 2: Identify adoption and implementation outcomes, determinants, and performance objectives, and develop matrices of change objectives

To facilitate the development of a project implementation plan that aligned with each CHC's hypertension management goals, the UTHealth team created a project planning guide to identify gaps in hypertension management and address specific priorities and tasks for program implementation. In collaboration with each of the CHC's program adopters and implementers, the project plan was finalized by the UTHealth research team and the CHC's leadership. The planning team identified adoption and implementation outcomes for adopters, implementers and maintainers (e.g., clinic's leadership, providers, administrative staff, non-physician team members [community health workers, physicians' assistants, etc.]) for each CHC see implementation outcomes for each (Table 3). The team worked together in the creation of performance objectives to identify "who needs to do what to ensure that the program is adopted, implemented, and maintained?" For example, the *CHC's leadership (decision-makers) agree to participate in the*

Target:BP program by enrolling in the *Target:BP* program with an AHA representative. These performance objectives served as a roadmap essential for the adoption, implementation, and maintenance of the *Target:BP* program.

After the identification of program outcomes and performance objectives for each of the CHC's stakeholder groups, we defined determinants for *Target:BP* program implementation (Table 4).

These determinants are derived from theoretical constructs that aligned with the barriers and facilitators identified in the needs assessment. The UTHealth team completed a thorough literature review related to *Target:BP* program implementation and similar evidence-based BP control programs. At this point, we used literature to inform the identification of the priority determinants given the results from each of the CHC's needs assessment, allowing us to identify potential determinants that could impact the CHC stakeholder group's ability to achieve their outcomes. Once determinants were reviewed by the teams, we created the change matrices. The matrices of change objectives for each CHC's stakeholder group list the various changes in each determinant necessary to achieve the associated performance objective. The use of these matrices helped ensure that content and messaging for the implementation of *Target:BP* addressed the most salient performance objectives and determinants to facilitate successful implementation.

While each clinic implemented the program based on their own goals and capacity, the team recognized some key factors that promoted implementation including the collaboration of change agents, such as the clinic site leadership team and stakeholders that were aware of the community and organization capacity as well as could identify potential resources.

Task 3: Select theory-based methods and associated practical applications

After defining the necessary changes needed within the CHCs for successful *Target:BP* program implementation, we then identified evidence- and theory-based strategies to address these changes at the provider and administrative levels, and developed tables highlighting methods and practical applications (Table 3). These strategies addressed determinants identified using theoretical constructs from the social cognitive theory and organizational level frameworks. We reviewed the behavioral and implementation science literature to ensure that the appropriate methods were identified to facilitate change and address determinants and change objectives for each CHC. For *Target:BP*, these methods and applications were developed from existing materials, messages, and recommended practices. For each of the recommended practices and steps of *Target:BP*, we identified how their implementation would address determinants and change objectives. This facilitated

CHCs' staff training, identification of materials needed for *Target:BP* implementation, and strategies to gain access to the materials needed. For example, in one CHC we found that while training addressed knowledge, self-efficacy and perceived norms for BP monitoring and capacity, the CHC did not have the proper equipment to implement the *Target:BP* protocols at the patient level. Specifically, many of the CHCs could not afford the BP cuffs for the necessary patient population and cuffs were not available in all the needed sizes (e.g., XL BP cuffs). However, we were able to work with other partners (i.e., AHA) to identify potential sources for the equipment at discounted prices. Implementation Mapping facilitated the review of contextual factors that influenced implementation and allowed for CHCs to identify resources and other actions needed to properly implement *Target:BP*TM.

Task 4: Produce protocols and materials related to implementation

Working together with the CHC's leadership and implementation team members, we developed protocols and activities needed for the implementation of key *Target:BP* objectives. These activities included training and re-training of CHC's staff on proper BP techniques, EHR optimization, and the development of tailored *Target:BP* materials. While *Target:BP* materials may be readily available for adaptation through the AHA (i.e., targetbp.org), we worked with the CHCs to ensure proper wording and design of certain materials (e.g., flyers on proper BP techniques) to target the CHC's hypertension management goals, clinical setting, and patient population. To ensure the appropriate selection of the intended audience, target determinants, change objectives, and material content, we closely collaborated with the CHCs in the development of protocols, workflows, and materials used for the implementation of *Target:BP*. The workflows identified potential adopters, implementers, and maintainers and visually depicted how *Target:BP* would be integrated into the CHC's current or new hypertension care management process. These workflows were then communicated and used to guide *Target:BP* implementation at the clinic. We carefully reviewed with the CHCs to ensure future uptake and dissemination and promote adoption and use as well as to help with future implementation and impact evaluation.

Task 5: Evaluate implementation outcomes

Ongoing evaluation of implementation outcomes for *Target:BP* use within CHCs has identified several key areas to improve reach, engagement, and impact, including the

TABLE 3 Example of implementation outcomes and performance objectives.

Program: Target:BP**Setting: Community Health Center (CHC)**

| Target: Role | Adoption, implementation and maintenance outcome | Performance objectives |
|--------------------------------------|---|---|
| Adopter: CHC leadership | CHC leadership will adopt the Target: BP program and associated recommendations within their practice to improve hypertension control among at-risk patient population. | <ol style="list-style-type: none"> 1. Establish/re-engage with AHA representative in selected public health region to register and plan implementation. 2. Designate a program champion and a point of contact to review Target: BP program and lead the implementation. 3. Agree, approve, and support the adoption of the Target: BP program. 4. Establish and sign MOU with AHA and UTHealth. 5. Assess that CHC is equipped with sufficient materials and equipment for identification of hypertensive patients and program implementation. 6. Approve steps and assure funding and practice of the Target: BP program. |
| Implementer: Program champion | The provider and program champion will implement the Target: BP program into their hypertension management protocol. | <ol style="list-style-type: none"> 1. Enroll and work with AHA representative in selected public health region to complete online registration and begin implementation of Target: BP program. 2. Obtain and distribute program materials focused on hypertension management and protocol recommendations for providers and patients. 3. Establish effective communication among CHC staff and ensure updates and feedback is delivered in a consistent manner. 4. Identify barriers and communicate suggestions for overcoming them. 5. Provide continuous support for decision making (feedback, quality check and monitoring consistency of delivery) and provide monthly reporting on program adoption and patient outcomes. 6. Report on Target:BP program adoption and patient outcomes once a month. |
| Maintainer: Program champion | Program champion will maintain the Target BP program and ensure the successful delivery of program resources and materials to the designated CHC staff. | <ol style="list-style-type: none"> 1. Discuss the integration of the Target: BP program with leadership and with the implementation team. 2. Maintain supply of resources and program materials, as well as any needed changes in any program materials given the CHC setting and patient population (health management action plan review) 3. Use EHR to maintain Target: BP patient outcome goals and ensure CHC hypertension evaluation data is submitted in a timely manner to the Target: BP program. |

The implementation outcomes and performance objectives for adopters, implementers and maintainers displayed in this table were established by the planning team for the adoption and implementation of Target:BP program. CHC, Community Health Center; AHA, American Heart Association; BP, Blood Pressure.

integration of key clinic specific team members and community partners to promote use of data and inform strategies to implement at each clinic. The collection of process data including reach of patients in most need will allow the team to identify the impact of implementation strategies as well as essential preconditions and changes at the CHC level that facilitated implementation, fidelity, and reach of the patient population. We expect that CHC organizational process evaluation and impact data will allow us to better identify barriers and enabling factors for *Target:BP* adoption, implementation, and sustainability outcomes. Once we complete the evaluation, we will use findings to improve *Target:BP* delivery and for interpreting patient-level outcomes. We will be able to better identify whom the program reached,

assess fidelity of implementation, and determine organizational factors that influence intervention, adoption, use, and/or maintenance (Figure 2).

Discussion

The implementation of the *Target:BP* program provides an example of the use of Implementation Mapping for the development and adoption of evidence-based strategies to increase successful implementation of evidence-based programs within CHCs. The use of implementation strategies can increase the use of *Target:BP* in CHCs (organizational level) and improve hypertension control outcomes (patient level). The

TABLE 4 Example of partial matrices of change objectives for selected examples.

Program: Target:BP**Behavioral outcome: Implement the Target:BP program into hypertension management protocol.**

| Performance objectives | Determinants | | | | |
|---|---|--|---|---|---|
| | Attitude | Knowledge | Outcome expectations | Self-efficacy/skills | Social norms |
| Program champion enrolls and works with AHA representative in selected public health region to complete online registration and begin implementation of Target: BP program. | A1.1. Express positive attitude towards the implementation of Target BP. | K. 1.1. Describes the components of the Target BP program. K.1.2. Describes the rates of uncontrolled BP in CHC. K.1.3. Describes requirements of the Target BP program | OE.1.1. Expects that by attending the training he/she will be able to successfully implement Target BP OE.1.2. Expects program champion and CHC leadership will reinforce and acknowledge them for completing the training successfully | SSE.1.1. Feels confident in ability to attend and learn from training. SSE1.2. Expresses confidence in attending Target BP training SSE.1.3. Expresses confidence in the ability to do what is expected by the Target BP (increase screening capacity, implementation of the program, work with a program champion, assess resources) | NB1.1 Expresses belief that other CHC like theirs are implementing Target BP NB1.2. Expresses belief that other coordinators attend training. |
| Program champion obtains and distributes program materials focused on hypertension management and protocol recommendations for providers and patients. | A.2.1. Expresses that Target BP program information will help patients with BP management. | K.2.1. Describes the role of each CHC team member for implementation. K.2.2. Describes patient education needs. K.2.3. Describes toolkits and other materials that support program implementation given specific staff role. | OE.2.1. Expects that by providing staff and patients with information Target BP uptake will be achieved. OE.2.2. Expects that patients will use Target BP information for BP control management | SSE.2.1. Feels confident in identifying Target BP components to share with specific team members based on role in CHC. SSE.2.2. Feels confident in identifying Target BP materials to share with the patient population. | NB2.1. Expresses belief that other coordinators are identifying Target BP components for staff and patients. |
| Program champion develops strategies to identify upcoming appointments for patients with uncontrolled blood pressure daily. | A.3.1. Believes in the importance of identifying upcoming appointments. | K3.1. Describe steps to searching schedule to identify upcoming appointments. K.3.2. Describes the data system of the CHC A.3.3. Describes process of using data systems to identify upcoming appointments. | OE.3. Expect that all scheduled patients will be identified for receiving Target BP program information. | SSE.3.1. Express confidence in and demonstrates ability to successfully identify all upcoming appointments | NB3. Express belief that other program coordinators are searching schedules for upcoming appointments. |
| Program champion oversee implementation efforts and provide feedback to CHC staff | A.4. Feels positive about overseeing implementation as important and useful for ensuring fidelity | K.4. Describes steps needed to oversee implementation. K.4.1. Describes daily and weekly activities associated with Champion Role. | O.E.4. Expects that through regular oversight and communication, the Target BP program will be implemented effectively. | SSE.4. Demonstrates confidence and ability to oversee implementation of Target BP. | NB.4. Believes that other individuals with similar positions in other CHCs act as champions to oversee and provide feedback. |

(Continued)

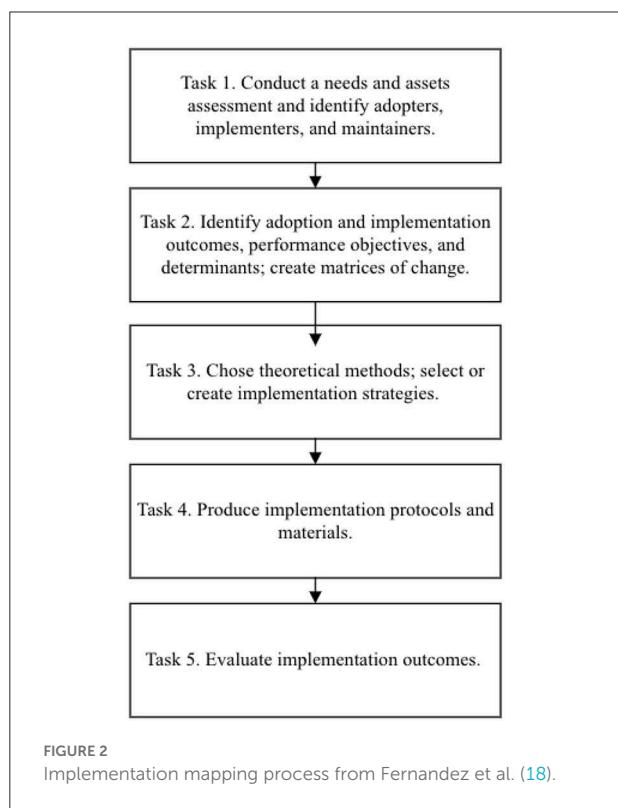
TABLE 4 (Continued)

Program: Target:BP**Behavioral outcome: Implement the Target:BP program into hypertension management protocol.**

| Performance objectives | Determinants | | | | |
|---|---|--|--|--|---|
| | Attitude | Knowledge | Outcome expectations | Self-efficacy/skills | Social norms |
| Program champion identify barriers and communicate suggestions for overcoming them. | A.5. Recognizes that identifying barriers is important to the success of the project. | K.5. Lists potential barriers to implementation and solutions that could address them. | O.E. 5. Expects that the early identification of barriers to implementation will lead to effective solutions that will facilitate continued program use. | SSE.5. Expresses confidence and demonstrates the ability to identify problems during implementation and to work with other implementers to resolve them. | NB. 5. Believes that other champions like them have a role that includes the identification and resolution of barriers. |

The performance objectives displayed in this table were established by the planning team for the adoption and implementation of Target:BP program using theoretical constructs from the social cognitive theory.

CHC, Community Health Center; AHA, American Heart Association; BP, Blood Pressure.



steps of Implementation Mapping allowed us to carefully integrate and address the specific needs of CHCs at their pace while addressing the importance of fidelity and reach of not only patients, but also adopters and implementers, to ensure success.

Team meetings ensured that both the CHC's leadership and the UTHealth team listened to implementer needs and facilitated changes in information technology (IT), EHR, and

training. This fostered the development of successful training to address the needs of facilitators as well as strategies to overcome adoption and implementation barriers encountered by the CHC teams including IT, managers, nurses, and other health care providers. The *Target:BP* implementation at CHCs allowed the research team to test the conceptual and practical gaps between identifying barriers and facilitators, and developing strategies for immediate communication and problem solving to strengthen and increase the ease for adoption and implementation of *Target:BP*. The CHCs identified and addressed changes in implementation to contextual factors that allow for greater learning, openness, and identification of CHC setting needs to impact health and quality of life of patients.

Given the ongoing challenges to implement EBIs successfully, the use of Implementation Mapping may help (a) increase the confidence, capacity, and readiness of CHCs to use EBIs by elucidating mechanisms for change within their CHC, (b) inform the planning process to ensure the identification of determinants of change, and (c) select implementation strategies with the greatest potential for impact on health outcomes over time.

As this is an ongoing program, we expect that our iterative approach to Implementation Mapping across additional CHCs will allow us to reach and expand our knowledge of the use of Implementation Mapping as a planning framework for the successful delivery of EBIs aimed to improve health. Ongoing process and impact evaluations using the Reach, Effectiveness, Adoption, Implementation, and Maintenance framework (RE-AIM) are underway to evaluate the *Target:BP* program (19).

It is well documented that EBIs may not be adapted or adopted in settings that may most benefit from their impact (20–23). However, Implementation Mapping outlines a practical step-by-step method for planning of implementation to

optimize reach, appropriateness, and impact over time, and that simultaneously will build capacity at CHCs and similar settings to adopt, implement and sustain evidence- and guidelines-based practices to improve health outcomes.

The CHCs implementing the *Target:BPTM* program will have tools to ensure maintenance and reach of patients with the most need.

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 University of Texas Health Science Center Houston, Institutional Review Board. Written informed consent for participation was not required for this study in accordance with the national legislation and the institutional requirements.

Author contributions

All authors listed have made a substantial, direct, and intellectual contribution to the work and approved it for publication.

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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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Using Implementation Mapping to increase uptake and use of *Salud en Mis Manos*: A breast and cervical cancer screening and HPV vaccination intervention for Latinas

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Background: Despite CDC recommendations for breast and cervical cancer screening and HPV vaccination, cancer control behaviors are underutilized among low-income Latinas. *Salud en Mis Manos* (SEMM), adapted from *Cultivando La Salud*, is a community health worker- (CHW-) delivered evidence-based intervention (EBI), shown to increase breast and cervical cancer screening.

Methods: We used Implementation Mapping to create SEMM-Dissemination and Implementation Assistance (SEMM-DIA), a set of implementation strategies designed to support implementation and maintenance of SEMM in clinic settings. Specifically, we used Implementation Mapping's five iterative tasks to guide the use of theories and frameworks, evidence, new data, and stakeholder input to develop strategies to accelerate and improve implementation fidelity, reach, and maintenance of the SEMM intervention. The resulting implementation mapping logic model also guides the SEMM-DIA evaluation plan to assess reach, effectiveness, implementation, and maintenance.

Discussion: Increased use of implementation planning frameworks is necessary to accelerate the translation of EBIs to public health practice. This work demonstrates the application of Implementation Mapping to develop SEMM-DIA, providing a model for the development of other implementation strategies to support translation of evidence-based health promotion interventions into clinic settings.

KEYWORDS

Implementation Mapping, implementation strategy, health equity, community health workers, cancer prevention, cervical screening, mammography, HPV vaccination

Introduction

Despite the availability and effectiveness of evidence-based interventions (EBIs), their implementation and dissemination have been slow, resulting in limited reach (1), and missed opportunities for positive public health impact (2–4). Challenges to EBI adoption, implementation, and maintenance are multifactorial and multilevel, and are influenced by environmental and organization-level factors (e.g., resources and capacity), as well as individual implementer-level factors (e.g., skills or self-efficacy). Implementation support strategies designed to address the complex factors that influence EBI adoption, implementation, and maintenance can promote translation of behavioral intervention research to effective public health practice.

Implementation strategies provide guidance and support to EBI adopters and implementers, helping to ensure effective program delivery, including attention to fidelity, such that essential elements of the intervention are preserved as they are implemented within their organization's context. Implementation strategies must also build on organizations' assets and address organizations' needs (2–4). We used Implementation Mapping, a framework for planning and developing implementation strategies to accelerate and improve implementation and maintenance of *Salud en Mis Manos* (SEMM), an evidence-based community health worker (CHW)-delivered intervention shown to increase breast and cervical cancer screening among low-income Latinas (5, 6). The Implementation Mapping framework guides a systematic planning process that incorporates perspectives and experiences of multiple stakeholders and uses evidence and theory to inform development of implementation strategies (7). While the SEMM intervention addresses an important problem (underutilization of breast and cervical cancer screening) and has the potential to reduce breast cancer survival disparities and the disproportionate burden of cervical cancers among Latinas (compared with non-Hispanic whites; NHWs) (8), widespread implementation of SEMM has been slow.

Briefly, SEMM is an evidence-based intervention based on *Cultivando la Salud* (CLS), a CHW-delivered breast and cervical cancer screening behavioral intervention originally developed for Mexican-American women living in farmworkers communities (9, 10). Adaptations of SEMM for medically underserved Latinas in urban and suburban settings increased the behavioral intervention's generalizability to Latinas from diverse backgrounds and to those living in areas with different environmental and social contexts (6). SEMM intervention planners adapted the original CLS CHW-delivered education intervention and referral protocol (to deliver referrals to low-cost services) guided by the Intervention Mapping framework for adaptation (IM ADAPT). This systematic approach to intervention adaptation planning informed integration of theory, evidence, and formative work to ensure retention of salient elements while increasing relevance to the new population and setting. In addition, the SEMM adaptation included development of a telephone-based health coaching and navigation component delivered by health coach navigators trained to help women overcome structural and personal barriers to completing needed cancer prevention services. Based on a randomized controlled trial (Cancer Prevention and Research Institute of Texas, CPRIT

award, PP110081), the adapted intervention effectively increased screening in the intervention compared with control groups for both mammogram (39.9 vs. 20.3%; $p < 0.001$) and Pap outcomes (55.8 vs. 27.4%; $p < 0.001$); intent-to-treat analyses were also significant (11). While proven effective, broad uptake and use of SEMM has been slow and implementation in clinical settings has been particularly limited.

We used Implementation Mapping, a systematic process for designing and tailoring implementation strategies to develop *Salud en Mis Manos- Dissemination and Implementation Assistance* (SEMM-DIA), a multifaceted implementation strategy, to support implementation of SEMM. This paper serves as a model for applying the Implementation Mapping framework to develop implementation strategies. In the case of SEMM-DIA, these strategies were designed to build capacity of clinic leadership and management, intervention champions, and CHWs to plan, manage, implement, and maintain SEMM.

Methods

Conceptual framework and theoretical basis for the development of the implementation strategy

The Implementation Mapping framework includes five tasks that guide implementation strategy planners in the design and tailoring of implementation strategies. These tasks are described below (see Figure 1) (7). Implementation Mapping is a step-by-step protocol that incorporates empirical evidence, stakeholder input and feedback, and is informed by theories, models and frameworks. In the development of SEMM-DIA, we used the Implementation Mapping framework to help integrate behavioral theory [i.e., Social Cognitive Theory (SCT)], to identify behavioral determinants at multiple levels (e.g., organization and CHW) (12) and implementation frameworks, including the Interactive Systems Framework for Dissemination and Implementation (ISF) (13) and the Exploration, Preparation, Implementation, and Sustainment (EPIS) framework (14). To guide planning evaluation outcomes, we used RE-AIM, focusing on Reach, Effectiveness, Implementation, and Maintenance (intention) (1). All behavioral and Implementation Science theories and frameworks used to develop the SEMM-DIA implementation support strategy are summarized in Table 1.

The Implementation Mapping planning process also supports a community-engaged approach to implementation strategy development, helping to integrate multiple stakeholder perspectives throughout development. Using a community-engagement approach, we included perspectives of stakeholders with previous experience implementing the SEMM intervention, as well as people with insight into the clinic practice setting (e.g., clinic leaders, clinic managers, and CHWs) who could also represent the patient perspective. Implementation stakeholders invited to participate in the planning process included managers working with The Breast and Cervical Cancer Collaborative of Texas, and representatives from the Centers for Disease Control and Prevention (CDC)-funded Texas Prevention Research

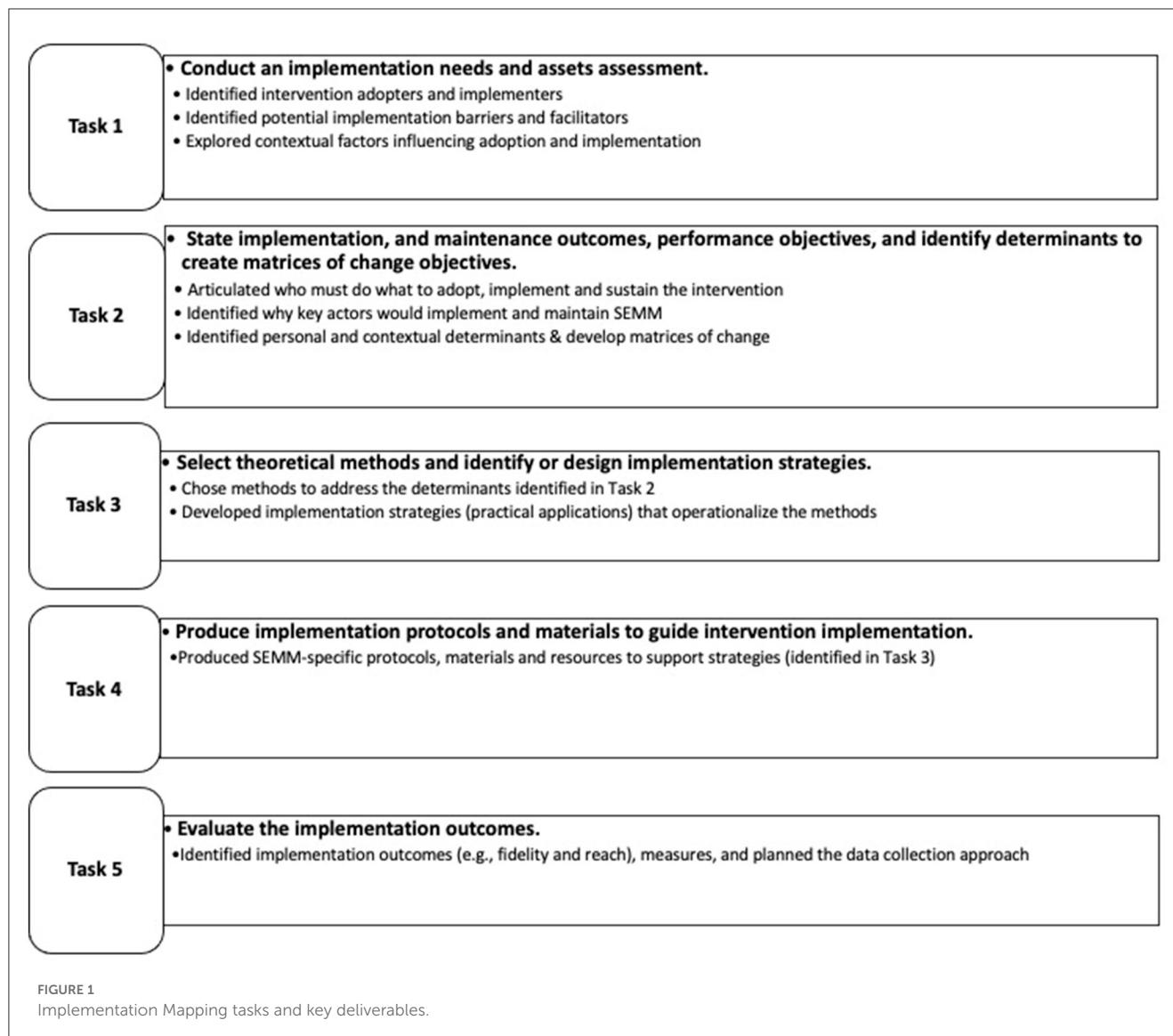


TABLE 1 Summary of theories, frameworks and models used to guide development of SEMM-DIA, an implementation intervention.

| Task # | Implementation science theories and frameworks | Role in informing implementation strategy design and/or evaluation planning |
|--------------|---|---|
| Task 1–5 | Social Cognitive Theory (SCT) (15) | <ul style="list-style-type: none"> - Helps to identify individual-level behavioral determinants (e.g., motivation, self-efficacy, and behavioral capability) at multiple levels (e.g., individual, and organizational levels) - Identifies corresponding methods for influencing determinants to change behavior (e.g., modeling verbal persuasion, and skills training) |
| Task 2 | Interactive Systems Framework (ISF) (13, 16) | <ul style="list-style-type: none"> - Explains the process of introducing and implementing a health intervention into a new practice setting by describing three systems and processes required to support dissemination and implementation: (1) the synthesis and translation system; (2) the prevention support system; and (3) the delivery system (e.g., the clinics with CHWs) |
| Task 2 and 4 | Exploration, Preparation, Implementation, and Sustainment (EPIS) framework (14) | <ul style="list-style-type: none"> - Guides the implementation process and identifies levels within and across organizational contexts - Provides a basis for ordering IM program performance objectives (who must do what to implement SEMM; specified in Task 2) - Guides and describes the SEMM implementation process (specified in Task 4) |
| Task 5 | Reach, Effectiveness, Implementation, and Maintenance (RE-AIM) framework | <ul style="list-style-type: none"> - Guides planning of the evaluation, including reach, effectiveness, level of adoption and implementation outcomes |

Center Community Advisory Board (CAB). The CAB included community leaders representing community-based CHW organizations (e.g., ProSalud, Inc. and South Coastal Area Health Education Center; AHEC), and CHWs with substantial field experience working with Latinas on breast and cervical cancer screening interventions in Federally Qualified Health Centers (FQHCs) in the Greater Houston area. It also included staff and leaders at community health centers, many of whom provided insights into the patient populations they serve, such as patient's concerns regarding undergoing cancer screening and barriers to completing screening services.

Methods for each Implementation Mapping task

Task 1. Conduct an implementation needs and assets assessment

The research team conducted 12 semi-structured Zoom-based interviews with clinic personnel representing clinic leadership (e.g., CEO, Medical Director), mid-management (e.g., Clinic Program Manager, MA/Director of Program Development, and CHWs at four different Texas Community Health Centers. Participants were provided with a five-minute PowerPoint overview of the SEMM intervention prior to their interviews. Three interview guides were developed respectively for leadership, mid-level, and CHWs, informed by SCT, ISF and the Readiness heuristic, $R = MC^2$ (readiness = motivation \times innovation specific capacity \times general capacity) (15). Interview questions focused on exploring clinic and program implementers' needs and assets (e.g., resources, infrastructure, and potential related experiences) that may influence SEMM implementation, such as: (1) What could be potential problems/barriers that you might face to implement the intervention? (2) Who would be involved in planning how the program would be incorporated into clinical workflows and practice? (3) What would make it easier to adopt and implement the intervention? and (4) What makes an organization ready (to take on a program like this/new programs)? Interviews were audio-recorded and professionally transcribed. Using an adapted rapid qualitative approach (RQA) (16), one independent reviewer (reviewer CC) analyzed all 12 interview transcriptions to identify potential implementation barriers and facilitators. Transcript data were tabulated in summary tables by content domain. For example, the question, "Your clinic has CHWs—can you tell me a bit about the program and how CHWs are used?" represents the domain "CHW utilization." The data were then coded for potential barriers and facilitators. A second reviewer (reviewer PL) reviewed the summary tables for clarity. Both reviewers then met to discuss and reach consensus on any discrepancies. The data were stratified by implementer level (leadership, mid-level, CHW) and by theoretical constructs (e.g., complexity and staff capacity (Readiness constructs). To further examine the data, an in-depth content and thematic analysis is currently being conducted by the research team using a traditional qualitative analysis approach. Findings will help better understand which additional environmental factors should be considered for improved program implementation and maintenance (17–20).

We also used core processes adapted from Intervention Mapping to aid in the identification of barriers and facilitators to implementation (21). As described by Fernandez et al., "Core processes are a set of helpful actions or tools that can provide a systematic way to answer questions raised during the planning process and aid in the identification of potential barriers and facilitators to implementation" (21, 22). These core processes were used throughout the five tasks of implementation mapping where appropriate and were fundamental in Task 1. They included: (1) Brainstorm potential factors (i.e., barriers and facilitators) based on experience, past needs assessments, and published literature, (2) Use theories and frameworks, (3) Collect new data, and (4) Prioritize the most important and changeable factors. We considered both health behavior theory (i.e., SCT) and implementation science frameworks (i.e., Interactive Systems Framework and Organizational Readiness) during the identification of factors potentially influencing implementation. Doing so enabled the research team to confirm if the listed barriers and facilitators previously identified aligned with constructs from existing theoretical models. This step also informed the identification of additional constructs that were relevant in similar implementation efforts and allowed the research team to refine performance objectives (who must do what to implement SEMM). Finally, the research team integrated diverse perspectives provided by the CAB members.

Task 2. State implementation and maintenance outcomes, performance objectives, and identify determinants to create matrices of change objectives

In Task 2, based on the needs and assets assessment conducted in Task 1, the research team articulated performance objectives (who must do what to implement SEMM) as well as the potential factors (from theory, evidence, and new data) that might influence key actors' pre-implementation, implementation, and maintenance of SEMM. We developed matrices of specific change objectives by crossing performance objectives and determinants and asking, "what has to change in X determinant in order to accomplish this implementation performance objective."

Task 3. Choose theoretical methods; and identify or design implementation strategies

In Task 3, we considered theoretical change methods (both those focused on changing behavior and those focused on influencing the implementation environment) that could address determinants identified in Task 2 (23, 24). We developed the implementation strategies by operationalizing the methods. We created practical applications of those methods such that they were feasible and appropriate for use in clinic settings. This task was also conducted in partnership with stakeholder engagement, e.g., those with previous experience implementing SEMM, as well as clinic and CHW experiences in general. The research team engaged CAB members monthly via Zoom to pose a series of questions/ideas/implementation strategies to CAB members to gain their insight into what resources would best serve and support

clinic personnel with the implementation of SEMM. By working with clinic representatives, selection of implementation strategies took into consideration relevance and feasibility for different implementers in clinical settings.

Task 4. Produce implementation protocols and materials to guide intervention implementation

Following the planning of implementation strategies in Task 3, we identified, adapted, or produced the SEMM implementation protocols, materials, and tools to include in the SEMM-DIA implementation package. This task was also informed by the EPIS “meta” framework (14). This “meta” framework consists of five phases that we used to order SEMM-DIA performance objectives, including (1) Exploration (Prioritizing SEMM), (2) Preparation (Assessing clinic readiness), (3) Preparation for implementation of SEMM, (4) Implementation, and (5) Maintenance. Each phase was associated with clinic personnel responsible for that phase (i.e., clinic leadership, SEMM program manager and/or champion, and CHW). We also developed documentation to support clinic stakeholders’ implementation planning and process monitoring of SEMM. The overarching goal of this implementation strategy package was to provide clear, user-friendly support to promote feasibility, and fidelity of implementation.

Task 5. Evaluate the implementation outcomes

Task 5 of Implementation Mapping focused on planning the evaluation of the SEMM-DIA implementation strategy, to assess the effect of SEMM-DIA on implementation outcomes, and on SEMM effectiveness outcomes (e.g., breast and cervical cancer screening and HPV vaccination). We also developed indicators and measures for the evaluation, informed by the matrices. Our evaluation plan included measures to assess organizational readiness for implementation, level of implementation, determinants of implementation, experiences with implementing SEMM, and implementation maintenance. Selection of mediators and moderators of implementation was guided by behavioral theoretical constructs based on SCT and ISF identified during the planning process.

Results

Task 1. Conduct needs and asset assessment

Stakeholder engagement played a critical role on the planning team (comprised of both stakeholders and research team members). The CAB weighed in on key actionable findings to ultimately inform implementation strategy development. Input from all CAB members during Zoom meetings helped to identify potential barriers and facilitators influencing the implementation and maintenance of the program. Included in these CAB meetings over the course of the needs assessment period were clinic leadership, clinic managers, as well as former SEMM CHW managers (heretofore referred to as SEMM champions).

Adopters and implementers

Potential barriers and facilitators to implementation corresponded to Readiness and SCT constructs. For example, related to Readiness, staff capacity, and complexity constructs were identified as potential barriers. Participants expressed concerns about staff capacity and the need to further expand CHWs’ role for program implementation and having to hire new clinic staff, “What we need are new people to perform this role, I don’t have people I could add more responsibility to.” Another potential barrier included complexity, as it is related to data management. Participants had concerns about data risk management and data protection (e.g., who will be responsible for acquiring and securing the program’s database?).

Facilitators

Regarding potential facilitators, leadership participants stressed the importance of intra-organizational relationships, stating that obtaining clinic staff buy-in for intervention implementation is important, “I’d also gain the feedback from people who will implement it, so that we can be on the same page that we’re going to do it.” Other potential facilitators related to SCT included positive attitudes among participants who recognized that having CHWs is instrumental, “Our community health workers are used in every capacity of the organization, from our clinic services, health education, outreach, they are the ones who are instrumental in doing the education and outreach activities for the clinics.” Participants emphasized CHWs’ role as one that can “wear multiple hats” and therefore would likely be able to play various roles related to implementation. Positive attitudes also included the belief that having a SEMM champion is critical for its success. Of note, participants also discussed the need to develop communication strategies to facilitate SEMM intervention promotion and implementation by clinic staff, “This is what I can just easily send [referring to email templates] to the staff. This is what we’re doing and how to refer a patient kind of things.”

Barriers

The planning team, including researchers and CAB stakeholders, (e.g., clinic staff, SEMM champions, and CHWs) prioritized which barriers needed to be addressed. Clinic participants provided insight into addressing implementation challenges and shared lessons learned and practical suggestions regarding factors affecting CHW implementation. For example, in one of the monthly CAB meetings, stakeholders validated the finding that CHWs do, in most cases, “wear multiple hats.” Stakeholders also added that when there is no CHW, they often have other staff (e.g., patient navigator, patient educators) who could (and do) serve in a similar role. While the original program was designed to focus on community outreach for identifying women in need of services, CAB members stressed the importance of in-reach (i.e., focusing on current clinic patients), in addition to outreach as an important way to identify women in need of screening and HPV vaccination.

CAB members also helped clarify who the potential implementers in clinic practice settings would likely be in the safety-net clinic context (e.g., FQHCs). CHW managers

with extensive experience managing CHW training and CHW delivery provided insight into potential barriers and facilitators to managing CHWs. CAB members discussed the importance of SEMM champions engaging in weekly meetings with CHWs, in which they use effective facilitation skills, such as facilitating discussions between CHWs to encourage CHWs to share their work challenges and successes. For clinic-based implementation, by talking with SEMM managers who supervised clinic delivery of SEMM, we identified the importance for clinic leaders to understand their patient population's needs and to prioritize SEMM delivery, focusing on current patients (in-reach recruitment strategy), or focus on delivering SEMM to women in surrounding communities to enroll women in the SEMM intervention (outreach recruitment strategy). **Table 2** presents an example of findings from the rapid qualitative analysis of interviews conducted at the leadership level.

Task 2. Identify pre-implementation, implementation and maintenance outcomes, performance objectives, and determinants, and create matrices of change

Results of the needs and assets assessment helped inform the expected pre-implementation, implementation, and maintenance outcomes and to develop a list of specific actions, referred to here as performance objectives (POs), that each potential implementer (e.g., clinic leader, SEMM champions, CHW, and health coach navigator) needs to perform at each of the implementation stages (see **Tables 3.1–3.3**). Direct feedback from the clinic staff confirmed that implementation and maintenance of the SEMM intervention as a standard practice would require the endorsement of clinic leadership and commitment of resources, including an emphasis on dedicated personnel time.

Insights of research team members with previous and current experience managing implementation of the SEMM intervention were leveraged to help identify implementer-specific POs. For example, the POs of a designated manager related to providing guidance and support to CHWs, such as developing CHWs' clinic-based recruitment or community-based outreach plans. Other manager POs related to facilitating routine CHW meetings to address challenges and share successes, to provide continuous process monitoring to ensure CHWs reach under-screened or unvaccinated women most in need of the SEMM education and navigation support, and to sustain CHW motivation for the work.

Finally, the research team reviewed each implementer's POs and finalized the list of POs for clinic leaders, SEMM program managers and/or champions, and CHWs. Review of the POs by current intervention implementers led to the identification of missing and overlapping tasks. **Tables 3.1–3.3** present examples of SEMM implementation and maintenance POs describing the specific actions for implementers (clinic leadership, SEMM program manager and/or champion, and CHWs). For the clinic leaders, for example, POs were identified by asking “*What does the clinic leadership need to do to garner clinic Board of Directors'*

commitment of resources to support the program? What do clinic leaders need to do to plan the staffing to manage and deliver SEMM?”

Next, the research team identified factors influencing implementation and developed the matrices of change objectives by crossing the selected behavioral and organizational determinants with identified performance objectives asking the question, “*What needs to change for the implementers to accomplish the specific implementation performance objective?*” The research team also considered behavioral science theories (e.g., SCT) and implementation science frameworks (e.g., ISF) in the identification of determinants and development of matrices of change (**Table 4**). For example, the ISF domain, “motivation,” guided the selection of specific attitudinal determinants expected to influence implementation and maintenance of the program. These included subconstructs, such as relative advantage, potential fit or compatibility, and the SEMM intervention's effectiveness in improving an important health problem prioritized by the clinic leadership (e.g., low cervical cancer screening rates and HPV vaccination rates). All ISF, and Readiness constructs from the $R = MC^2$ heuristic (readiness= motivation \times innovation specific capacity \times general capacity) informed the types of implementers that may need to be involved to support implementation and deliver the program as well as the types of capacity needed for implementation to be successful ([15](#)). These matrices of change objectives served as the roadmap for designing the SEMM-DIA implementation strategies. **Table 4** presents an example matrix for clinic leadership.

Task 3. Select theoretical methods and identify or design implementation strategies

The planning group selected evidence-based methods based on the targeted determinants and performance objectives, as well as informed by types of methods that have worked before to address identified implementation challenges (e.g., such as potential lack of motivation, capacity of staff to manage or deliver the program). For example, to address the potential skills and self-efficacy required of CHWs to implement SEMM, the team identified implementation strategies to target CHW training needs, targeting potential implementation threats (see **Table 5**). For example, the team identified the need to provide video testimonials of CHWs with previous experience implementing SEMM in their clinics. The research team would design the testimonial to show a CHW discussing how the SEMM training helped them to learn to deliver the intervention, and as a result, the implementer's satisfaction of seeing that their delivery of SEMM helped women they served to complete their breast and cervical cancer screenings, and HPV vaccinations. The previous implementers would also share their perspectives regarding the types of supporting materials and protocols (e.g., simple) that enabled CHWs to learn to deliver education and navigation support to patients. The testimonials also would include patients sharing their own positive experience with SEMM.

Based on their influence on determinants (e.g., attitudes, self-efficacy, and skills; see **Table 4**) and contextual factors, guided

TABLE 2 Example findings of leadership barriers and facilitators from rapid qualitative analysis.

| Potential barriers | Potential facilitators |
|---|--|
| <p>Readiness construct(s)</p> <ul style="list-style-type: none"> • Staff capacity (e.g., expanding CHWs role, hiring new CHWs) • Complexity-related to risk management and data protection (e.g., who will be responsible for upkeep of data and securing it) | <p>Readiness construct(s)</p> <ul style="list-style-type: none"> • Intra-organizational relationships (e.g., obtaining clinic staff buy-in) <p>SCT construct(s)</p> <ul style="list-style-type: none"> • Positive attitudes about CHWs being instrumental (e.g., CHWs are able to “wear multiple hats”) • Positive attitudes about having a program champion (e.g., program champion is critical for the success of the innovation) |

TABLE 3.1 Implementation outcomes and performance objectives: leadership level (example).

| Implementer | Implementation outcome | Performance objectives |
|-------------------|---|--|
| Clinic leadership | Clinic leadership will support implementation of the SEMM intervention. | <ol style="list-style-type: none"> 1. Review SEMM intervention objectives, components, experiences of other clinics, and identify relative advantages of implementing SEMM 2. Evaluate clinic needs: Note clinic BCS and CCS, and HPV vaccination rates 3. Communicate with and obtain buy-in from the Board/clinic leadership 4. Communicate the benefits of implementing SEMM to clinic staff. <ul style="list-style-type: none"> • PO4a. Talk informally to the staff about the importance of SEMM • PO4b. Use effective communication style (clear, coherent, and consistent communication) to support SEMM implementation • PO4c. Use data on SEMM effectiveness to persuade clinic staff of program importance • PO5d. Inform staff about how SEMM will help improve performance on their BCS and CCS quality measures 5. Communicate to the clinic staff that implementing SEMM is a priority 6. Determine clinic's high-level goals and goals for implementing SEMM (i.e., # of women recruited, # educated, # navigated, and # screened) 7. Identify resources (e.g., budget, space for education sessions, and staff time to complete training and implement SEMM) 8. Build relationships with key external stakeholders to support community outreach (e.g., local CBOs that serve the target population, state/county Public health officers, etc.) 9. Receive and report program updates to Board to ensure alignment to clinic goals |
| | Clinic leadership will maintain delivery of the SEMM intervention in their clinic | <ol style="list-style-type: none"> 1. Discuss and seek funding approval 2. Identify opportunities for technical assistance and additional staff training |

TABLE 3.2 Implementation outcomes and performance objectives: program manager/champion level (example).

| Implementer | Implementation outcome | Performance objectives |
|--------------------------------------|--|---|
| SEMM program manager and/or champion | SEMM program managers and/or champions will support and motivate CHWs to deliver the program | <ol style="list-style-type: none"> 1. Train CHWs to deliver SEMM 2. Communicate to CHWs that by implementing SEMM they are helping women in their community increase prevention and early detection of cervical cancer and early detection of breast cancer 3. Facilitate regular CHW meetings to debrief CHWs, coordinate implementation, and identify areas of need for retraining to build CHW capacity 4. Communicate summary reports to CHWs regarding numbers of women reached and served by SEMM (e.g., numbers of women screened or completion of HPV vaccinations as a result of CHW work) |

by SCT, the team identified behavioral change methods (e.g., modeling verbal persuasion, and communication). These methods were operationalized to guide adaptation of the existing CHW manager trainings. For example, CHW manager trainings included a train-the-trainer guide with step-by-step demonstrations of how to facilitate CHW peer learning (e.g., modeling). Trainings were adapted to build the CHW manager's capacity to supervise CHW delivery of SEMM, and to facilitate peer learning and peer support strategies during regular CHW team meetings. Empowerment and support of CHWs, managers and leadership were also addressed by planning testimonials based on positive experiences of previous program implementers who share benefits of promoting

the intervention within their clinic systems (e.g., helping to meet performance measures for cervical cancer screening) and benefiting their communities by addressing high priority problems in vulnerable communities. The implementation support planning process, therefore, not only provided practical support (e.g., knowledge and resource transfer to potential users), but also included implementation strategies and theoretically informed methods to help address both implementation challenges and user-related determinants of implementation (e.g., capacity to deliver SEMM, outcome expectations that SEMM will help women they serve to complete screenings and HPV vaccinations, and motivation to implement the program).

TABLE 3.3 Implementation outcomes and performance objectives: *Promotora/CHW/Health Coach Navigator* level (example).

| Implementer | Implementation outcome | Performance objectives |
|--|---|---|
| CHW/ <i>Promotora/CHW/Health Coach Navigator</i> | <i>Promotora/CHW/Health Coach Navigator</i> will support implementation of <i>Salud en Mis Manos (SEMM)</i> to improve breast and cervical cancer screening (BCS, CCS) and HPV vaccination among eligible Latinas (21–65 years) | <p>PO1. Understands the goals, purpose, objectives, and target group of SEMM intervention</p> <ul style="list-style-type: none"> PO1a. Participates in SEMM training PO1b. States importance of screening and vaccination for early detection and control of cervical and breast cancer PO1c. Learns how to use the SEMM data tracking system to record data <p>PO2. Understands the importance of her role as CHW in the SEMM intervention</p> <ul style="list-style-type: none"> PO2a. Identifies eligible Latinas through in-clinic and outreach PO2b. Screens, enrolls eligible and interested Latinas and takes informed consent PO2c. Collaborates with external stakeholders and partners for outreach <p>PO3. Delivers education sessions with fidelity using SEMM intervention materials</p> <p>PO4. Assesses participants' readiness, intention, and barriers to get screened or vaccinated (Health Coach Navigation)</p> |

Task 4. Produce implementation protocols and materials to guide intervention implementation

The fourth task of the Implementation Mapping process included designing the SEMM-DIA implementation strategy materials, protocols, and training. This involved describing the SEMM-DIA design document, creating the SEMM-DIA resource inventory, designing the SEMM-DIA website, and programming the SEMM-DIA website.

SEMM-DIA design document

SEMM-DIA is a multi-faceted multi-component implementation strategy. The SEMM-DIA design document was derived from the matrices of change objectives developed in Task 2 (Figure 2). It represents a top-level conceptualization of how SEMM-DIA functions. The performance objectives were ordered in a chronological sequence according to when they would occur during implementation (Table 6). On review, these performance objectives suggested a natural clustering that corresponded approximately to the Exploration, Preparation, Implementation, and Sustainment (EPIS) framework (14). This overriding "meta" implementation framework comprised five phases to support SEMM implementation and maintenance. These phases were (1) Exploration (prioritizing SEMM), (2) Preparation (assessing clinic readiness), (3) Preparation for implementation of SEMM, (4) Implementation, and (5) Sustainment (or maintenance). Each phase was associated with clinic personnel responsible for that phase (i.e., clinic leadership, SEMM champion, CHWs and health coach navigators).

The SEMM-DIA design document lists performance objectives embedded within this framework in thematic clusters representing: (1) Orientation; (2) Inventory checklist (for the implementer to assess delivery capacity and patient/community outreach needs); (3) Clinic Implementation Action Plan; (4) SEMM components: CHW-delivered education and referrals and health coach navigator-delivered barrier mitigation to help women

overcome personal and system-level barriers to accessing and using clinic services; and (5) Maintenance planning (Figure 2). This provides a context for when the performance objective occurs within the SEMM-DIA implementation process. Each performance objective refers to resources that are required to complete the objective, represented as row numbers within the SEMM-DIA resource inventory.

SEMM-DIA resource inventory

The SEMM-DIA resource inventory lists the resources that enable clinic personnel to complete each performance objective in SEMM-DIA (Table 6). The inventory provides information on the phase and performance objectives, agent (responsible clinic personnel), methods and strategies (from Step 3), and the SEMM implementation resources. The resources include written information about SEMM, a clinic inventory form to assess readiness for SEMM, a training curriculum for SEMM champions and CHWs, a template SEMM preparation plan, a CHW screening and tracking form, CHW patient and community awareness educational materials, and template maintenance plan (Figure 3). The resources are categorized as either "Existing" implementation resources (those implementation materials that had already been developed) that could be adopted or adapted, (such as CHW delivery guides) or as "Pending" resources (those in need of development; Table 6, Columns 6 and 7). This provides guidance on what pre-existing SEMM resources (again see Figure 3) could be leveraged in the SEMM-DIA development effort and to identify the extent of resource development required.

SEMM-DIA implementation support resources were designed to align with the varied implementation delivery goals, including if the priority for SEMM implementation was on "In-reach" (engaging existing patients within a clinic), or "out-reach" (engaging the broader community). Further materials, and tools were designed to facilitate varying delivery modalities including CHW-mediated one-on-one or group-based SEMM education and varying delivery channels including in-person, phone-based, or video-conference platforms.

TABLE 4 Matrices of change for implementation (example): clinic leadership.

| Performance objective | Determinant | | | | | |
|---|---|---|---|---|---|--|
| | Attitude | Knowledge | Skills and self-efficacy | Outcome expectations | Feedback and reinforcement | Normative beliefs |
| Clinic director will review SEMM objectives, components, experiences of other clinics, and relative advantages of implementing SEMM | AT1a. Believe that SEMM fits with organizational priorities | K1a. Describe SEMM as an evidence-based intervention for Latinas that was shown to be effective in increasing BCS and CCS among Latinas (21–65 years) | SSE1a. Feels confident in identifying SEMM components to share with team members based on clinic role | OE1a. Expect that implementing SEMM will increase guideline recommended BCS, CCS, and HPV vaccination rates among Latinas | OB1a. Believe that by implementing SEMM clinic demand for services will increase | NB1a. Recognize that other clinics review program objectives, components, and relative advantage before implementing a new cancer prevention program |
| | AT1b. Review SEMM components, materials, experiences of other clinics implementing SEMM in a favorable manner | K1b. Recognize SEMM is culturally appropriate | SSE1b. Feels confident in using SEMM-DIA to identify SEMM materials to share with clinic staff | OE1b. Expect that by providing staff and patients with information SEMM uptake will be achieved | OB1b. Believe that by implementing SEMM Texas will achieve Healthy People 2030 goals | NB1b. Believe that the other clinic systems that implemented SEMM had successfully implemented it |
| | AT1c. Believe SEMM is better suited for the clinic compared to other programs and/or usual practice | K1c. Describe that SEMM is available at no cost | | OE1c. Expect that patients will use SEMM information for BCS, CCS, and HPV vaccine uptake | OB1c. Expect that by knowing the experiences of other clinics that have implemented SEMM, s/he will be able to evaluate the pros and cons of adopting/implementing SEMM | |
| | AT1d. Believe that SEMM has unique components and benefits that make it relevant for the community | K1d. Recognize that the program will provide resources to the clinic and CHWs | | OE1d. Believe that the SEMM intervention will improve BCS, CCS and HPV vaccination rates among participating women | OB1d. Expect that by knowing the experiences of other clinics that have implemented SEMM will help successfully implement SEMM | |
| | AT1e. Believe that SEMM meets the standards of previously implemented programs | K1e. Describe the program as a tool for increasing BCS, CCS, and HPV vaccination among Latinas (21–65 years) | | | | |
| | AT1f. Recognize that other clinics have successfully implemented SEMM | K1f. Describe potential availability of CHWs to deliver SEMM | | | | |
| | AT1g. Believe that SEMM is an easy program to implement and will serve the needs of the community | K1g. Describe the steps needed to adopt and implement SEMM | | | | |
| | AT1h. Believe that SEMM is an easy program to implement in clinic settings | K1h. Describes patient education needs | | | | |
| | | K1i. Describe SEMM components and advantages | | | | |

TABLE 5 SEMM-DIA program implementation intervention plan (example).

| Agent/ Implementer | Determinants | Implementation strategies | | |
|---|--|---|---|--|
| | | Theoretical change methods | Practical applications of methods | Component |
| Clinic leadership and/or Program manager/champion | <ul style="list-style-type: none"> - Awareness/perceptions - Outcome expectations - Skills and self-efficacy - Feedback and reinforcement | <ul style="list-style-type: none"> - Persuasion - Modeling | <ul style="list-style-type: none"> - Informational video describing SEMM goals, components, and benefits - Video testimonials of clinic leaders discussing how/why they implemented SEMM in their clinics - Video/animated tutorial for implementers - Program manager/champion train-the-trainer guide | <ul style="list-style-type: none"> - SEMM-DIA program orientation session - Program tracking tools (online and/or electronic) - SEMM manager training - Technical assistance |
| | | <ul style="list-style-type: none"> - Communication - Mobilization | <ul style="list-style-type: none"> - Technical assistance <i>via</i> tele-mentoring platform Project ECHO - E-newsletter template to engage with stakeholders | |
| | <p><i>Characteristics of the innovation:</i></p> <ul style="list-style-type: none"> - Relative advantage - Comparability - Complexity - Trialability | <ul style="list-style-type: none"> - Organizational consultation planning - Advanced organizers - Environmental reevaluation | <ul style="list-style-type: none"> - SEMM implementation inventory/implementation readiness checklist—for assessing clinic resources (personnel and infrastructure) - Roles and Responsibilities SOP manual: for SEMM manager/champion and CHWs - Program implementation guide, clinic handbook - Quality monitoring tools and systems | |
| CHW | <ul style="list-style-type: none"> - Awareness/perceptions - Outcome expectations - Skills and self-efficacy - Feedback and reinforcement | <ul style="list-style-type: none"> - Information - Persuasion | <ul style="list-style-type: none"> - Informational video on benefits of implementing SEMM - Video testimonials of CHWs discussing implementation benefits and challenges | <ul style="list-style-type: none"> - SEMM-DIA online tool - Program orientation session - CHW online training - Technical assistance |
| | | <ul style="list-style-type: none"> - Technical assistance/capacity building - Facilitation | <ul style="list-style-type: none"> - Program implementation guide, Clinic handbook - SEMM implementation inventory/implementation readiness checklist—for assessing clinic resources (personnel and infrastructure) - CHW Training manual/curriculum - SEMM in-reach/outreach strategy toolkit - Technical assistance <i>via</i> tele-mentoring platform Project ECHO - Collaborator manual to support implementation | |
| | <ul style="list-style-type: none"> - Skill building - Guided practice - Vicarious reinforcement | | <ul style="list-style-type: none"> - Computer assisted SEMM training scripts | |

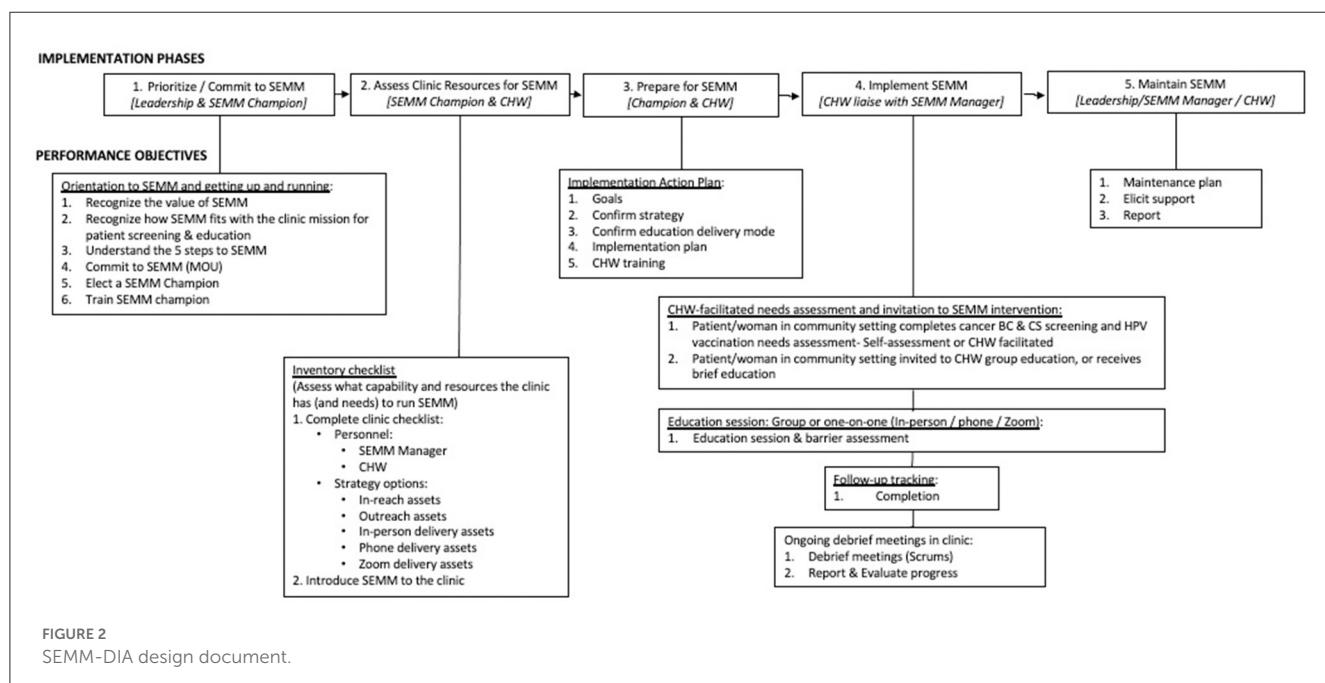
SEMM-DIA website design

The SEMM-DIA website was designed to be a multi-faceted multi-component implementation support strategy to guide planning and implementation of the SEMM EBI. A design document was developed to be the “blueprint” to guide construction of the SEMM-DIA website. The

document was informed by the previous implementation planning tasks and describes the website’s purpose and context, functional parameters (protocols, activities, and flow), design features, and resources (associated materials and assets to support adoption, implementation, and maintenance).

TABLE 6 SEMM-DIA resource inventory (example for phase 1, step 1).

| PHASE 1. Prioritize/commit to SEMM in your clinic | | | | | | |
|---|--|------------|--|---|--|---|
| I | II | III | IV | V | VI | VII |
| Step | Program phase tasks (performance objectives and change objectives) | Agent | Methods | Implementation strategies (methods and components) | SEMM implementation resources | |
| 1 | PO1. Leadership reviews SEMM intervention objectives, components, experiences of other clinics, and recognizes the relative advantages of implementing SEMM Change objectives: AT1a-j, K1a-d, OE1a-d, OB1a-d | Leadership | M1. Environmental reevaluation M2. Framing M3. Cultural similarity M4. Modeling M5. Persuasive communication M6. Goal setting M7. Belief selection | 1. Video introducing the SEMM intervention, components, and benefits (M:1-7; online tool) 2. Program implementation guide and clinic handbook (M:1-7; program orientation session) 3. Clinic SEMM needs and resources assessment checklist (M:1-7; online tool) 4. Implementation readiness checklist/SEMM implementation inventory (M:1-7; online tool, program orientation session) 5. SEMM clinic example workflow (M:1-7; online tool, program orientation session) | 1. Collaborator agreement form 2. SEMM recorded presentation 3. Overview materials/toolkits included in SEMM | 1. Update SEMM-DIA presentation 2. Update SEMM-DIA MOU scope of work |

FIGURE 2
SEMM-DIA design document.

The SEMM-DIA website was designed as an asynchronous, easily accessible, and user-friendly online guide and reference to SEMM implementation. The website guidance was designed to support navigation through the “5 steps to SEMM” in accordance

with the SEMM-DIA design document (Figure 4). Development was also informed by clinic staff’s preference for a simple, form-based approach that could be easily integrated into CHW workflow. They preferred to be able to download needed forms for use

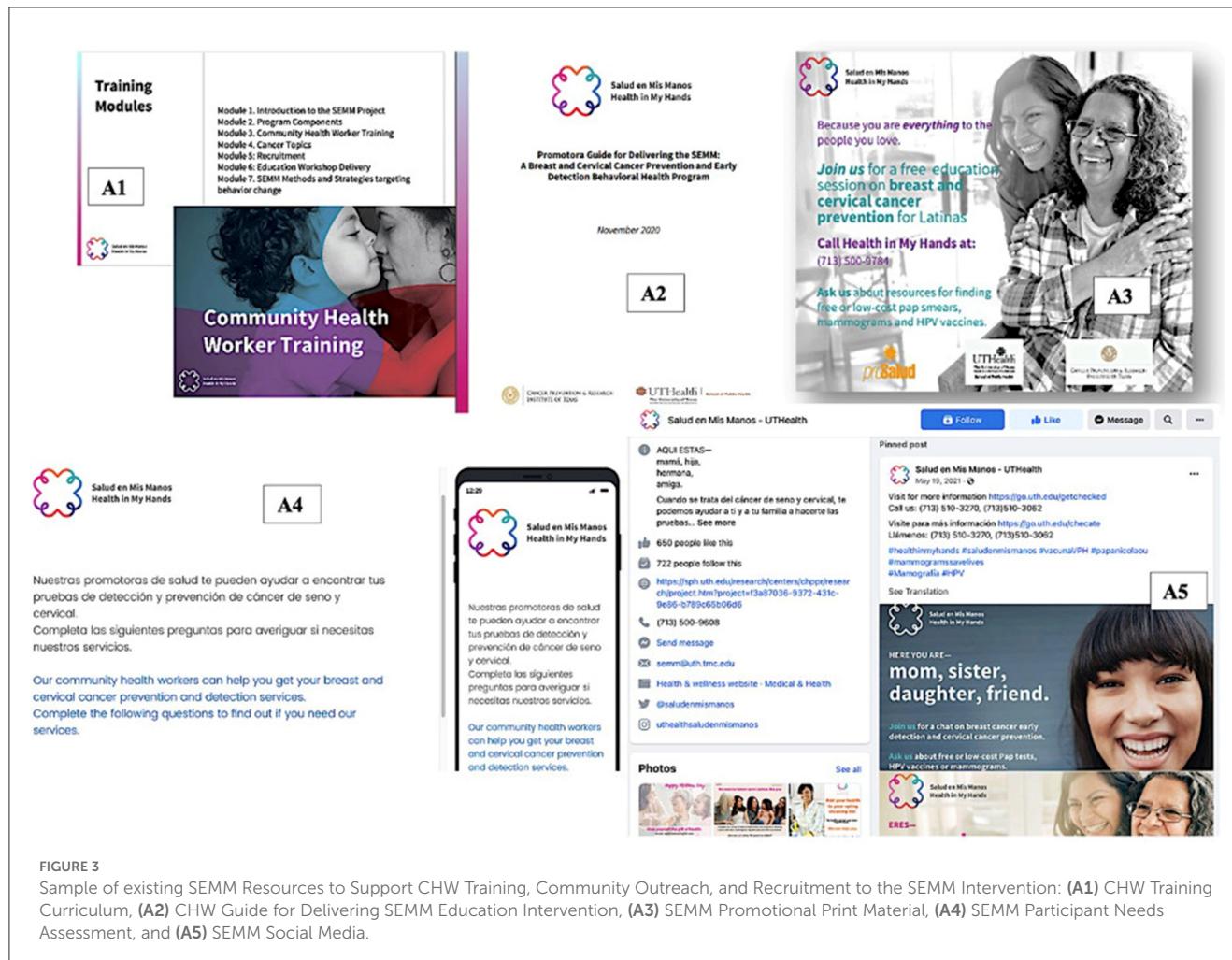


FIGURE 3

Sample of existing SEMM Resources to Support CHW Training, Community Outreach, and Recruitment to the SEMM Intervention: (A1) CHW Training Curriculum, (A2) CHW Guide for Delivering SEMM Education Intervention, (A3) SEMM Promotional Print Material, (A4) SEMM Participant Needs Assessment, and (A5) SEMM Social Media.

in the clinic or community rather than use of mHealth or technology-dependent applications for real-time use with patients (e.g., electronic data collection surveys or decision support tools). Thus, to enable accomplishment of each step the website was designed to provide SEMM resources for download (e.g., pdf forms that are the core of the SEMM screening and education for CHWs to use as hardcopy versions) or streaming (e.g., testimonial videos) in a manner that provided context and rationale for use within the SEMM-DIA design document. The website was designed to accommodate the needs of relevant clinic stakeholders including clinic leadership, SEMM champions, and CHWs.

SEMM-DIA website programming

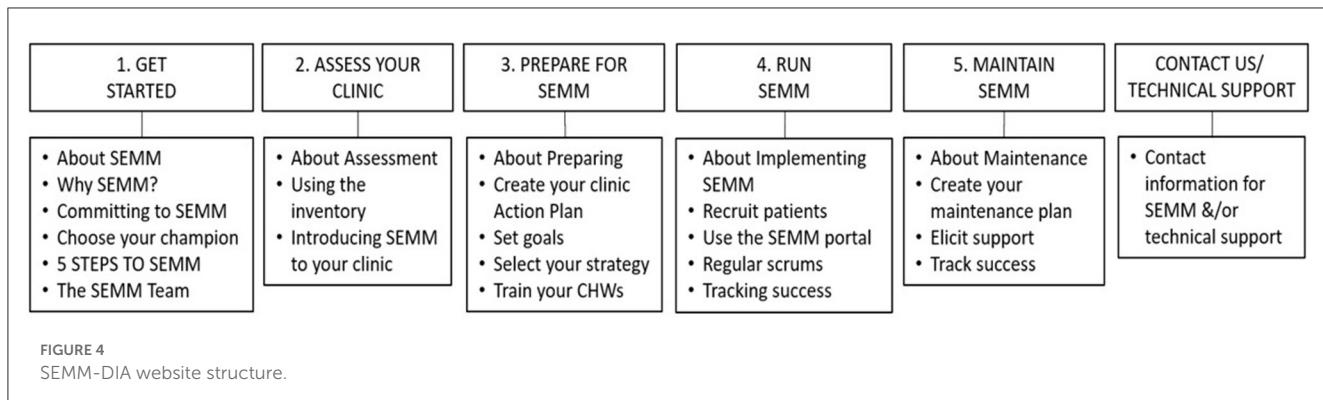
SEMM-DIA website programming was guided by the design document which provided the specifications previously described, priority audience (e.g., program adopters, SEMM champions, CHWs, or health coach navigators), scripts (e.g., for video testimonials planned for creation), and images (e.g., stock photos, or existing program photographs). In addition, a SEMM-DIA description, and specific instructions of each element in the SEMM-DIA plan, were provided to the SEMM-DIA website developers. This included the existing graphic design assets to retain the same

look and feel of the original intervention design. Figure 3 provides a sample of the SEMM material design “look and feel,” as used in existing SEMM CHW training curriculum, recruitment, and community outreach materials.

The Implementation Mapping planning process helped incorporate guidance from theoretical frameworks and informed the design and content of all the SEMM-DIA implementation strategies, including the SEMM-DIA website, as well as technical assistance strategies such as an initial program orientation session with clinics (either in-person or virtually), the SEMM-DIA Project ECHO tele-mentoring series, and IMAdapt.org to support EBI and implementation strategy adaptation. These additional individual technical assistance strategies are accessible *via* the online SEMM-DIA website. The implementation strategies embedded within the SEMM-DIA website component are the ones highlighted in this paper.

Task 5. Evaluation the implementation outcomes

In Task 5, design of the evaluation plan focused on determining the effect of the SEMM-DIA implementation strategy



on implementation outcomes, as well as the overall effectiveness of the SEMM intervention on increasing breast and cervical cancer screening and HPV vaccination rates. We will conduct a hybrid type 2 effectiveness-implementation group randomized trial to determine effectiveness and compare the effect of SEMM-DIA vs. Usual Implementation Practice (usual practice) on Reach, Effectiveness, Implementation, and Maintenance of SEMM, focusing on intentions to maintain SEMM due to the time constraints on evaluating long-term maintenance outcomes (25). These primary outcomes (four of the five RE-AIM dimensions) are defined in Table 7. A cost-effectiveness analysis to produce data on the economic details of SEMM-DIA implementation in clinic practice settings is planned as part of a future phase of this study.

To guide the overall evaluation, the planners articulated implementation evaluation questions to assess whether the SEMM-DIA implementation strategy influenced implementation determinants and outcomes such as fidelity of the SEMM implementation plan. Other implementation questions included whether SEMM-DIA was acceptable to the program implementers (e.g., implementer satisfaction), and did SEMM reach the priority implementers as planned. At the SEMM intervention level, process evaluation questions focused on whether each implementer delivered the intervention as planned (e.g., assessing fidelity of CHW implementation of SEMM), and whether the intervention reached the intended priority population (e.g., women overdue for breast and cervical cancer screenings, or HPV vaccination).

Implementation facilitators and barriers identified in Task 1 (needs and assets assessments) helped to identify potential mediators and moderators for the evaluation plan. In the selection of determinants and the development of matrices of change objectives, which focused on “*what needs to change in the determinants (e.g., attitudes, skills, knowledge)*,” the research team had considered behavioral science theories, such as SCT. Consequently, the evaluation plan also selected measures to evaluate targeted individual-level constructs identified, such as to evaluate the effect of CHW training on implementers’ knowledge, skills, self-efficacy, and outcome expectations.

In addition, implementation science frameworks (e.g., Integrated Systems Framework; ISF) that guided synthesis of the formative work conducted in Task 1, and informed implementation planning, consequently informed evaluation planning. Specifically, we identified the contextual factors of implementation to include in the evaluation plan at the organizational level, such as organizational readiness. Using the heuristic for organizational

readiness—motivation \times innovation-specific capacity \times general capacity, ($R = MC^2$) from ISF—we identified important constructs to include in the evaluation plan related to motivation (e.g., relative advantage, compatibility, complexity, priority), general capacity (e.g., culture, resource utilization, leadership, staff capacity), and innovation-specific capacity (e.g., knowledge/skills/abilities, program champion). Thus, the matrices developed in tasks 1–4 served as a road map to guide development of the evaluation plan.

Finally, the research team developed a logic model to provide a graphical representation of how strategies influence implementation and effectiveness of outcomes as part of the process for planning implementation strategies (Figure 5). This Implementation Mapping logic model illustrates the planned linkages between the implementation strategy, mechanisms, determinants of implementation, and proximal and distal implementation outcomes, thus helping describe the SEMM-DIA strategy’s mechanisms of change. The logic model begins with the intervention (SEMM) on the far left and progresses to implementation strategies that deliver change methods. The research team designed these strategies to influence determinants, which in turn effect change in the implementation behaviors and conditions, leading to implementation.

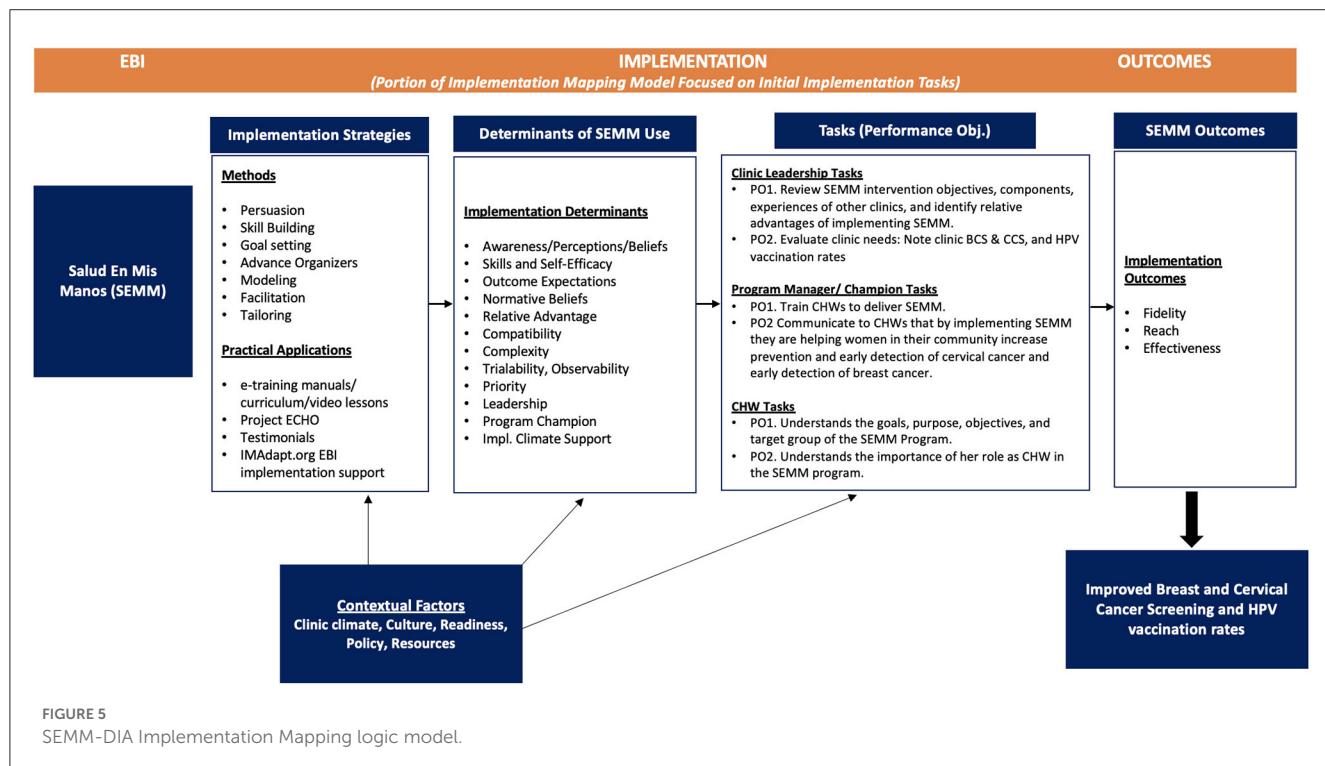
This logic model thus helps to define our SEMM-DIA implementation outcomes as well as SEMM effectiveness outcomes (breast, cervical and HPV vaccination), to be examined in the planned hybrid type 2 study. The comprehensive SEMM-DIA implementation support plan facilitates implementation of the SEMM intervention as planned (increasing implementation fidelity) among a priority population in need of the program (increasing efficiency in reach, minimizing over-inclusion and under-inclusion of the target population). The logic model also represents how the plan results in an intervention that effectively increases breast and cervical cancer screening, and HPV vaccination among underserved Latinas. Finally, the logic model is especially useful for communicating both the evaluation outcomes, and the causal mechanisms of the SEMM implementation and evaluation plan to non-academic clinic or community partners.

Discussion

Effective and feasible implementation strategies are needed to increase the use of evidence-based cancer prevention and control interventions in community and health care

TABLE 7 RE-AIM framework utilized constructs defined.

| Construct | Definition |
|-------------------------|---|
| Reach | Proportion of women who participate in the SEMM education session among those eligible |
| Effectiveness | (For screening and HPV vaccination) % of women who complete screening or vaccination among all eligible women participating in the program |
| Implementation | Extent to which SEMM program components were used |
| Level of implementation | Number of implementation steps that have been carried out |
| Implementation fidelity | Degree to which SEMM components are implemented by CHWs as prescribed (degree of implementation for each CHW; frequencies and proportion of CHWs performing the required behaviors; proportion of patients recommended for screening and HPV vaccination) |
| Implementation dose | Time spent in education sessions; # of navigation calls |
| Maintenance intention | Intention to implement the program in the next 6 months |

FIGURE 5
SEMM-DIA Implementation Mapping logic model.

settings. Implementation support is also needed to promote implementation with fidelity to retain effectiveness when EBIs are translated from research to practice. This paper described the use of Implementation Mapping to plan a multifaceted implementation strategy for the delivery of an effective breast and cervical cancer screening intervention targeting Latinas. The development of SEMM-DIA provides an opportunity to illustrate how Implementation Mapping can help implementation strategy planners use theory, evidence, and community engagement to inform strategy selection and tailoring. The use of Implementation Mapping also results in a logic model that presents a graphic depiction of the planned linkages between the implementation strategy, mechanisms, determinants of implementation and proximal and distal implementation outcomes, helping to describe the SEMM-DIA strategy's mechanisms of change.

A major strength of this work is that it provides a model for developing a multi-component, multi-level implementation support strategy to enable the implementation of a CHW delivered intervention in clinical settings (26, 27). CHW-delivered peer-to-peer behavioral interventions and patient navigation are recognized strategies to increase access to and utilization of preventive health care services, serving as effective approaches to increase parity for medically underserved ethnic and racial minorities (28–37). However, there are notable gaps in implementation and maintenance of such EBIs. The Implementation Mapping process used to plan SEMM-DIA provides a model to help identify common challenges to implementation and maintenance specific to CHW-delivered interventions, and provides an example for strategies selected, or designed, to address these CHW intervention-specific implementation challenges. Strategies identified may benefit other CHW-delivered interventions, these

include: (1) provide online CHW training materials to help maintain continuity of the program when there is CHW turnover, (2) embed materials developed to promote the program to reduce difficulty accessing materials in a timely manner, and (3) provide CHW manager training materials, to develop manager capacity to deliver CHW training, and provide continuous support and motivation to CHWs (9, 28, 38).

Another major strength of this work is the integration of multiple stakeholders in the planning process, using a collaborative approach (39–43). Implementation Mapping includes, as a foundational principle, the integration of implementers, community partners and other interested parties in the strategy development process. This includes people with experience delivering and managing the SEMM intervention (or similar CHW interventions), as well as other stakeholders and implementers (e.g., clinic leaders at FQHCs, clinic managers, and CHWs working in clinic settings). The importance of integrating stakeholders with extensive experience delivering and managing SEMM—specifically also helped to identify potential problems future implementers might encounter, and thus helped develop and select needed implementation support strategies. The SEMM-DIA planning team members with extensive experience managing and delivering SEMM provided their perspectives to planning and design decisions, such as identifying existing protocols and materials and resources that proved successful in supporting implementation that were leveraged in the design of SEMM-DIA. By engaging stakeholders with different roles and from different clinic settings, we were able to develop relevant and feasible methods and strategies with consideration of multiple perspectives and contingencies, ensuring that the implementation strategies addressed the needs and resources of the different organizations and the communities they served. Thus, throughout the process, we provided tailored options within the implementation strategies to influence different determinants and performance objectives for different types of users. The approach helped maximize generalizability of the SEMM-DIA design to a variety of potential users, as well as to diverse clinic and environmental contexts.

A challenge to this collaborative approach was scheduling meetings with clinic leadership and health care providers who often have competing priorities (e.g., during this study, clinic stakeholders' time was limited due to the COVID-19 pandemic). We learned that conducting regular virtual meetings with CAB members was essential to ensure inclusion of community stakeholders' perspectives. In addition, we used an iterative engagement process, circling back to different stakeholders to integrate their insights and feedback at key decision points, enabling participation by clinic coordinators and CHWs during the intervention development process, but also cognizant of their limited time.

The existing SEMM-DIA strategy is primarily focused on implementation and maintenance. Since this project works with clinics who have already expressed some interest in SEMM, the strategy does not include a major focus on clinic leaders' initial decision to adopt SEMM. The research team focused on designing SEMM-DIA to support the pre-implementation phase following initial adoption, to ensure SEMM alignment with the clinic organization's goals and capacity, as well as to facilitate SEMM

implementation within their clinic organization. This assumed that the clinic leadership had made a decision to adopt SEMM. Thus, we focused on developing implementation support for clinic leaders, managers and CHWs rather than on supporting leadership in a decision process to adopt SEMM. Future research is needed to examine the effect of the SEMM-DIA intervention on promoting adoption of SEMM as well as program maintenance. Further, because the implementation support system is designed as a multi-component multi-faceted implementation strategy, primarily within an online website, CHWs with limited technology skills may have difficulty accessing it, increasing reliance on SEMM CHW champions to provide SEMM-DIA resources to CHWs. Planned pilot testing of SEMM-DIA will help identify initial challenges, and pilot results will be used to identify solutions and further refine the implementation support strategies. Finally, ongoing evaluation will examine SEMM-DIA implementation outcomes, such as usability, feasibility, and acceptability, and SEMM intervention outcomes (e.g., completion of overdue breast and cervical cancer screenings, and HPV vaccination). To understand the degree of implementation, and degree of engagement with the SEMM-DIA dissemination and implementation support strategy, we will continuously monitor program implementation and stakeholder (clinic implementers) engagement. We will assess use of implementation materials and resources by clinic implementers through surveys and in-depth interviews. For the intervention group (SEMM-DIA study arm), we will also analyze implementers and decision makers' user data captured by SEMM-DIA (e.g., use, pathways, and Google Analytics), to examine the level of engagement with this implementation assistance. Because each clinic may use the SEMM-DIA implementation support differently (selecting elements that they decide will help their organization to implement SEMM effectively in their own clinic context and for the population they serve), there is not a predetermined "right" way to use SEMM-DIA. Therefore, in this study we will seek to identify potential mechanisms by which SEMM-DIA promotes fidelity in implementation outcomes and effectiveness of SEMM. Implementation monitoring and evaluation of the use of the implementation strategies will inform future adaptations of SEMM-DIA. Future SEMM-DIA implementation research will also include an implementation planning goal to develop and evaluate implementation strategies focused on supporting SEMM adoption, and will monitor maintenance over a longer period, to further improve widespread diffusion of SEMM.

In summary, we used Implementation Mapping to plan SEMM-DIA, a multifaceted implementation strategy (set of strategies). This paper describes the application of Implementation Mapping to develop implementation support strategies embedded in the SEMM-DIA website to serve as an example of how a systematic protocol can help apply theory and evidence for implementation strategy selection and development, describe the expected mechanisms of action of implementation strategies, and provide a framework for evaluation of implementation and effectiveness outcomes. Importantly, this approach integrates theory, empirical evidence, and EBI stakeholders' perspectives to develop relevant methods and implementation strategies, as well as to promote fidelity of implementation in the new adoption context. To promote implementation of evidence-based behavioral

interventions into community practice, increased reporting of processes used to select and tailor and develop implementation strategies are needed. This paper begins to fill that gap (44).

Data availability statement

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

Author contributions

MF, LS, and RS contributed to the conception and design of the study. LS, MF, PL, EA, CC, AA, and RS wrote sections of the first draft of the manuscript. LS, RC, and CC conducted interviews. CC and MA performed the qualitative analysis for the study's needs assessment. LS, EA, and MG summarized findings representing previous experience of SEMM implementers on the team. LS led final writing of the manuscript with substantive contributions from MF, RS, and CM. AA led final revision changes and responses to reviewers during the resubmission process and finalized all tables and figures. PL finalized all citations. LS and MF read and approved the final manuscript.

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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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Application of implementation mapping to develop strategies for integrating the National Diabetes Prevention Program into primary care clinics

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Background: Diabetes is considered one of the most prevalent and preventable chronic health conditions in the United States. Research has shown that evidence-based prevention measures and lifestyle changes can help lower the risk of developing diabetes. The National Diabetes Prevention Program (National DPP) is an evidence-based program recognized by the Centers for Disease Control and Prevention; it is designed to reduce diabetes risk through intensive group counseling in nutrition, physical activity, and behavioral management. Factors known to influence this program's implementation, especially in primary care settings, have included limited awareness of the program, lack of standard clinical processes to facilitate referrals, and limited reimbursement incentives to support program delivery. A framework or approach that can address these and other barriers of practice is needed.

Objective: We used Implementation Mapping, a systematic planning framework, to plan for the adoption, implementation, and maintenance of the National DPP in primary care clinics in the Greater Houston area. We followed the framework's five iterative tasks to develop strategies that helped to increase awareness and adoption of the National DPP and facilitate program implementation.

Methods: We conducted a needs assessment survey and interviews with participating clinics. We identified clinic personnel who were responsible for program use, including adopters, implementers, maintainers, and potential facilitators and barriers to program implementation. The performance objectives, or sub-behaviors necessary to achieve each clinic's goals, were identified for each stage of implementation. We used classic behavioral science theory and dissemination and implementation models and frameworks to identify the determinants of program adoption, implementation, and maintenance. Evidence- and theory-based methods were selected and operationalized into tailored strategies that were

executed in the four participating clinic sites. Implementation outcomes are being measured by several different approaches. Electronic Health Records (EHR) will measure referral rates to the National DPP. Surveys will be used to assess the level of the clinic providers and staff's acceptability, appropriateness of use, feasibility, and usefulness of the National DPP, and aggregate biometric data will measure the level of the clinic's disease management of prediabetes and diabetes.

Results: Participating clinics included a Federally Qualified Health Center, a rural health center, and two private practices. Most personnel, including the leadership at the four clinic sites, were not aware of the National DPP. Steps for planning implementation strategies included the development of performance objectives (implementation actions) and identifying psychosocial and contextual implementation determinants. Implementation strategies included provider-to-provider education, electronic health record optimization, and the development of implementation protocols and materials (e.g., clinic project plan, policies).

Conclusion: The National DPP has been shown to help prevent or delay the development of diabetes among at-risk patients. Yet, there remain many challenges to program implementation. The Implementation Mapping framework helped to systematically identify implementation barriers and facilitators and to design strategies to address them. To further advance diabetes prevention, future program, and research efforts should examine and promote other strategies such as increased reimbursement or use of incentives and a better billing infrastructure to assist in the scale and spread of the National DPP across the U.S.

KEYWORDS

underserved, implementation mapping, diabetes, prevention, primary care, prediabetes

Introduction

Prediabetes is one of the most prevalent chronic health conditions diagnosed in the United States (U.S.), estimated to affect 88 million individuals (1). Nearly 40% of those diagnosed with prediabetes will likely be diagnosed with diabetes within 4 years (2). This progression can be largely prevented through behavioral lifestyle changes that incorporate a sustainable healthy diet and physical activity resulting in a 5–7% weight loss (2, 3). The National Diabetes Prevention Program (National DPP) is an effective, evidence-based lifestyle change program shown to reduce the incidence of diabetes (4, 5). The National DPP includes a 22-h curriculum delivered *via* group sessions over the course of 12 months and focuses on helping participants make healthy lifestyle changes including improving nutrition, physical activity, and psychological well-being to achieve sustainable weight loss (5, 6). Individuals eligible to participate in the National DPP are typically referred to the program by health care providers but they can also self-enroll (7).

Although the National DPP has shown to be effective in delaying diabetes diagnoses (8, 9), its widespread adoption and implementation have been hindered by multiple barriers (10–12). At the provider level, barriers include limited awareness of the program among clinic staff and/or healthcare providers, limited provider referrals to the program, and lack of provider buy-in (10–12). In their assessment of multi-level barriers to program implementation, Baucom et al. (12) identified clinicians' lack of knowledge about the National DPP as the primary barrier to referring patients. At the clinic level, limited use of electronic health records (EHR) features to assist with referrals, lack of

reimbursement or incentive structures to support National DPP referrals and delivery, and lack of health educators to deliver the program are impediments to wider adoption and implementation of the program (13). Patient-level barriers include time, cost, and inconvenient program locations (12). Raising provider and patient awareness about the National DPP and increasing "brand recognition" remains an important priority to increase participation in the program.

Investigators from The University of Texas Health Science Center at Houston School of Public Health Center for Health Promotion and Prevention Research and the Center for Quality Health IT Improvement at the School of Biomedical Informatics (hereafter referred to as UTHealth team) partnered with the Texas Department of State Health Services (DSHS) to carry out a five-year project funded by the Centers for Disease Control and Prevention (CDC). The goal was to use Implementation Mapping to design and implement strategies to implement diabetes prevention guidelines and the National DPP in primary care clinics located in the DSHS Public Health Region (PHR) 6/5S (Gulf Coast). This process has real-world applications that can guide healthcare institutions in their efforts to scale the National DPP in their communities.

Methods

The UTHealth team first recruited primary care clinics to participate in the project and identified partner National DPP sites. The UTHealth team and clinic partners (hereafter "team") then used Implementation Mapping, a systematic planning framework, to

develop strategies to adopt, implement, and sustain a referral system to National DPP sites (14).

Clinic recruitment

The UTHealth team recruited primary care clinics to participate in the project using purposeful sampling based on their location within the Texas DSHS PHR 6/5S and their previous relationship with the UTHealth Center for Quality Health IT Improvement. UTHealth team members (e.g., research coordinators, and quality improvement specialists) created a list of clinics in the selected public health region that were currently or had previously received quality improvement, data analysis, and reporting services from the Center for Quality Health IT Improvement. Clinics' leadership staff from the identified clinics were contacted by phone and email and were provided with a brief overview of the project, including the goal of assisting clinics with National DPP implementation. Once a clinic indicated interest in participating, an introductory teleconference was scheduled with the clinic leadership team. During the introductory meeting, the DPP program was described, and clinic staff responded to unstructured questions to learn more about the clinic's priorities and its overall diabetes prevention and management goals.

Partnering with National DPP

The UTHealth team identified and recruited CDC-recognized National DPPs based on their coverage area within the Texas DSHS PHR 6/5S, ability to offer virtual classes, cost to participants, and ability to provide program materials in English and Spanish. As the initial step in the recruitment process, the UTHealth team created a list of CDC-recognized National DPPs registered on the CDC website located in the selected public health region. Additional National DPPs were identified in advertisements in the American Medical Association newsletter and through referrals from the funding agency. The UTHealth team reached out to each program to gauge their interest in partnering with one of the participating clinics. The recruitment process focused primarily on National DPP that could offer classes that could meet the needs of the clinics' patient population who were primarily under or uninsured and Spanish-speaking. Thus, the selected National DPPs offered classes at no cost to the participants (i.e., their program was already funded by public or private grants) and had classes in English and Spanish. Furthermore, since this implementation started while social distancing restrictions were still in place due to the COVID-19 pandemic, we selected programs offering remote or in-person classes. The National DPPs selected who partner with the clinics were a City of Houston-sponsored program, a Silicon Valley-based program, and a local private practice.

Strategy planning using implementation Mapping

Implementation Mapping incorporates theory, stakeholder input, and data to guide implementation strategy development (15). The process leads planners through five iterative tasks: (1) conduct a needs and assets assessment and identify program adopters, implementers,

and maintainers; (2) identify adoption, implementation, and maintenance outcomes, performance objectives (i.e., specific tasks or sub-behaviors required to adopt, implement, and maintain a program), and determinants, and create matrices of change objectives (i.e., changes required in each determinant that will influence the achievement of each performance objective); (3) select evidence- and/or theory-based methods and identify or develop implementation strategies; (4) produce implementation protocol and materials; and (5) evaluate implementation outcomes (14).

Task 1: Conduct a needs and assets assessment and identify program adopters, implementers, maintainers, and champions

Leaders at the four participating clinics completed an online 56-item survey and 60-min interviews to assess: (1) awareness of National DPP; (2) barriers to National DPP adoption, implementation, and maintenance; (3) clinics' approaches to prediabetes diagnosis and management; (4) the use of clinical decision support for chronic disease management and technological capabilities; (5) existing referral systems to external lifestyle change programs; and (6) use and capacity of the clinic's EHR system. Clinic decision support (CDS) is any EHR tool designed to enhance decision-making in the clinical workflow. Tools may include alerts and reminders to care providers and patients, clinical guidelines, condition-specific order sets, focused patient data reports and summaries, documentation templates, diagnostic support, and contextually relevant reference information. Upon completion of the needs and assets assessment survey and interviews, the UTHealth team worked with each clinic to develop and sign a Memorandum of Understanding (MOU) indicating an intent to adopt the National DPP.

The team defined the following roles responsible for adopting and integrating National DPPs into clinic processes at each clinic site. A *program adopter* was defined as a clinic staff member with the decision-making authority to start using a National DPP program (i.e., clinic leadership) and/or a staff member (i.e., clinic administration) directly involved in deciding to set up program referral processes. A *program implementer* was a staff member (i.e., physician, nurse practitioner, physician assistant) responsible for making program referrals and/or a clinic administrator responsible for educating staff. A *program champion* (i.e., a health care provider or clinic administration) was an implementer that advocated for promoting the National DPP among other clinic staff (e.g., communicating with technical support personnel to ensure that EHR referral procedures were in place and fit the goal of being able to refer patients to a program in a timely manner). Finally, *program maintainers* (i.e., clinic leaders from administration, health care providers, and National DPP providers) were those who were responsible for ensuring that the program was maintained over time.

Task 2: Identify adoption, implementation, and maintenance outcomes, performance objectives and determinants, and create matrices of change objectives

In Task 2, the team stated the adoption, implementation, and maintenance outcomes, and performance objectives associated with each outcome. The overall goal is a statement that clinics intend to adopt, implement, and maintain a program while adoption, implementation, and maintenance outcomes are specific to each

adopter, implementer, and maintainer. Performance objectives are the specific actions or sub-steps required to adopt, implement, and maintain the National DPP in each clinic (14). To create performance objectives, the team asked, “who needs to do what to ensure that the program is adopted?” with similar questions asked for implementation and maintenance.

Next, the UTHealth team identified determinants influencing adoption, implementation, and maintenance. Determinants answer the question why an adopter, implementer, or maintainer would complete performance objectives and outcomes (14). For example, “why would clinic leadership adopt the National DPP at their clinic?” The UTHealth team identified an initial list of determinants based on Task 1 data, a review of the literature, health behavior theories, and implementation and dissemination frameworks, and then provided clinic stakeholders with the list and solicited feedback to select final determinants. Stakeholders rated determinants based on perceived importance and changeability.

Finally, the team created a matrix of change objectives by crossing performance objectives (rows) with determinants (columns). Change objectives in each cell stated what needs to change in a determinant to achieve the performance objective and provided a blueprint for identifying, selecting, or developing implementation strategies (14).

Task 3: Select theory-based methods and identify implementation strategies

In Task 3, the team collaborated to identify evidence- and theory-based methods targeting determinants. Evidence- and theory-based methods are techniques influencing determinants and may work at the individual- and/or clinic-levels (14). Collaboration to identify methods included brainstorming, identifying previously successful methods in implementing organizational change at each clinic, and reviewing the literature. Next, the team operationalized methods as implementation strategies, the specific approaches to enhance National DPP adoption, implementation, and maintenance in participating clinics (14, 16, 17).

Task 4: Produce implementation protocols and materials

In Task 4, the team produced protocols and materials to facilitate National DPP adoption, implementation, and maintenance. Clinic action plans and supporting materials were developed and discussed during monthly TA calls to ensure the clinics' feedback was incorporated. Clinic action plans delineated the implementation timeline. Supporting materials were developed and tailored to meet the needs of the clinics (e.g., staff, EHR capability, and patient population).

Task 5: Evaluate implementation outcomes

Data collection for evaluation is ongoing. Evaluation will include assessment of National DPP referrals *via* the EHR and adoption and implementation outcomes including program appropriateness, acceptability, feasibility, and fidelity measured *via* healthcare provider and clinic leadership surveys (15). Evaluation methods will include clinic leadership and healthcare provider surveys and document review of meeting notes, EHR screen captures, workflow/process flowcharts, and clinic policies.

Results

Clinic and National DPP partnerships

Four clinics meeting eligibility criteria agreed to participate. These included: Clinic A, a federally qualified health center (FQHC) with four clinic sites; Clinic B, a Rural Health Center (RHC); and Clinics C and D, two private community-based healthcare clinics. FQHCs are community-based health facilities eligible to receive federal funds because they provide affordable services to patients based on their ability to pay (18). RHCs are clinics that serve both private and publicly insured populations in rural, underserved areas; they can be for-profit or non-profit clinics (19). All participating clinics serve diverse patient populations and provide services to primarily under and uninsured patients with limited access to healthcare. The UTHealth team worked closely with stakeholders from each clinic including clinic leadership (e.g., chief executive officer, chief operations officer, chief medical officer, chief nursing officer); clinic administrators (e.g., technology/data analyst, practice administrator, practice manager); and health care providers (e.g., physicians, nurse practitioners, physician assistants).

The UTHealth team established partnerships with three National DPP, all of which were providing only virtual sessions as a result of the COVID-19 pandemic. The National DPPs were paired (i.e., the clinic needs matched with the program services) with clinics based on the capacity and preferences of the two partnering entities. For example, one clinic was paired with a local National DPP that offered face-to-face classes in English and Spanish reflecting the language needs of the clinic's patient population.

Implementation mapping

Task 1: Conduct a needs and assets assessment and identify program adopters, implementers, maintainers, and champions

Conduct a needs and assets assessment

Table 1 summarizes the results of the clinics' needs assessment survey and interviews. Each clinic provided some form of patient education about diabetes prevention, although sources for materials differed by clinic. Screening for the risk of diabetes also varied by clinic, and only one clinic used clinical decision support to identify patients with prediabetes. Three of the four clinics were not aware of the National DPP or of its availability in their communities.

Clinic stakeholders identified the following two provider-level barriers to referring patients to the National DPP: (1) a perceived lack of time during appointments for the provider to use decision support tools, discuss the National DPP, and make referrals; and (2) the provider perception that patients will not adhere to the National DPP. The clinic stakeholders identified the following six perceived patient barriers to participating in a National DPP: (1) low understanding of diabetes risk perception; (2) language barriers; (3) financial and time constraints; (4) transportation difficulties; (5) childcare concerns; and (6) lack of health insurance.

Clinics reported using different EHRs including NextGen, Athena, Practice Fusion, and eClinicalWorks. Four clinics' digital systems were not certified EHR products, had basic capabilities for

setting appointments and billing, and were connected through the regional health information exchange and electronic provider-to-provider (P2P) referral networks. Most clinics used reminders for the treatment of diabetes as a CDS tool.

Identify program adopters, implementers, champions, and maintainers

Program adopters at clinics included clinic leadership (i.e., chief executive officer, chief operations officer, chief medical officer, and chief nursing officer). Program implementers included clinic administration staff (i.e., technology/data analyst, practice administrator, and practice manager), and healthcare providers (i.e., physicians making referrals, nurse practitioners, and physician assistants). Program champions were identified from both health care providers and clinic administration staff in each clinic. Finally, program maintainers were identified from leadership (i.e., chief executive officer, chief operations officer, chief medical officer, and chief nursing officer), clinic administration (i.e., technology/data

analyst, practice administrator, and practice manager), and healthcare providers (i.e., physicians making referrals, nurse practitioners, and physician assistants).

Task 2: Identify National DPP adoption, implementation, and maintenance outcomes, performance objectives, and determinants and create matrices of change objectives

The identified outcomes were to adopt, implement, and maintain guidelines for diabetes prevention and the National DPP. **Table 2** lists all adoption, implementation, and maintenance outcomes and performance objectives.

Adoption, implementation, and maintenance determinants that clinic stakeholders considered important and changeable included those from the Social Cognitive Theory (20) and Interactive Systems Framework (21). These included: stakeholder and providers' attitudes toward the importance of diabetes prevention, knowledge about the program, perceived severity of failing to refer prediabetic patients,

TABLE 1 Summary of the 2019 needs assessment survey and interview responses from clinics participating in the National Diabetes Prevention Program.

| Key themes | Clinic A | Clinic B | Clinic C | Clinic D |
|---|---|---|--|---|
| Location | Rural | Urban | Urban | Urban |
| Clinic type | FQHC | FHQC | Private practice | Private practice |
| Patient population | 7,500 | 21,254 | 6,000 | 1,000 |
| Pre-diabetes education for patients | Education material provided includes materials from EHR, ADA, pharmaceutical companies, and counseling. No CHWs, but tech aides assist with patient management. | Education is provided by the MA and <i>via</i> pamphlets. Dieticians provide educational information and material on nutrition. Standard protocol with patients who have pre-diabetes is to provide education on lifestyle changes and referral to a dietician. | Education and instructions are given verbally by the physician. | Education handout was given <i>via</i> EHR. |
| Diabetes screening | Any patient at risk for diabetes is tested annually. | Any patient 40+ with risk factors of diabetes is tested. | Any patient at risk for diabetes is tested. No tools or algorithms are used for testing. | New patients are tested automatically at baseline. |
| Use of clinical decision support | Not applicable | Not applicable | Not applicable | Reminders for treatment |
| Awareness of the National DPP | No | Yes – did not make referrals | No | No |
| Awareness of local National DPP | No | Yes – did not make referrals | No | No |
| Provider-level barriers to referring patients to the National DPP | Perception that patients will not adhere to the National DPP. Perceived lack of time during appointments to discuss the National DPP and make referrals. | Perceived lack of time during appointments to use decision support tools, discuss the National DPP, and make referrals. | Lack of time during appointments. Perceived lack of time during appointments to discuss the National DPP and make referrals. | Perceived lack of time during appointments to use decision support tools, discuss the National DPP, and make referrals. |
| Perceived patient-level barriers to participating in the National DPP | Financial and time restraints. Patients low perceived risk. | Language transportation and childcare. Finding community resources. | No response | Finding community resources insurance consideration. |

The data presented in this table was collected from the four participating clinics' needs assessments completed in 2019.

ADA, American Diabetes Association; CHWs, community health workers; EHR, electronic health records; FHQC, federally qualified health center; MA, medical assistant; National DPP, National Diabetes Prevention Program; CDC, Centers for Disease Control and Prevention.

TABLE 2 Sample adoption, implementation, and maintenance outcomes and performance objectives.

| Program: National DPP Setting: Clinic-based | | |
|--|---|---|
| Target: role | Adoption, implementation, and maintenance outcomes | Performance objectives |
| Adopters | | |
| Clinic leadership | Clinic leadership adopts National DPP to prevent diabetes among patients with prediabetes. | <ol style="list-style-type: none"> Partners with a CDC-recognized National DPP. Delineates the clinic's National DPP referral goals. Approves legal agreement with National DPP. Designates a clinic program champion to spearhead the implementation of the National DPP referral process. Establishes reporting of participants who meet prediabetes criteria to National DPP. |
| Clinic administration | Clinic administration optimizes EHR to identify patients with prediabetes and refer them to the National DPP. | <ol style="list-style-type: none"> Optimizes EHR to facilitate the referral process. Joins the P2P network. Collaborates with EHR vendors to obtain the needed EHR updates and establish a patient identification process. Enables EHR identification of National DPP-eligible patients. Edulates staff on EHR National DPP updates. Incorporates the National DPP referral process into the clinic's workflow. Edulates clinics staff about National DPP referral patient criteria. Establishes quality control to monitor the referral process. |
| Implementers | | |
| Clinic administration | Clinic administration monitors the referral system. | <ol style="list-style-type: none"> Educate clinic staff about the National DPP workflow and make changes to improve productivity. Encourages health care providers to make patient referrals. Identifies gaps in data reporting. Conducts monthly reports of patients who meet prediabetes criteria for National DPP referral. Submits referrals data report to National DPP quarterly. |
| Health care provider | Health care provider makes referrals of patients with prediabetes to National DPP. | <ol style="list-style-type: none"> Reviews patient's medical records. Identifies patients with prediabetes. Discusses National DPP referral with patients with prediabetes. Connects patients to the National DPP providers. Encourages patients to enroll in National DPP. Submits patient referral to National DPP in the EHR. Shares appropriate patient information with National DPP providers. |
| Program champion | Program champion promotes and educates other clinic staff about the implementation of National DPP. | <ol style="list-style-type: none"> Advocates for the implementation of National DPP. Motivates clinic health care providers to make National DPP referrals. Ensures that the EHR referral process is operational. Communicates with the National DPP provider to ensure referral feedback. Receives confirmation about patients' National DPP referral status. |
| National DPP provider | National DPP provider delivers the National DPP to referred patients with prediabetes. | <ol style="list-style-type: none"> Coordinates how to receive patients' referrals with the clinic. Pulls and reviews the database of eligible National DPP patients from the clinic EHR continuously. Coordinates logistics for hosting introductory sessions and National DPP classes throughout the year-long program. Motivates patients to promote adherence to the National DPP program. Provides enrollment and outcome feedback to the clinic. |
| Maintainers | | |
| Clinic leadership | Clinic leadership maintains contractual /data agreements with National DPP providers. | <ol style="list-style-type: none"> Ensures that the contract is up to date and renews data agreement with National DPP as needed. Monitors fidelity of the referral system. |
| Clinic administration | Clinic administration consistently monitors the National DPP referral system. | <ol style="list-style-type: none"> Updates EHR as needed. Continues to review patient outcomes on a regular basis. Collects referral data and reports to providers. Providers continue guidance and training for current and new staff on completing referrals. |
| National DPP provider | National DPP provider maintains the delivery of the program to patients with prediabetes referred to from clinic. | <ol style="list-style-type: none"> Coordinates ongoing enrollment of new National DPP cohorts from patients' referrals. Works with the clinic to continue providing patient status updates. |

This table shows a sample of the adoption, implementation, and maintenance outcomes and performance objectives selected for the implementation of the National DPP. CDC, Centers for Disease Control and Prevention; National DPP; National Diabetes Prevention Program; EHR, electronic health records.

Implementers: clinic administration, health care providers, program champions, and National DPP providers. Maintainers: identified included clinic leadership, clinic administration, and National DPP providers.

Healthcare providers: physicians making referrals, nurse practitioners, and physician assistants.

Program champion: health care providers or clinic administration.

Clinic leadership: chief executive officer, chief operations officer, chief medical officer, and chief nursing officer.

Clinic administration: technology/data analyst, practice administrator, and practice manager.

National DPP provider: lifestyle change coach and program administrator.

TABLE 3 Sample matrices of change objectives for the adoption of the National Diabetes Prevention Program among the participating clinics in Texas, United States.

| Adoption outcome: Clinic leadership adopts National DPP to prevent diabetes among patients with prediabetes. | | | | |
|--|---|---|---|--|
| Performance objectives | Knowledge | Perceived severity | Attitudes | Perceived benefits |
| PO1. Clinic leadership partners with a CDC-recognized National DPP. | K1a. Describe the steps for partnering with a National DPP provider. | PS1a. Understand that adopting the National DPP will decrease patients' risk of developing diabetes. | A1a. Believe that lifestyle change programs can help patients with prediabetes decrease the risk of developing diabetes. | PB1a. Expresses that referring patients with prediabetes to the National DPP will decrease their risk of developing diabetes. |
| PO2. Clinic leadership delineates the clinic's National DPP referral goals. | K2a. List the number of patients with diabetes and prediabetes (at risk). K2b. Describes the expected change/patient outcomes in preventing diabetes. | PS2a. Understand the importance of setting goals for referrals to track referral outcomes. PS2b. Understand that setting achievable referral goals will help the clinic prevent diabetes. | A2a. Express a positive attitude about setting referral goals to promote referrals to the National DPP. | PB2a. Recognize that identifying clinic-wide referral goals will help providers make more informed decisions about making referrals. PB2b. Understand that by identifying referral goals, they will be able to track success. |
| PO3. Clinic leadership reviews and approves legal agreement (MOU) with National DPP. | K3a. Lists terms of the agreement. AK3b. Describes what the partnership will entail in detail. | PS3a. Perceives that the National DPP partnership will help the clinic prevent diabetes. | A3a. Believes that the MOU will establish guidelines and scope work of the relationship with the National DPP. | PB3. Expresses the need to have an MOU to guide the partnership successfully and provide accountability. |
| PO4. Clinic leadership designates a clinic program champion to spearhead the implementation of the National DPP referral process. | K4. Acknowledge that the program champion can successfully lead the clinic's National DPP referral process. | PS4a. Believe that the program champion understands that the National DPP referral process fits the clinic's diabetes management goals. | A4a. Express that the program champion will acknowledge the benefits of the adoption of National DPP. | PB4. Recognize that the program champion will support the National DPP referral efforts. |
| PO5. Clinic leadership establishes reporting of participants who meet prediabetes criteria to the National DPP. | K5a. List criteria for diagnoses of prediabetes. K5b. Understand how to pull patients with prediabetes based on lab values. K5c. Describe inclusion and exclusion criteria for National DPP participation. | PS5a. Understand the complications patients may experience if they progress from prediabetes to diabetes. PS5b. Understand that diabetes is a serious disease that can be prevented through early intervention in identified patients. | A5a. Express a positive attitude about pulling information of patients with prediabetes. | PB5a. Recognize that identifying patients with prediabetes will help the patients and providers make more informed decisions about the patient's health. PB5b. Understand that by identifying patients with prediabetes, they will now be able to connect them with useful educational resources. |

This table shows a sample of the performance objectives for the adoption of the National DPP program based on the determinants from the Social Cognitive Theory (SCT) and Health Behavior Model (HBM).

CDC, Centers for Disease Control and Prevention; EHR, electronic health records.

Healthcare providers: physicians making referrals, nurse practitioners, and physician assistants.

Program champion: health care providers or clinic administration.

Clinic leadership: chief executive officer, chief operations officer, chief medical officer, and chief nursing officer.

Clinic administration: technology/data analyst, practice administrator, and practice manager.

National DPP provider: lifestyle change coach and program administrator.

perceived program benefits, perceived program effectiveness, staff capacity and motivation to overcome barriers, and staff capacity and motivation to implement the program. The team crossed all determinants with performance objectives to create change objectives. Tables 3, 4 provide example matrices of change objectives for National DPP adoption and implementation in clinics.

Task 3: Select theory-based methods and identify implementation strategies

The team identified three primary evidence- and theory-based methods to influence determinants: enhancing network linkages; participatory problem solving, providing technical assistance, facilitation, goal-setting, framing, tailoring, and guided practice.

Methods were operationalized as specific implementation strategies to increase National DPP adoption, implementation, and maintenance. These included: (1) developing and distributing

providing education materials; (2) monthly meetings between the clinic staff, the National DPP provider, and the UTHealth team; (3) changing clinic records systems to include an EHR-based referral system between clinics and partner National DPPs; and (4) provider-to-provider mentoring. Table 5 depicts determinants, linked theoretical methods, and implementation strategies operationalizing the methods.

Task 4: Produce implementation protocol and materials

Once the referral network was established between the clinics and the National DPP providers, the partnering program began to contact and enroll participants. Through participatory planning sessions with each clinic and its assigned program provider, we identified the need for introductory sessions, referred to as "Session 0," to help participants become familiar with the virtual platform used by the National DPPs.

TABLE 4 Sample matrices of change objectives for the implementation of the National Diabetes Prevention Program among participating clinics in Texas, United States.

| Implementation outcome: Health care provider makes referrals of patients with prediabetes to the National DPP. | | | | |
|---|--|--|--|---|
| Performance objectives | Perception and awareness | Outcome expectations | Feedback and reinforcement | Interorganizational relationships |
| PO1. Health care providers reviews patients' medical records. | PA1a. Perceive that reviewing patient records is necessary and important to identify and properly refer patients with prediabetes to National DPP. | OE1a. Expect that review of patient records is necessary and important to make a proper National DPP referral. OE1b. Expect that reviewing the patient's health records will be of value for making the referral to National DPP. | FR1a. Express that reviewing patient records will result in increased referral of patients with prediabetes to the National DPP. | IR1a. Acknowledge the benefits of other clinic members reviewing the medical records pre-appointment. |
| PO2. Health care providers identify patients with prediabetes (at risk of diabetes). | PA2a. Perceive that identifying patients with prediabetes is an important step toward making referrals to the National DPP. PA2b. Perceives that understanding the inclusion and exclusion criteria of DPP participation is key to making a referral to the National DPP. | OE2a. Expects that the identification process will help refer patient population at risk of diabetes. OE2b. Expects that lab values are important to identify patients susceptible to diabetes. | FR2a. Expresses the importance of identifying patients at risk of diabetes. FR2b. Expresses that diabetes is a serious disease that can be prevented through early identification and prevention. | IR2a. Acknowledges the impact of identifying patients with prediabetes to help the clinic's efforts to prevent diabetes. IR2b. Recognizes that screening patients for prediabetes will help them and the clinic staff to refer patients to the National DPP. |
| PO3. Health care providers discusses National DPP referral with the patient | PA4a. Perceive the success of the National DPP program in preventing diabetes. PA4b. Acknowledge the ability to discuss the National DPP referral with patients. | OE4a. Expect that the patient may not trust the National DPP program without a conversation with their provider. | FR4a. Express positive attitude about discussing the National DPP referral with the patient. | IR4a. Recognize that provider-patient communication increases trust in the patient for the National DPP. IR4b. Recognize that the discussion with the patient may increase their likelihood of attending and fully adhering to the National DPP. |
| PO5. Health care providers encourage patients to enroll in the National DPP. | PA5a. Feel that the National DPP referral process is necessary and important for the success of the intervention and patient enrollment. | OE5a. Expect that National DPP referral will incentivize patients to buy-in the enrollment process. | FR5a. Believe that encouraging patients to enroll in the National DPP will enhance patient enrollment. | IR5a. Recognize that encouraging patients to enroll in the National DPP may help patients enroll in the program. |
| PO6. Health care providers submit patient referrals to National DPP in the EHR. | PA6a. Perceive that submitting patient referrals is easy and important for patients to join the National DPP to prevent diabetes. | OE6a. Expect that submitting referral is key for patients to enroll in the National DPP. OE6b. Expect that submitting referrals will help patients connect with the National DPP. | FR6a. Express that submitting patient referrals will result in increased enrollment of patients with prediabetes in the National DPP. | IR6a. Acknowledge that submitting referrals will facilitate patient enrollment to prevent diabetes. |
| PO7. Health care providers share appropriate patient information (contact information and lab work) with National DPP providers. | PA7a. States the importance of sharing patient information with the National DPP to support enrollment. PA7b. Acknowledge the importance of submitting the patient's information as part of the referral process to the National DPP. | OE7a. Expect that sharing patient information will ensure timely program enrollment. | FR7a. Express satisfaction about sharing patients' information with the National DPP as part of the referral process. | IR7a. Recognize that providing the patient's information will help the National DPP communicate with patients. IR7b. Recognize that providing the patient's information will ensure eligibility to the National DPP. |

This table shows a sample of the performance objectives and determinants for the implementation of the National DPP program based on the Interactive Systems Framework (ISF) for Dissemination and Implementation.

CDC, Centers for Disease Control and Prevention; EHR, electronic health records.

Healthcare providers: doctors making referrals, nurse practitioners, and physician assistants.

Program champion: health care providers or clinic administration.

Clinic leadership: chief executive officer, chief operations officer, chief medical officer, and chief nursing officer.

Clinic administration: technology/data analyst, practice administrator, and practice manager.

National DPP provider: lifestyle change program and program administrator.

TABLE 5 Sample matrices of change objectives for the maintenance of the National Diabetes Prevention Program among participating clinics in Texas, United States.

| Maintenance outcome: Clinic administration consistently monitors the National DPP referral system. | | | | |
|---|---|--|--|---|
| Performance objectives | Perception and awareness | Outcome expectations | Feedback and reinforcement | Interorganizational relationships |
| PO1. Clinic administration updates EHR as needed. | PA1a. Acknowledge that the program champion can successfully lead the clinic's National DPP referral process. | OE1a. Believe that the program champion understands that the National DPP referral process fits the clinic's diabetes management goals. | FR1a. Express that the program champion will acknowledge the benefits of the adoption of National DPP. | IR1a. Recognize that the program champion will support the National DPP referral efforts. |
| PO2. Clinic administration continues to review patient outcomes on a regular basis. | PA4b. Describes referring patients with prediabetes to National DPP as a good fit for the clinic to decrease prediabetic patients' risk of developing diabetes. | OE3a. Expects that incorporating the National DPP referral process into the clinic's workflow will contribute to the successful implementation of the National DPP referral. | FR3a. Recognize that incorporation of the National DPP into the clinic's workflow will result in increased referrals to National DPP. | IR3. Recognize that incorporating the National DPP workflow can help healthcare providers and other clinic staff complete the necessary steps to identify new and existing patients with prediabetes. |
| PO3. Clinic administration collects referral data and reports to providers. | PA4a. Perceive the success of the National DPP program in preventing diabetes. PA4b. Acknowledge the ability to discuss the National DPP referral with patients. | OE4a. Expect that the patient may not trust the National DPP program without a conversation with their provider. | FR4a. Express positive attitude about discussing the National DPP referral with the patient. | IR4a. Recognize that provider-patient communication increases trust in the patient for the National DPP. IR4b. Recognize that the discussion with the patient may increase their likelihood of attending and fully adhering to the National DPP. |
| PO4. Clinic administration provides continues guidance and training for current and new staff on completing referrals. | PA4. Describes resources and the importance for continuing provider about the DPP. | OE4. Expects that prioritizing continuing education will help current and new providers stay up to date with referral protocols for identifying and refer patients to the National DPP. | FR4. Expresses that continuing training is important to keep up with guidelines and help new staff gain the knowledge needed to make referrals. | IR4. Recognizes the importance of continuing education to maintain the referral numbers/process when new staff are hired. |

The partnering program established a virtual meeting, assigned participants to 15-min time slots, and provided guidance to the team on what aspects of the program were critical to communicate to participants. The clinic's program champion, the program's lifestyle change coaches, and the UTHealth team facilitated Session 0 by introducing participants to the National DPP, connecting them to their coach, and answering any questions about the virtual platform (Table 6).

During planning sessions with the clinics, the team identified a need for materials to educate and inform patients and healthcare providers about the National DPP and the importance of program referrals. Collaborating with each clinic, the team developed National DPP referral policies, workflows, flyers and posters. Clinical workflows delineated who did what during the rooming, identification, referral, and follow-up process of patients eligible to the National DPP. Clinical pathways were captured during one-on-one TA calls with the clinic's EHR specialist and a step-by-step document of the EHR referral process was shared with the clinic staff to orient providers making referrals using the clinics EHR. The flyers and posters were displayed on the clinics' websites and within the clinics' waiting and exam rooms. Flyers for providers included messaging about National DPP eligibility criteria and the selected National DPP provider(s) that had partnered with the clinic. In contrast to provider flyers, patient flyers provided an overview of the program and prompted them to speak with their health care provider about the program. While creating these

materials, the team focused on integrating messaging that would address the change objectives in the matrices. For instance, an infographic was developed for clinic staff to use and post on their intranet that prompted providers to ask, "Are your patients at risk for diabetes?" and then prompted them to act with the call to action, "Refer patients at risk of diabetes to the National DPP to reduce their risk of developing type 2 diabetes." Which was reinforced with the eligibility criteria of the program and a description of the benefits provided by the program. All of these developed protocol documents and materials were co-created and clinic staff provided the final review and approval prior to implementation.

Task 5: Evaluate implementation outcomes

Evaluation is ongoing and future manuscripts will report National DPP referrals made, adoption outcomes, and implementation outcomes.

Discussion

Successful integration of the National DPP into the U.S. healthcare system is critically needed to counter the rapidly rising incidence of diabetes nationwide. By utilizing the Implementation Mapping planning framework, our coalition of primary care clinics and National DPP providers implement strategies to implement diabetes prevention guidelines and the National DPP with the intent of

TABLE 6 Example determinants, theoretical methods, and implementation strategies.

| Implementation outcome: Health care provider makes referrals of patients with prediabetes to the National DPP. | | |
|--|---|--|
| Determinants | Methods (Theory) | Implementation strategies |
| Perception and awareness Outcome expectations | Modeling (Social cognitive theory; diffusion of innovations theory) Framing (Protection motivation theory) Tailoring (communication-persuasion matrix) Discussion (elaboration likelihood model) Goal-setting (Goal-setting theory) Feedback (Theories of learning; social cognitive theory). Guided practice (Social cognitive theory) | Develop and distribute tailored materials Educational materials include salient, gain-framed messages highlighted: <ul style="list-style-type: none">National DPP eligibility criteria and policies.EHR referral pathways Models of clinics implementing National DPP highlighted: <ul style="list-style-type: none">National DPP providers discussing the importance of submitting patient referrals.How other clinics prioritize National DPP referrals and integrate the process in their current workflows.Testimonials from health care provider about the impact of the National DPP.Thank you notes to providers including a message of support for their referral's effort and the number of referrals made each quarter. Training materials included: <ul style="list-style-type: none">Walkthrough presentations and handouts illustrate proper identification of patients to promote diabetes prevention and referral submission Reminder materials included: <ul style="list-style-type: none">Flyer with diabetes risk factors, eligibility criteria, and program details. The flyers also included the National DPPs contact information and a message about the National DPP benefits from a participant's point of view and a gain-framed message ("Refer patients at risk of diabetes to the National DPP to reduce their risk of developing type 2 diabetes"). Monthly meetings between the clinic staff (e.g., leadership, administration, and program champion), National DPP and the UTHealth team to share knowledge and relay clinical data to providers. Presentations and discussions to: <ul style="list-style-type: none">Describe how to conduct referrals, including the use of decision support tools and benefits on patient outcomes.Discuss clinics' diabetes prevention efforts, number of referrals made.Review patient records and referral numbers to identify opportunities for improvement. Provider-to-provider mentoring Meetings to give feedback on the progress of the providers' goals and referrals. |
| Interorganizational relationships | Discussion (Elaboration likelihood model) Participatory problem solving (Organizational development theories; social capital theory; models of community organization). Enhancing network linkages (Social networks and social support theory) | Monthly meetings included the National DPP, the clinic staff (e.g., leadership, administration, and program champion), and the UTHealth Team. Regular interaction between the National DPP, the clinic staff (e.g., leadership, administration, and program champion), and the UTHealth Team facilitated: <ul style="list-style-type: none">Rapport and linkage building between teams.Troubleshooting as adoption or implementation barriers occurred. Change clinic records systems to include EHR-based referral system between clinics and partner National DPP. Updates/changes made to the clinics and National DPP EHR included: <ul style="list-style-type: none">Connecting the health center EHR and the National DPP into the same network.Establishing direct messaging between the clinic and the National DPP to facilitate the referral process.Integrating lab results into the clinics EHR. Promote network weaving by partnering the clinic with local food bank. Facilitate integration of food bank services with the National DPP and clinics. |
| Feedback and reinforcement | Technical Assistance (TA) (Organizational development theories; diffusion of innovations theory; social capital theory; models of community organization) | Centralized monthly technical assistance meetings with the National DPP, the clinic staff (e.g., leadership, administration, and program champion), and the UTHealth team. Monthly meetings included: <ul style="list-style-type: none">Training on how to use EHR-based referral system, benefits of using CDS to facilitate referralsSupport and troubleshooting for EHR-based referral systemAssistance with EHR/CDS optimization and workflowsDiscussions about the importance of reviewing and interpreting data trends on a continuous basis. |

This table shows a sample of the methods and practical applications for environmental outcomes for clinics.

CDS, clinical decision support; EHR, Electronic Health Records; National DPP, National Diabetes Prevention Program; TA, Technical Assistance.

improving the identification of people with prediabetes and refer them to CDC-recognized lifestyle change programs for Type 2 diabetes prevention.

Through systematic planning using Implementation Mapping, we designed implementation strategies to address barriers, build capacity, and create systems to foster the adoption and

implementation (10–12). We chose evidence- and theory-based methods and practical applications to improve acceptance and uptake of the implementation.

In the present project, Implementation Mapping proved to be a useful, systematic approach for identifying POs centered around the multiple actor-specific tasks required to ensure proper integration of the National DPP into the four clinics' workflows. The Implementation Mapping framework helped us map practical applications to address determinants needed to achieve the POs needed to promote and identify local National DPP providers, promote the program's value to clinic patients and providers, and optimize EHR capabilities to effectively communicate referrals between clinics and National DPP providers.

Strengths and limitations

An important strength of this project was the experience and background of a collaborative transdisciplinary team including engaged partners. Team members included those experienced in using Implementation Mapping to scale preventive health programs, and others skilled in providing technical assistance on EHRs and referral pathways for clinical use. This rich history of collaboration and capabilities were instrumental in building rapport and trust with the four participating clinics, and in facilitating culturally appropriate support and materials that were individualized for each of the clinics.

A limitation of the project was the design of the needs assessment. The original survey and interviews did not ask about the clinics' level of readiness nor their capacity to adopt and implement the referral procedures that are necessary to refer patients to National DPP providers. The focus of the project was implementation and promotion of the National DPP referrals. However, gaps in knowledge of the readiness and capacity of the clinics likely impeded some of the actions that could be taken during the Implementation Mapping process (22). As a result, the UTHealth team suggested examining inner setting factors that impact the sustainability of the National DPP and future studies.

Conclusion

Diabetes is among the most prevalent chronic diseases in the U.S. This condition has devastating impacts on the quality of life of patients, with these negative consequences ranging from premature death and coexisting morbidity from complications to loss of work productivity and high health care costs (15, 23, 24). Yet, identifying individuals who are at risk for diabetes (i.e., people with prediabetes and/or a history of gestational diabetes) and helping them lower this risk have not been priorities for many health systems, even though evidence-based programs like the National DPP are available to patients and are now reimbursable under Medicare and several state Medicaid plans (24). Emerging research on program implementation suggests that patient and health care providers limited knowledge of the National DPP, along with the difficulties in maintaining patient attendance, and the sustainability of referrals process to the National DPP have been barriers to the wider use of this program (12). The implementation strategies developed helped clinics overcome barriers by educating providers about the National DPP and its benefits on diabetes prevention, promoting patient education, and facilitating the use of EHRs (12).

Enrollment is just the first step in this process, and adherence is also critical. There is a need for studies that explore how to increase adherence and how implementation could include use of incentives. For example, the UTHealth team is currently piloting an intervention that includes participation incentives to better understand its effect on patient adherence to promote National DPP attendance (12). The program demonstrated how Implementation Mapping can be used to help clinics and National DPP providers overcome implementation barriers. In the long term, healthcare leaders can use experiences of programs such as these to expand and help improve the quality of National DPP delivery and to increase its access for patients who are at high risk of developing diabetes.

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 authors.

Ethics statement

The studies involving human participants were reviewed and approved by the Committee for the Protection of Human Subject University of Texas Health Science Center. The ethics committee waived the requirement of written informed consent for participation.

Author contributions

WP directed research directly and helped study design and wrote manuscript. PM and FV-H project manager, wrote the manuscript, and reviewed extensively. CP project manager, wrote the manuscript, and reviewed. SB worked in project, wrote manuscript, and reviewed. NH designed the project, reviewed implementation mapping process, wrote the manuscript, and reviewed. SR reviewed implementation mapping manuscript. PF worked in project and reviewed. BR and JM reviewed manuscript. RC oversaw project and reviewed. MF and PI were responsible project and wrote and reviewed manuscript. GW a reviewer of the manuscript requested an extensive reorganization of the methods and discussion section of the manuscript. I played a key role in this organization process making the manuscript which included rewriting parts, adding additional literature citations and adding new dimensions to the discussion. All authors contributed to the article and approved the submitted version.

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