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Edited by
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Women in health services: Implementation science 2021

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ORIGINAL RESEARCH
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A Family-Centered Intervention to Monitor Children's Development in a Pediatric Outpatient Setting: Design and Feasibility Testing

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The patient experience team at a private tertiary care hospital used the Theory of Change to design a family-centered developmental monitoring intervention, building on an ongoing initiative. The design entailed (i) a monitoring form: Survey of Well-Being of Young Children (SWYC) being an easy parent-report measure; (ii) family support intervention: the Care for Child Development module to enhance parent-child interactions; (iii) timing: utilizing wait time to also enhance families' experience; (iv) the service providers: psychology trainees as volunteers; and (v) reinforcement: by the pediatrician in the regular consultation health visit capitalizing on the established rapport with families. All families with children under 5 years 5 months 31 days of age in selected acute, complex, and developmental care clinics were eligible. Feedback from stakeholders indicated that the monitoring process was useful and imparted important information for parents and pediatricians, while the trainees felt the experience to be significant for their own learning. The authors conclude that the designed intervention model for a family-centric approach was acceptable and feasible. Key recommendations have been presented for further scale-up.

Keywords: Care for Child Development, developmental monitoring, family-centered support, nurturing care, Survey of Well-Being of Young Children

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Early identification of children at risk of sub-optimal development or delay and subsequent interventions can lead to improved developmental outcomes (1). Hence, developmental monitoring at different times in a child's life (to be completed at least at 9, 18, and 30 months of age during a child's critical developmental period) for adequate referral is considered an integral practice in high-income settings, such as the USA (2). Despite a high burden in low- and middle-income countries (LMICs) with more than 250 million children not meeting their potential (3) and 1 in 6 of these children experiencing developmental difficulty (4), integrated developmental monitoring with appropriate referral is not a priority of the healthcare system as it requires continued efforts and engagement on the part of both the health care provider and the families (5–7). When available, screening is seldom followed by accessible evidence-based interventions. This was identified in a technical meeting by the World Health Organization (WHO) where the experts recommended broadening the scope of developmental monitoring to also include family-centered participatory support interventions ensuring nurturing care for all (4). Examples of family-centered interventions include the nurturing care interventions which aim to enable families to create an environment that meets the needs of young children i.e., nutrition and health, freedom from threats, and opportunities for early learning, through emotionally warm interactions (8). The experts have argued that these guidelines will support promotion of early development, acting as a preventive strategy for future developmental difficulties which is critical given the scale of the problem. The guidelines place the primary care providers in a unique position to promote children's development given their relationship with the family and being aware of the specific strengths built on regular contacts which can support children's development (9).

Sustainable integration of nurturing care into primary healthcare at scale requires partnerships not just between family and providers or between different providers but also broadly within and across sectors like public, private, and civil society (10, 11). Private healthcare providers are an important partner to tap into, especially in contexts where they are the major contributors. In Pakistan, the private sector covers up to 75% of the population's healthcare (12, 13) and only 2.8% of the country's budget is annually invested in healthcare, which is globally one of the lowest (14).

Pakistan has a substantial burden of children at risk for not attaining their developmental potential with high rates of maternal mortality (140/100,000), under-five mortality (69/1,000) and stunting (38%) (15). Moreover, no national data on provision of nurturing care practices at home for children under 3 years of age are available. Evidence suggests a loss of 20% in adult productivity if the risk is not mitigated through timely interventions (16). Similarly, epidemiological data related to childhood disability from Pakistan are limited but a few studies suggest physical disability to be its leading cause (17). Barriers such as social stigma and cultural norms, inadequate health infrastructure, and shortage of qualified professionals in early child development (ECD) prevent parents from seeking appropriate timely support for their differently abled child (17). There were reportedly only 54 qualified rehabilitation professionals in the country in 2016 (18). Children with disabilities face additional challenges and are denied admission to schools and parents may be advised to take their children to special schools (19).

The majority of the ECD and disability research and programmatic work in Pakistan is community-based in the public sector with scarce evidence of collaboration from the private health sector. A study with private outpatient clinics with mothers of young children found that counseling focused on promoting development were more engaging and helpful than the usual/standard care provided by pediatric consultants (20). However, the program was funded through a research grant, and scale-up of the innovation will likely remain dependent on philanthropy for further implementation. Given the financial adversity currently in the country, it is not a sustainable option. Long-run integration of family support practices within pediatric care to transform the development of millions of children requires context-specific and cost-effective approaches similar to social innovations taking into account not just technical feasibility but also market sustainability and economic viability of the population and the healthcare providers to ensure uptake (21). The nurturing care operational framework also recommends partnership with the private sector as one of the strategies to innovate and scale-up (22).

Examples of social innovations from similar contexts like India operate on these principles for a successful scale-up: designing interventions emphasizing a value for more rather than a perfectly designed model serving a few, utilizing and strengthening existing systems for reduced costs, and ensuring respect and experience of the families served (23). Additionally, literature from implementation sciences strongly suggests the use of a robust framework like Theory of Change (ToC) to design complex behavior change interventions involving multiple touch points and actors (24). The ToC methodology outlines how the intervention will work in real settings, describing the processes through which the change will happen and the assumptions inherent but specific to the context (25). World Health Organization (4) recommendations for a family-centered approach to developmental monitoring will require further guidelines on operationalization in primary care. Use of ToC to implement these guidelines following the principles of social innovation has not been tested yet.

Implementation of family-centered interventions requires additional effort to create a culture of family-centeredness in healthcare settings for sustainable behavior change (26). An ongoing initiative in the pediatric services at a tertiary hospital aiming to improve child and family experience outcomes with a focus on inpatient care (27) provided an excellent opportunity to test a model of family-centered developmental monitoring. The objective of this study was to develop and test the feasibility of integrating a family-centered developmental monitoring intervention as part of a larger initiative in a private pediatric care setting in Pakistan.

METHODS

Setting

The study was conducted at a tertiary care teaching hospital and Joint Commission International-accredited hospital (JCIA) in Pakistan. Annually about 75,000 patients visit the pediatric outpatients' clinics. Major child specialties include but are not limited to: cardiopulmonary, neurology and rehabilitation, gastroenterology, endocrinology, nephrology, genetics, fetal and neonatal problems, and infectious diseases. Well-baby clinics are conducted, but developmental monitoring is yet to be established in the system. Rehabilitation services are available for children with needs under the section of neurology. A physician was under training in Canada for developmental pediatrics (the first in the hospital) during the course of the study to join as faculty in the coming year. The fee structure is comparable to other private tertiary health centers within the city. Since it is a private elite setting, relatively affluent families seek consultation. Data from previous work indicate about half of the mothers' accessing pediatric services have completed 10 years of education or more (28). Patients are primarily from the city and surrounding urban and rural areas within the province of Sindh. The physicians mostly communicate in the clinic in Urdu (the national language of the country). However, a significant majority of the families can also converse in English given it is the main administration language in the country and hence also used for hospital documentation. The implementation of the World Health Organization Global Disability Action Plan in Pakistan (GDAP) requires engagement of healthcare professionals and public-private institutional partnerships in order to provide appropriate awareness and rehabilitative access to patients and parents with ECD needs (29). The study was approved as a quality improvement project by the institutional Ethics Review Committee.

Workflow

In the outpatient clinics, patients book their appointments online or by calling the hospital helpline. Patients are expected to arrive and register and pay the consultation fee 20 min prior to the appointment time. Next, the child/parents are then called into the assessment room where a nurse records, in the patient file, the child's height, weight, temperature, blood pressure, risk of fall, known allergies, and any prescribed medications. The patient file is shifted to the file tray outside the physician's consulting room and parents/families are then requested to sit in the waiting area until they are called to meet with the consultant. Average time spent in the clinic from start to finish ranges from 75 to 120 min. Waiting time varies between physicians, ranging from 40 to 80 min which is an opportunity to engage patients in an educational activity. No toys, play equipment, or books are currently available in the waiting area for children and their parents to utilize during long waiting times. One physician on average may see up to 112 patients per month (ranging from 55 to 235 patients monthly per physician, depending on specialty).

Research Design

This feasibility study (30) was conducted as a quality improvement project (31) in the pediatric service line at the hospital for improved patient and family experience of care. The primary considerations of feasibility were physical space/design, human and material resources, and physician follow-up with patients identified to be at developmental risk.

Sample

The inclusion criteria comprised all the children (patients) who visited the 10 selected physicians in the outpatient department (OPD), with an age range of 1 month, 0 days to 65 months, 31 days. The physicians were selected to cover a broad range of disease: acute care (6 out of 18 general pediatricians), complex care (3 of 6 pediatric cardiologists), and developmental care (1 of 2 specialists). Prior permission from physicians was sought to complete developmental screening with their patients. Permission was obtained from the physicians and the psychologist to conduct research with their patients. The parents of the patients were briefed about the purpose of the survey and verbal consent was obtained before being interviewed.

Intervention Design

The implementation opportunity was identified by an ECD researcher, practicing as a developmental psychologist and also serving as the Director Patient Experience of Care in the service line (first author). The study was conducted between August 2019 and February 2020 as part of the larger initiative in place since October 2017 allowing the focus to shift to family and patient experience in the outpatient department. The intervention model was designed using the ToC guided by the following principles: ensure value addition for all stakeholders, leverage existing strengths, and keep it simple and cost-effective yet comfortable while being grounded in science at the same time. We used a backward mapping approach with a main focus on also intervening for the assumptions we were making as part of the strategy as recommended by Mayne (32), e.g., it required physician engagement which meant leadership buy-in and support. Hence, we started this service, once the larger initiative was fairly established. Moreover, we needed engaged delivery staff with minimal financial implications. Based on our previous experience, psychology trainees were selected, and we had a memorandum of understanding with the University to credit the trainees with internship hours. The ToC was developed after thoughtful considerations by the patient experience team about how the intervention would work in the context. It was realized that the intervention had to be framed to also benefit family experience to gain leadership buy-in as developmental disabilities may not be a priority in a system burdened with physical diseases. Hence, it was housed in the Office of Patient Experience. The context for assumptions around different intervention components was analyzed based on the observations and experience of the team members which included the Director Patient Experience of Care (first author) and the Service Line Chief (last author) (**Figure 1**).

Developmental Monitoring Tool

Given the intervention was meant to enhance the parental role in children's development, it was important to ensure any child who could potentially benefit from just a conversation with the family was not missed. A tool was needed that was feasible to be completed by parents and for subsequent use by primary care providers. The Survey of Well-being of Young Children (SWYC) is a freely available, first level developmental-behavioral screening tool developed by researchers at The Floating Hospital for children under 65 months, 31 days of age at Tufts Medical Center (33). The form is simple, provides a holistic screening across developmental domains, emotional & behavioral adjustment, and also environmental factors emphasizing the role of the context. The SWYC has age-specific forms with a total of 12 different forms for 12 age groups.

The Family Support Intervention

The psychosocial support intervention was based on principles of the *Care for Child Development* (CCD) module (34). The module includes messages to enhance nurturing parent-child interactions using developmentally appropriate play activities. The addition of this intervention was meant to shift the focus from a deficit model to nurturing the strengths of the

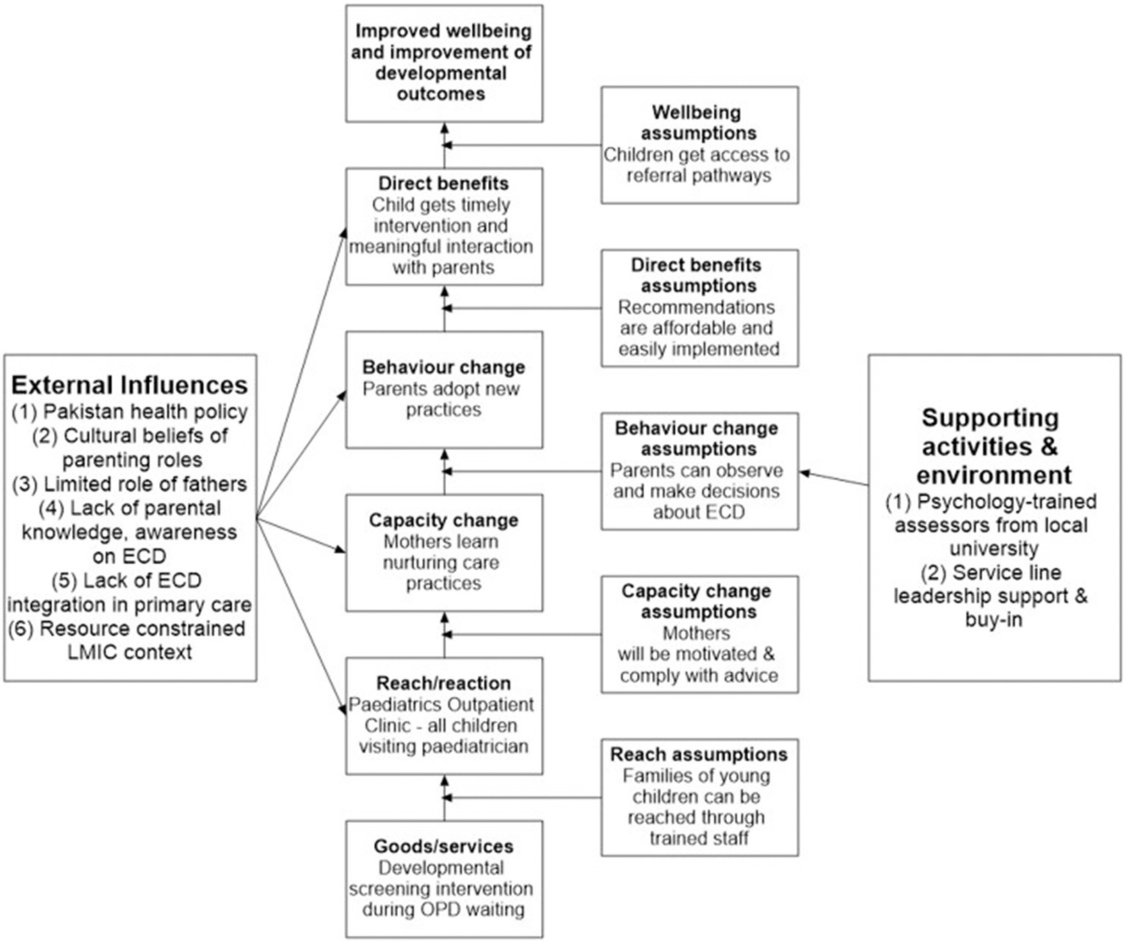

FIGURE 1 | Theory of change model for integration of family-centered developmental monitoring. ECD, early child development; LMIC, low-and middle-income countries; OPD, outpatient department.

families, enabling them to provide early learning and stimulation opportunities to their child. All families can positively contribute toward the development of their child and may just need minimum coaching. The first author is a certified trainer for implementing the CCD module and has successfully used it as an intervention for in-patient children and families in collaboration with psychology trainees as the delivery staff (28).

Timing for Administering the Developmental Monitoring Form

Pediatrician clinics are busy and adding on monitoring forms may be seen as a burden affecting engagement with the intervention. However, an opportunity of utilizing the long wait between clinical assessment and the appointment was identified—which was a major main pain point for families (35). When wait time cannot be reduced, some hospitals have utilized these times to encourage play (36) and reading (37) through volunteers for families of young children for a productive use of time. A study in Jamaica in the waiting area in primary care implemented a video-based ECD intervention led by community health workers. The results showed benefits for parental knowledge and child development when compared to controls (38). Moreover, utilizing the wait time, the family experience of an otherwise cumbersome wait, can improve significantly. Patient and family experience is increasingly being recognized specifically within the private sector as a key strategy for enhancing patient satisfaction with the services resulting in buy-in from hospital leadership in patient experience strategies (39).

Delivery Staff

The country has a handful of developmental pediatricians (40) with few training opportunities in residency programs (41) suggesting the urgency of initiating intervention models with opportunities to iteratively refine during implementation. The limited supply of professionals qualified in ECD is reflective of the low demand from parents of young children to monitor development. Such non-medical services are not usually valued enough for families to pay additionally for them. Moreover, such a service would be seen as burdensome by most families resulting in low uptake if initiated in silo (42). Developmental screening though important is not done routinely as not enough demand has been created. Hence, it is not seen as valuable by patients and physicians who do not see it generating revenue which is a crucial aspect for the survival of the services especially in a private center (43). Making this part of the regular clinic would mean identifying an additional cadre of care providers but without major financial investment. The cadre identified was psychology trainees from a local university who had a memorandum of understanding (MOU) with the service line. The trainee-led model was successfully implemented in the inpatient care facility whereby they received credit for internship hours spent at the hospital and were supervised which was an added incentive (28). A similar model would give the pediatrician additional, important information that adds value to that regular clinic visit for health issues at no cost to the practice. The developmental monitoring and support could be henceforth feasibly integrated by the pediatrician within their routine consultation services. The recommendations for follow-up for parents when reinforced by the pediatrician who are seen to be more trustworthy by families could enhance families' trust in the process (44). This would also allow pediatricians to assess the effect of child health issues on their functioning. Thus, creating value around child development may increase engagement and parental ownership.

Intervention Procedure

The final delivery model included: (1) completing the developmental monitoring form (SWYC) and support recommendation (CCD), (2) during wait time, (3) by the psychology trainees, (4) followed by integration in the routine pediatrician follow-up, capitalizing on the rapport and relationship between parent and physician while leveraging the on-going patient and family-centric initiative in the service line (**Table 1**).

The developmental monitoring and support component was administered by a team of four: two research associates (psychology graduates) with significant experience with assessment of children with developmental disabilities and two psychology student trainees. Each student trainee was paired with an associate for quality assurance, and also supervised experience contributed toward their learning. As part of the procedure, the family was guided to see the trainee once the clinical assessment was completed by the nursing staff. The SWYC was completed during the wait time. Language (either English or Urdu) was chosen based on the family's preference, and trainees asked parents if they would like to fill the survey themselves or with the support of the trainee as an interviewer reading out the questions and tracking their responses for the parents. The raw scores on SWYC were calculated for a developmental milestones checklist covering cognitive, motor & language domains, emotional & behavioral symptom items, and family stress. The scores were then classified as "Appears to be meeting expectations" or "Needs review" based on the SWYC guidelines. This description was entered on a summary form attached to the patient file to be seen by the pediatrician. The follow-up reinforcement by the pediatricians was integrated as part of the routine consultation. Based on the SWYC summary form, they provided advice and recommended a referral if needed as reflected in the informal conversations with the nursing team assisting the physician. The physicians would usually sign a referral form or verbally inform the consultant they referred the child to which could either be a psychologist or a neurologist based on the nature of the issue. About 15% of the forms were re-evaluated by the first author with the families. Feedback was thereafter given to the trainees for any clarification or elaboration.

Data Collection

Data from the parents were collected through a feedback form administered by the psychology trainees once the SWYC was completed. The parental feedback form comprised six questions, of which two were open-ended ("How did you feel before filling the form and after completing the [monitoring] session?" and "What did you like best about this mini-session?") and four close-ended questions ("Do you think understanding your child's developmental progress and emotional needs is required?," "Would you like to discuss the results of this form with your child's pediatrician?," "Would you like further information on ways to stimulate your child, such as a brochure with guidelines for activities for various age groups?," and "Have you ever visited a neurologist or psychologist before?" We could approach only the first 60 families for feedback. We could not continue due to logistic concerns in the waiting area and trade-off between collecting data on the developmental milestones and the feedback on the process. The former was deemed more important to make a case for integrating the service.

The psychology team members were asked to share their reflections as a qualitative written narrative shedding light on their experiences, perceived benefits to families, the physician response, and specific barriers and enablers to implementation or continuation of the service once the study ended. Physician feedback was obtained *via* email in response to findings shared with them about the developmental status of their patient population part of the study. The email was shared at two time points in the study: when one third of the sample was complete and when the study sample was completed. The data collection continued until the patient and family-centric initiative was in place.

Data Analysis

The responses on the SWYC were scored based on the cut-off available with the form. Data were entered into an excel sheet by the trainees and were shared on a weekly basis with the first author. Frequency and percentages were calculated for children indicated at risk for further review by the pediatrician. Ongoing and overall trends were monitored as a team along with discussion of any challenges. The Bowen et al. (45) framework which describes the common focus areas of feasibility studies was used to evaluate the study across two areas: acceptability (How attractive, suitable, or satisfying was the intervention?) and implementation (How well was the study implemented as planned?). Data were analyzed in SPSS V22.0 for cross-sectional descriptive statistics. Qualitative feedback from parental experience and physicians and trainee reflections were analyzed using thematic analysis for an understanding of their experience

TABLE 1 | Outcomes, assumptions, need assessment, and interventions of the theory of change model.

Domain	Outcome	Assumptions	Needs assessment	Intervention
Reach & reaction: Will the intervention delivered reach the intended target groups with the right reaction?	Eligible children are reached.	Families of young children can be reached through trained staff. There is a demand for monitoring services to promote children's development. Families and pediatricians will accept the intervention.	Pediatricians do not have enough time in the clinic for developmental monitoring form administration. However, if the initial assessment is supported by another cadre, pediatricians can guide the families. The additional cadre needs to have time and relevant experience but cannot burden the existing staff. The country has a handful of developmental pediatricians with limited training opportunities in residency programs. The limited supply of professionals qualified in ECD is reflective of the low demand from parents of young children to monitor development. Hence, service in silos for developmental advice will not result in significant uptake. The pediatricians would not be invested in spending additional time or training effort on developmental consultation without due reimbursement. There has been significant value creation for psychosocial needs during the "*The Patient and Family-Centric Initiative*" for buy-in from physicians. Psychology clinic experience indicates families welcome discussion of emotional behavior problems and greater acceptance when reinforced by the pediatrician.	Partner with a psychology university and use psychology trainees. Provide training and clinical supervision. A form which provides greater false positives is preferable as no potential child and family in need is missed for a conversation about promotion of nurturing care. Utilize wait time for monitoring which is already a pain for the families. When wait times cannot be reduced, opportunities of utilizing it meaningfully to add value to overall experience can engage families. The service has to be free of cost to begin with. Personnel costs for psychology trainees can be reduced through training, clinical supervision, and credit for internship hours to administer the form. However, it has to be reinforced by the pediatrician capitalizing the trust and relationship. For the pediatricians it will be value added as they provide additional messaging on the health functioning of the patient within the same fee. Leverage the already in place "*The Patient and Family-Centric Initiative*" which values nurturing experiences as one of the core processes of care. Moreover, it is also now being recognized in the system that ECD is a long-term health outcome.
Capacity change: Will the intervention delivery and reach lead to the intended capacity changes?	Mothers acquire new capacity about nurturing care practices.	The advice will be understood and mothers will comply. Mothers have the capability to seek new knowledge. Mothers are motivated to improve the development of children.	Approach has to be simple with focus on milestones and also the environment. Pediatricians at AKUH are trusted as it is considered an elite hospital in the city. Families are generally from the middle class and educated. Schools heavily emphasize cognitive skills for entry which is a factor that can be heavily leveraged for engagement.	Use a simple checklist created for monitoring in the OPD with a focus on the role of the environment. This can help the parents reflect on their role in children's development. Reinforcement from the pediatrician is needed with focus on long-term achievement in school. This can help the parents reflect on their role in children's development.
Behavior change: Will the capacity change lead to the intended behavior changes?	Parents, specifically mothers, adopt new practices.	Mothers can make decisions about their child. Parents can observe improvement in child's development.	Generally, fathers have a greater role in decision-making. Generally, parents lack knowledge of developmental milestones.	Pediatricians reinforce both parents for uptake. Psychology trainees can provide guidance to parents for relevant websites or other sources for monitoring their children's development.
Direct benefits: Will the behavior changes lead to the intended direct benefits?	Children have greater opportunities to engage in play activities and interact meaningfully with parents.	Recommendations are mutually enjoyable and easy to implement. Families can afford play materials.	General parenting style is authoritative and less focused on nurturing interactions. Families come from the middle class and generally have access to toys and gadgets.	The recommendation should be based on enhancing interactions between the parent and child which can be inherently rewarding. Guide parents to sensible use of toys but also gadgets—which have become a part of families' lives.
Development changes: Will the direct benefits lead to the intended well-being changes?	Child's developmental outcomes improve.	Children have access to healthcare. Appropriate referral pathways exist for children in greater need.	Well-baby clinic visit does not include developmental monitoring as part of the core messages.	Reinforce completing scheduled well-baby visits. Include monitoring in every visit. Establish liaison with the developmental pediatrics department.

AKUH, Aga Khan University Hospital; OPD, outpatient department.

TABLE 2 | Children identified for further review and referral.

Developmental domain from SWYC	Identified for further review and referral-N (%)			
	Complex care ***N* = 24**	**Acute care** ***N* = 129**	**Developmental care** ***N* = 29**	**Total** ***N* = 182**
Cognitive, motor, and language milestones	10 (42)	64 (50)	24 (83)	98 (54)
Emotional and behavioral symptoms	13 (54)	89 (69)	23 (79)	138 (76)
Family questions	9 (38)	22 (17)	18 (62)	49 (27)

from their respective perspective to inform scalability and hence scalability of the initiative. The analysis team included the ECD researcher (also Director Patient Experience of Care) and a developmental psychologist—who was independent of implementation to reduce bias. An inductive approach was employed for analyses following the standard procedures (46). The responses were coded independently by two team members for the qualitative data and then finalized in an agreement meeting. The codes were then broadly reduced under two aspects of feasibility, (i) acceptability defined as the extent to which the stakeholders perceived developmental monitoring and support to be attractive, suitable, and satisfying and (ii) implementation defined as how well the intervention could be implemented as planned within the available resources and what barriers and facilitators were identified.

RESULTS

A total of 182 families with 67 girls and 115 boys participated in the study. About 70% of families preferred administration in English. Additionally, 30% preferred to fill the form in themselves, and 70% asked the trainee to conduct the interview. The results indicate that 54% were detected as at risk on cognitive, physical, and language milestones and 76% were found at risk on emotional and behavioral symptoms requiring further advice about nurturing care and also referral (**Table 2**). Moreover, the trends indicated a greater number of positives in the developmental clinic as expected.

Acceptability

Feedback to inform acceptability was collected from 49 of the total 60 families approached. Though interviews were intended for all, they could not always be conducted due to unavailability of families at times, e.g., if they were called in for the consultation. Parental feedback data from the 49 families indicated that 86% ($N = 42$) of parents felt understanding their child's developmental progress and emotional needs was important, 78% ($N = 38$) wanted to discuss the results of the form further with the pediatrician (3 parents said the decision to follow-up on the screening was at the pediatrician's discretion), and 73% ($N = 36$) of parents wanted further information in the form of a booklet for stimulation activities to conduct with their child, and only 1 had been to a pediatric neurologist or psychologist prior to the pediatric appointment.

Table 3 summarizes qualitative data from parents' feedback regarding acceptability across different domains: the content of monitoring items, overall feedback on the process, and the trainee. Most parents regarded the monitoring session as a "*good initiative*" as it helped them understand the significance of their role in their child's development and an increased awareness about developmental milestones and emotional needs in general. One of the families said "*I was surprised to know that emotions of parents play a major role in the child's life*" while another appreciated the session saying *"In the beginning we thought the questions would be irrelevant, but in the end we realized that these are important questions that will help the child in the future."* A family shared their interest in having more of these sessions: *"It was relatable, I would like more of such sessions."* A few parents enjoyed thinking about and answering family risk-related questions: *"[I appreciated] the personal family questions."* Two parents also reported that completing the form made them feel the hospital was concerned about their child's health and well-being.

The patient experience team shared data about the families' responses on the SWYC and the number of children screened at risk with the pediatricians for their reflections. Two pediatricians formally responded with comments about their patients' outcomes and parental satisfaction. One physician (complex care physician) was interested in further exploring why 50% of his screened patient population was found to be at risk for delayed milestones, with 61% at risk of developing neurotic symptoms and 75% at risk for either reason. His response to this information was "*75% is a huge number, why do you think that is the case? Is it a selection bias - these kids are sick with chronic diseases and that is why they are at risk? Is there any correlation with complexity of disease and risk? Maybe an analysis of that will be insightful.*" Another physician (acute care specialist) reported, "*I am happy to assist. You can continue with my outpatient and inpatient [patient population]. This is excellent and amazing data. I would suggest continuing this.*" The developmental psychologist felt it was helpful to have the parents complete a form before the consultation saying "*It sets the tone, and the conversation becomes easier in the clinic. Moreover, having some sort of screening makes the parents feel it is an objective assessment compared to just clinical observations. It also saves time.*" When asked about the role of trainees, her view was that it can be a great way of exposing trainees to the field of ECD: "*There is no formal teaching in place for developmental problems in young children. Having trainees and supervising them can be a way of hands-on training and exposing them at the right time when they are about to begin their careers.*" A similar view was shared by one of the trainees, *"This service should have trainees because it's a win-win situation for both sides* *as trainees need experience and obviously, they will learn a lot, and this service can't be handled by one person only, so having trainees is a sustainable idea. It's like, the more the merrier because more trainees, more surveys done in less time and accurate results"* (Trainee 2).

TABLE 3 | Parental qualitative feedback regarding the screening process.

Content of the monitoring form

[I liked] the questions related to the spouse/partner (F5, 4 months, GP).
[I liked] the questions related to the spouse/partner (F12, 13 months, GP).
[I liked] the questions related to the spouse/partner (F21, 2 months, Cardio).
[I appreciated] the personal family questions (F43, 35 months, Cardio).
[I appreciated] questions about the child's sleeping habits (F15, 6 months, GP).
[I appreciated] questions that asked whether the child is involved in fights (F59, 60 months, GP).
…it was good you asked about the relationship of parents with the child (F3, 32 months, GP).
I was surprised to know that emotions of parents play a major role in the child's life (F24, 8 months, GP).
I think I gained new information from the questions (F1, 19 months, GP).
I liked the questions related to emotional changes with a new baby (F17, 16 months, Cardio).
I liked the questions related to emotional changes with a new baby (F20, 2 months, GP).
[The questions] helped me recall important things about my child (F9, 13 months, GP).
[The questions] helped me recall past memories about my child. (F31, 12 months, GP).
The questionnaire is very comprehensive (F2, 2 months, GP).
The questionnaire highlighted important points that usually parents would ignore (F25, 61 months, GP).
I didn't know these questions were real issues (F35, 7 months, GP).
In the beginning we thought the questions would be irrelevant, but in the end, we realized that these are important questions that will help the child in the future (F59, 60 months, GP).
The conversation highlighted important points [about our children] that we usually ignore (F25, 61 months, GP).

The monitoring process (during the waiting period)

It was relatable, I would like more of such sessions (F4, 11 months, GP).
It was good. There should be more activities like this one (F34, 60 months, GP).
You concluded and connected the behavior of the child with the parents (F3, 32 months, GP).
You connected my current situation with my wife and children, I really appreciate that (F38, 7 months, Cardio).
This would help a parent whose child is suffering (F8, 14 months, GP).
So many things are cleared up that we were stressed out about (F52, 4 months, GP).
The hospital is very interested in the development and mental health of a child. It was good, laughed a lot, made us feel good (F39, 53 months, Cardio).
[It seems] the hospital is concerned about us (F51, 49 months, GP).
This was something new related to children (F40, 60 months, GP).
Very useful, would want to continue such sessions in the future (F3, 32 months, GP).
We felt like we know our children better after this conversation (F54, 30 months, GP).

The trainee

It was really nice talking to you (F38, 7 months, Cardio).
It felt good to talk to you (F57, 10 months, GP).
Your behavior with us was good (F51, 17 months, Cardio).
I'm satisfied after meeting you, it felt good to talk to you (F56, 12 months, GP).

Cardio, Cardiology; F, Family; GP, General Pediatrics.

All four team members including trainees shared their reflections and indicated they found the process helpful for themselves, aiding their counseling skills. One of them said: "*I learnt a lot. Like... different milestones, items regarding autism, at [the] same time to assess parental stress... which help[s] us in parental counseling…*" (Associate 1). Another one shared that interacting with families was something she enjoyed the most: "*One thing I loved the most was the clinical experience. I got to meet and interact with patients directly*" (Trainee 2). A student trainee expressed that the experience had inspired her to pursue a career as a child psychologist: "*I implemented my bookish knowledge in real-life scenarios which made clear that child development is the path I would love to [choose] for my further studies*" (Trainee 1). The student trainees were also provided with an opportunity to present the study findings in a departmental research event which was an additional motivating factor: "*I also got a chance to take part in [the] research poster review. The experience taught me how to present and defend my findings*" (Trainee 1). When student trainees were asked if this project benefited them in anyway, one of the trainees expressed, *"Yes, as a student, I learned the importance of milestones myself. This project made me more conscious about delayed milestones that I often ignored in the children of my friends and family. I also realized that post-partum depression is something in which I should work on in future. I also learned that a healthy bond between the husband and wife is very essential for their child's healthy mind*" (Trainee 1).

The significance for the families was also felt by the trainees: "*A quick screening like OPD screening helps us to guide parents properly, it helps us to refer children to concerned people according to the child's problem*" (Associate 1). Another trainee felt the process was kind of relieving for families: "*Monitoring in the OPD is challenging but it's important. We need to continue with the monitoring. Parents felt better when we spoke to them about their child's behaviors especially those stressed due to the child's illness*" (Associate 2). Another trainee shared similar observations while interacting with the families, *"When families got a friendly person to talk in clinic, they opened up to us easily and most of them talked their heart out which made them feel good*" (Trainee 2).

Implementation

Practical challenges related to constrained resources and clinical referral pathways were identified over the course of the study by the trainees conducting the screening. Firstly, while all staff were cooperative, they were occupied in multiple duties, so occasionally forgot to share information on study-eligible patients with the trainee for SWYC assessment, *"The obstacles I faced. Like, unable to figure out how to find the family that we need[ed] to [interview], so basically the system needs to be changed a bit, so that no parent is missed during the process."* (Trainee 1) as mentioned by one of the trainees as well when asked how this service can improve. Another trainee reported time as a challenge, *"Some of the physicians didn't value what we did so they used to ask us to do our survey after their consultation and others used to give us time to talk to the patients*" (Trainee 2). Secondly, the trainee had to carry 12 versions (relevant to different age groups) of printed SWYC forms and identify the correct form in a limited time period and constrained space, while conversing with waiting parents and children; identifying the correct form based on the child's age was made more difficult by parents giving vague or incorrect answers about the child's precise age. Out of all the methods that were used to assess SWYC with the client's parents, it was found to be most convenient when dedicated space was available, *"The only improvement I think it needs is the time management and I guess a proper room where we can do our survey without any distraction"* (Trainee 2) as reported by one of the trainees. When requested for recommendations two of the trainees felt physician understanding could be improved, *"Physicians need awareness training about developmental and emotional problems. I also think there need[s] to be more developmental psychologists available in the out-patient [clinic] for individual counseling"* (Associate 1). Another student trainee shared similar feedback after interacting with the pediatricians, *"The ones with whom I interacted; they were more than happy to receive the score sheet. There were times when they were amused to see the contrary results. For example, there were [a] couple of times when we shared the results with the doctors, they did not realize that a child's milestones w[as] not fully achieved, or the parents need[ed] counseling, or the mother [wa]s going through post-partum depression. These were some of things which [a] few of the physicians did not notice, but were surprised to see such results. Due to lack of time, doctors were mainly focusing on the problem that the parents brought, rather than observing the parents"* (Trainee 1).

DISCUSSION

The findings from this study indicate that developmental monitoring with support for families was largely acceptable to families and trainees with evidence of preliminary operational feasibility. A greater number of children indicated a need for intervention for the behavior symptoms compared to other developmental domains. Another observation from the data was that of parents whose children were put forward for further review, many were not concerned about their child's milestones and therefore had never consulted any physicians. It could also be due to the fact that mild cases may go unnoticed by parents and also by physicians (47). A similar observation from Pakistan has been highlighted by Mushtaq and Rehman (48). These findings have implications for early intervention and support for children at risk of developmental difficulties but also for those who can benefit from general parenting advice. It also creates the opportunity to provide a vision for ECD in healthcare beyond disability to optimal development pertaining to all children through provision of nurturing care (49). Developmental status is indeed one of the key indicators of long-term health outcomes beyond survival (50). A few parents also appreciated the items related to the family environment as helpful. As the program grows and pediatricians feel more confident, this form may be an opportunity to touch upon the family environment which can be a stress factor affecting the health and development of young children. The addition can be valuable as dedicated family services do not exist in the country.

Feedback from one of the pediatricians and some of intervention team members suggested a need for greater understanding and discussion between ECD professionals and pediatric consultants with regards to the data on SWYC outcomes. This feedback was from a pediatrician who dealt with chronic conditions and perhaps required more information that could help create an integrated care plan. One recommendation can be to involve a developmental pediatrician in future as part of the team who also understands the health needs along with development. Another pediatrician who dealt with acute care issues felt it was a great addition to his ongoing clinic. The developmental psychologist had an interesting perspective with respect to not just the service but also how utilizing trainees could address training of the next generation of psychologists for early development. Unfortunately, we could not conduct interviews with pediatricians but the difference in feedback from the three pediatricians seems to be due to the fact that they were dealing with different patient populations. It also highlights that developmental monitoring and support can have a different value to ongoing services for acute and chronic health issues.

Psychology trainees were important stakeholders as they were envisioned to be the key delivery staff for future scale-up. Their feedback was encouraging, and they enjoyed the experience. We think it is because the health center is an elite prestigious center and hence valued by the trainees for their future career aspirations. We ensured that they were supervised and hence were paired with psychology associates with considerable experience in developmental assessments. Regarding the larger feasibility of the intervention, the feedback from the trainees highlighted aspects related to survey administration while no feedback was received from physicians. One reason could be that a family-centric initiative was ongoing for about 2 years before the roll-out of this study. Hence, we did not face any challenges upfront in physician engagement or buy-in for the idea to move to a family-centric approach. We also believe successful demonstration of feasibility lies in designing the intervention as value added for all stakeholders. That was possible because the team spent considerable time designing the ToC, laying out all opportunities and risks. Additional effort was designed for the risks. A meta-analysis of home visiting programs to prevent child neglect and abuse found that programs with a clear ToC with intervention components aligned to population needs had a higher chance of success (51). The intervention had value for families and pediatricians but also psychology trainees who got an opportunity to learn and also contribute toward child health. In the long-run, the hospital benefits from improved services in terms of patient and family experience (52). Moving forward on the journey from invention to social innovation at scale, initiators should make a conscious effort to leverage partnerships between key stakeholders to achieve optimal development for children (53, 54). Effective implementation of partnerships between public and private health sectors can be achieved through a robust ToC entailing creating partnership norms, crafting collaborative work plans, conducting regular audits, and evaluation using such tools as the Partnership Assessment Tool (55).

The strengths of the study include a cost-effective design at the outset to leverage existing resources and context-specific

TABLE 4 | Future directions.

Theme	Domain	Recommendations and implications
Operational	Communication gap between administrative staff and developmental trainee	Parents/patients can connect with the trainee at the time of registration at the clinic reception
	Managing paper copies of 12 different age-group forms was cumbersome. Parents had various language preferences. Some parents preferred to be interviewed, while others were comfortable completing the SWYC questions themselves.	An app for use on a tablet or smartphone can be developed for auto-calculation of the patient's exact age and identification of the appropriate screening form in the respondent's preferred language. This app can be designed for surveys/questionnaires that can be completed by the parents and by the trainee. For parents with lower literacy levels, the app can include an audio option (read out loud the survey questions) or speech to text and text to speech options.
	Limited space in clinic, with no toys/books/play area/material available for waiting children	Dedicated space for screening and counseling with parents is required, which can also help address patient privacy concerns, while providing children resources to play with while their parents are engaged in the screening process.
	Ensuring leadership buy-in.	Ensure leadership willingness for continued services. In addition, all the staff members, that includes doctors, nurses, and administration staff, etc. should be briefed about the purpose of the QI of this questionnaire for their engagement. Should also be communicated to families as a new meaningful initiative.
Technical	Communicating news about developmental risks to parents, particularly when parental knowledge is low at the outset of screening	It was observed that while parents reported being satisfied with their child's current behavior and development, some were usually unaware that their child could be at risk. Parental education and counseling by the pediatric consultant needs to be sensitive to parental distress that can be caused when communicating results. Training for the pediatricians needs to be incorporated.
	Physician engagement is limited due to time constraints	Structured monthly or bi-monthly meetings are required to share trends, challenges experienced and addressed by physicians and the Patient Experience team. Include a developmental pediatrician in the team.
	Limited trained/qualified human resource	Dedicated staff are required to counsel and screen the parents/patients; pediatric residents can be trained in-house. Additionally, collaborations with partner universities can encourage internships for medical students or psychology/allied health students to complete the screening and provide a training opportunity simultaneously. Maintain a liaison with the university and share feedback about student progress. This enhances engagement of the students and ensures professionalism.
	Engagement of stakeholders	Ensure added value to engage all stakeholders: parents, physicians, leadership. Regular meetings and streamlined communication between pediatricians, developmental specialists, and hospital administration can improve referral pathways from primary to specialist care, while incorporating parental feedback into these processes.
Research	Evaluation	Evaluation of families' knowledge, attitude, and practices (KAP) about early childhood development should include a randomized sampling approach. It will be important to capture their waiting experience, and the data can be used for leadership buy-in. Physician and trainees KAP are also an important set of process outcomes. Moreover, follow-up of children connecting with services should also be considered through a follow-up call. Qualitative data from parents also need to be ensured for greater insights about the process.
	Intervention	Co-design the intervention with different disease specialties. Start slow, ensure bottlenecks are ironed out and follow a phased roll-out with different specialties. Ensure implementation is evaluated for fidelity, acceptance, demand, and use of services.

QI, Quality Improvement; SWYC, Survey of Well-being of Young Children.

strengths. The trainees were interns/associate psychologists from a local psychology university seeking capacity building for clinical training. Studies from healthcare have found positive benefits of volunteers on patient experience (56). Parental trust in pediatricians and parental perceptions regarding the credibility of the study site as a teaching hospital were utilized to enhance feasibility. Another strength was that the study was implemented as part of an on-going patient and family-centric initiative emphasizing compassionate care. This allowed for a quick buy-in of the physicians whereby they were aware of the elements of psychosocial care and effect on health outcomes. There were several limitations of the study. One, the SWYC is not validated for the Pakistani population. However, the SWYC was intended to be used as an indicator of need for parental conversation by the pediatrician. In case of due concerns, children and their parents were then referred to developmental specialists. A study using SWYC in the Brazilian context found a similar performance of children between birth to 36 months as North American children (57). Moreover, the authors felt given the scale of the problem, this limitation of validated tools in the Pakistani context should not be a barrier to initiation of developmental monitoring processes. Secondly, we could not collect feedback from all the families about their experience with the intervention process nor could we approach physicians through in-person conversations for their insights about the services owing to resource constraints. An additional limitation is that for the purpose of this study, we were not able to follow up with parents and children to collect data on how many referred/identified at-risk children went on to connect with specialist services for additional support and if there was any agreement on the clinician diagnosis and screening results. However, the primary purpose of the initiative was to help the parents become aware of early developmental milestones and what their role could be in a manner that was acceptable. Since relatively educated families use the services at the hospital, we felt the increased awareness in itself could be an intervention acting as a nudge for the families in every outpatient visit for their child (in the first 5 years of his/her life). Several children with indicated need were referred as noticed through informal conversations but a systematic record could not be maintained. Also, there was no protocol in place in the service for referral of children with identified developmental and emotional needs. Decisions were usually based on the physician's preferences of services and providers, and creating a protocol was beyond the scope of the study. It was also not feasible for the research team to follow-up with the physicians to understand how the results were discussed with the families and if they developed distress. Given that pediatricians have an on-going relationship with families, we assume that may have mitigated some of the risks. Finally, two of the authors were also part of the consultant team and their reflections could be biased. Hence, the data analysis team included a developmental psychologist independent of the intervention team.

Future Direction

Further suggestions and key feasibility findings for the intervention are summarized in **Table 4**. A key recommendation is to continue the model with relevant changes suggested by the feasibility findings and to subsequently test the model using a robust evaluation strategy while ensuring adequate resources. Continued leadership buy-in and support will be important to sustain engagement of the physicians for family-centric care. Though feedback was received from only three consultants it had made us realize that the intervention model has to be co-designed in the next phase and tailored to the different sets of patient needs to maximize benefits. Moreover, developmental outcomes will need to be included as a key indicator of patient-reported health outcomes for continued improvement in quality of services. We conclude that when designing implementation models for developmental monitoring, the context needs to be carefully considered for feasibility and should include iterative learning cycles for continuous improvement. Due time and effort should be invested to understand how the intervention would operate but also how it would lead to a behavior change.

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 Ethics Review Committee at the Aga Khan University as an exemption. Written informed consent for participation was not required for this study in accordance with the national legislation and the institutional requirements.

AUTHOR CONTRIBUTIONS

MR conceptualized and designed the study, trained volunteer psychologists to implement the intervention in the outpatient clinic, prepared analysis plan, and led the writing of the manuscript draft. WM analyzed and interpreted the study findings and contributed to the manuscript draft. KE contributed to the analysis of family experience data and contributed with reflections on her experiences as an assessor in this program. BH provided intellectual input toward the study design in his capacity as Pediatrics service line chief and to the manuscript drafts. All authors contributed to the article and approved the submitted version.

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Engaging Healthcare Staff and Stakeholders in Healthcare Simulation Modeling to Better Translate Research Into Health Impact: A Systematic Review

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Objective: To identify processes to engage stakeholders in healthcare Simulation Modeling (SM), and the impacts of this engagement on model design, model implementation, and stakeholder participants. To investigate how engagement process may lead to specific impacts.

Data Sources: English-language articles on health SM engaging stakeholders in the MEDLINE, EMBASE, Scopus, Web of Science and Business Source Complete databases published from inception to February 2020.

Study Design: A systematic review of the literature based on a priori protocol and reported according to PRISMA guidelines.

Extraction Methods: Eligible articles were SM studies with a health outcome which engaged stakeholders in model design. Data were extracted using a data extraction form adapted to be specific for stakeholder engagement in SM studies. Data were analyzed using summary statistics, deductive and inductive content analysis, and narrative synthesis.

Principal Findings: Thirty-two articles met inclusion criteria. Processes used to engage stakeholders in healthcare SM are heterogenous and often based on intuition rather than clear methodological frameworks. These processes most commonly involve stakeholders across multiple SM stages *via* discussion/dialogue, interviews, workshops and meetings. Key reported impacts of stakeholder engagement included improved model quality/accuracy, implementation, and stakeholder decision-making. However, for all but four studies, these reports represented author perceptions rather than formal evaluations incorporating stakeholder perspectives. Possible process enablers of impact included the use of models as "boundary objects" and structured facilitation *via* storytelling to promote effective communication and mutual understanding between stakeholders and modelers.

Conclusions: There is a large gap in the current literature of formal evaluation of SM stakeholder engagement, and a lack of consensus about the processes required for effective SM stakeholder engagement. The adoption and clear reporting of structured engagement and process evaluation methodologies/frameworks are required to advance the field and produce evidence of impact.

Keywords: translation, simulation model, data driven healthcare organization (DDHA), data driven (DD), participatory research, healthcare improvement, stakeholder engagement

WHAT IS KNOWN ON THIS TOPIC

- Simulation modeling is an effective research methodology to address complex and "wicked" problems in healthcare and public health.
- Involving stakeholders in healthcare simulation modeling is assumed to produce better (and more relevant) models which are more readily accepted by problem owners and thereby more likely to be implemented, but there is limited evidence to guide choices of methods for engaging stakeholders to enhance the design and implementation of these models.

WHAT THIS STUDY ADDS

- We document the large gap in the current literature of formal evaluation of SM stakeholder engagement, and a lack of consensus about the processes required for effective SM stakeholder engagement.
- Processes used to engage stakeholders in healthcare simulation modeling are heterogenous and often ill-defined in the literature, generally involving multiple stakeholder types across multiple simulation modeling stages.
- Possible process enablers of impact are the use of models as "boundary objects" and structured facilitation *via* storytelling for non-technical communication of model logic. These enablers may work by providing a common language and mutual understanding between stakeholders and modelers.
- Adoption and clear reporting of structured engagement and process evaluation methodologies/frameworks are required to advance the field.

INTRODUCTION

Healthcare decision-makers are facing increasingly "wicked" problems, which have both a technical (complex and uncertain symptoms and solutions) and social (divergent stakeholder perspectives) dimensions (1, 2). Confronting the technical dimension requires research methods which can account for scientific complexity and uncertainty whilst addressing the social dimension requires stakeholders to be engaged in the research process in order to produce solutions with real-world utility (3, 4).

Simulation Modeling (SM) is an established but historically under-utilized methodology in healthcare (5). SM creates a virtual environment which captures dynamic, interdependent and emergent system behaviors in formal models or mathematical representations (5, 6). These models can be used to "advance the understanding of the system or process, communicate findings, and inform management and policy design" (6). SM comprises three methods—system dynamics, discrete event simulation, and agent-based modeling—which Marshall et al. claim are "well suited to healthcare delivery problems" (6).

SM has increasingly been combined with approaches intended to engage stakeholders in the modeling process. Engaging stakeholders, traditionally managers and clinicians in the relevant healthcare field, has been claimed to yield both more technically and socially robust simulation solutions (7) and improve on the poor model implementation that has plagued SM for many years (5, 7–11). Barreteau et al. outline three expected benefits of combining a participatory process with SM: (1) to upgrade the quality of a simulation model, (2) to improve the suitability of the simulation model's use (implementation), and (3) to support participation itself, and account for different perspectives (function of models within participatory process) (12). Despite these expected benefits, SM stakeholder engagement research and practice in healthcare lags behind other sectors (e.g., defense and commerce) (13).

Knowing how best to involve themselves or others in research is a challenge for clinicians, decision-makers and stakeholders in healthcare, as well as for the researchers. Yet involving frontline clinicians, decision-makers and other relevant stakeholders in research that aims to promote a change in practice is key to translating research "off the shelf and into practice" (14). Several authors have identified barriers to successful stakeholder engagement unique to SM research. Jahangirian et al. determined the primary causal factor of poor engagement as the "communication gap between simulation and stakeholder groups" as simulation modelers may have particularly technical backgrounds (9). Brailsford et al., drawing on their experiences within the UK, discuss commonly encountered barriers, including cultural differences and ethical hurdles (8). Whilst an understanding of barriers to engagement is important, guiding decisions in practice about how to effectively engage different stakeholders in designing healthcare simulation models requires further understanding of who should be engaged, when this engagement should occur, and how this engagement should be done to generate the intended impacts. Several simulation studies in healthcare have provided descriptions, reflections or evaluations of their stakeholder engagement process (15, 16), however, there is no coherent body of literature in this area.

The aim of this review is to systematically synthesize the evidence on how far and by what means stakeholder engagement in SM results in outcomes with more practical utility and prospect of successful implementation. A key objective is to identify the processes used to meaningfully engage stakeholders in SM research and to analyze the impacts of this engagement in enhancing the design and implementation of healthcare simulation models. In order to accomplish this, we analyzed the extent to which these intended purposes or expected benefits of SM have materialized in applications to healthcare problems, and we identify the contribution of engagement processes to facilitating this.

METHODS

Study Design

This systematic review is reported according to the PRISMA statement (17) and used an a priori established protocol (**Supplementary Material**).

Eligibility Criteria and Search Strategy

Eligible articles were original studies that (1) used dynamic SM (intervention), (2) reported a health-related primary outcome (context), (3) engaged stakeholders during the *model design* stage (population), and (4) reported stakeholder engagement impact (outcome). The search was not limited to a specific study design and did not include a comparator. English-language articles were searched in MEDLINE, EMBASE, Scopus, Web of Science and Business Source Complete databases published from inception to February 2020. Common keywords included: simulation, system dynamics, discrete event or agent based; health care, healthcare, hospital, primary care, public health, health policy or health service; group model building, stakeholder, client, customer, implementation, focus group, interview, steering group, advisory board, advisory committee, co-design, co-production; and participatory simulation or participatory model. Full details are in **Appendix A** including the title and abstract screening criteria and the full text inclusion criteria.

Study Selection, Data Extraction and Analysis

Title and abstract, and then full-text screening (see **Appendix A** for full details) were conducted by TZ (all studies) and KL (25% of studies), with disagreement resolved by discussion. Data were extracted using a data extraction form adapted from Concannon et al. (18) and located in **Appendix A**.

Data were analyzed using summary statistics, deductive and inductive content analysis, (19) as well as a narrative synthesis approach (20). Summary statistics were used to analyze study characteristics. Content analysis was applied to synthesize qualitative data describing the participatory process and intended or reported impacts of this process. We used matrices to explore the overlap between process characteristics and intended or reported impacts, in order to map how the nature of the process may link to impacts. To obtain a richer understanding of the participatory processes, a narrative synthesis approach was used to analyze the role of stakeholder engagement activities within the SM process. Topic areas were categorized according to Mielczarek and Uziałko-Mydlikowska (21), and stakeholder types were categorized according to an adaptation of the 7P's framework, with purchasers and payers combined into a single category (14). The generic stages of SM lifecycles (**Figure 1**) were used to represent modeling stages– problem formulation, conceptual modeling, computer modeling, model verification and validation, experimentation and implementation (22). Other stages which engaged stakeholders that didn't fit into the generic stages were inductively coded. The intended and reported benefits of the participatory process were coded within a framework adapted from Barreteau et al., comprising three broad types of benefits for (1) the design of the model, (2) the implementation of the model, and (3) the stakeholder participants (12). Within this framework, inductive content analysis was used to identify and quantify the sub-groups of benefits.

The evidence synthesis concentrated on authors' reporting of the participatory process in SM studies, which meant that outcome measures from the studies were not included. Therefore, no formal assessment of risk of bias was necessary either in individual studies or across studies (23).

RESULTS

The search yielded 1,682 titles and abstracts for initial screening, with 119 articles included for full-text screening. Of full-text articles screened, 29 met the eligibility criteria, with a further three identified and included from included articles reference lists (see **Figure 2** PRISMA diagram). The final 32 articles reported on 27 studies (see **Table 1** for a summary of included studies).

Study Characteristics

Of the 27 studies included, the majority were conducted in the UK ($n = 8$, 30%), US ($n = 7$, 26%) and Australia ($n = 4$, 15%). The most common topic areas were *Health and Care Systems Operation* (56%) and *Epidemiology, Health Promotion and Disease Prevention* (41%), with few studies in *Health and Care Systems Design* (3%) and *Extreme Events Planning* (3%). None of the included studies addressed the topic of *Medical Decision Making*. Years of publication ranged from 2000 to 2019, with 78% published since 2014 ($n = 21$). There was a change in trend in study topic areas over time: initially dominated by *Health and Care Systems Operation,* and in recent years by *Epidemiology, Health Promotion and Disease Prevention* (**Figure 3**).

Stakeholder Participants

The number of studies reporting stakeholder engagement during different stages of SM are shown in **Figure 4**. The type and number of stakeholders involved in the participatory process

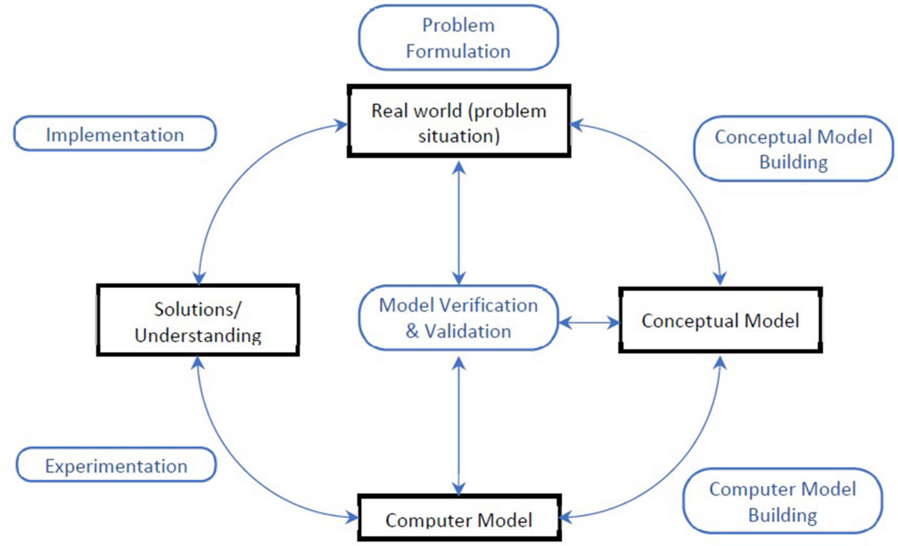

FIGURE 1 | Generic stages in SM.

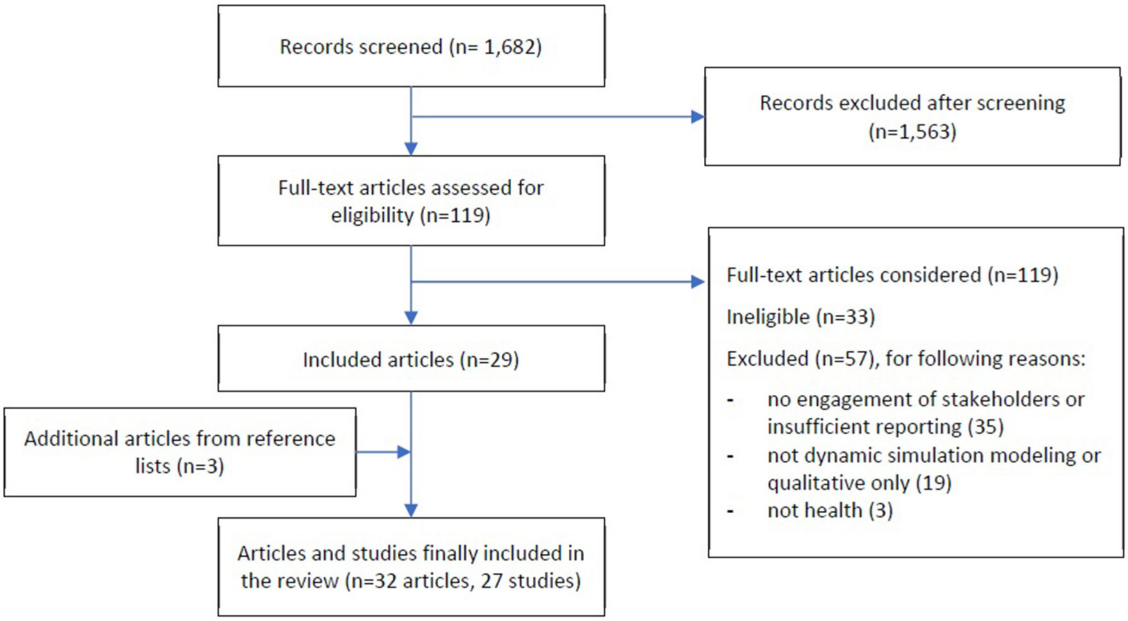

FIGURE 2 | PRISMA flow diagram of study selection.

varied widely between studies. The most frequently-engaged stakeholders were Providers ($n = 23$), with less engagement with Policy-makers ($n = 7$), Purchasers/Payers ($n = 9$) and Patients/Public ($n = 6$). Each study, on average, engaged two different types of stakeholder participants. Further details on the numbers and types of stakeholders are in **Appendix B**. Recruitment methods for stakeholders are also in **Appendix B**.

The Participatory Process: Stakeholder Engagement Stages, Modes and Activities

The stages during which stakeholders were engaged are depicted graphically in **Figure 4**. All but one study engaged stakeholders in more than one stage of the SM process. In nine studies (33%), stakeholders were engaged in all the generic stages (from the beginning to the end of the SM lifecycle—excluding computer

TABLE 1 | Summary of studies included in the systematic review ($n = 27$).

References and country	Model			Stakeholders		Stakeholder engagement		Impacts
	Topic area	**Type**	**Health-related outcomes**	**Type and number**	**Recruitment method**	**Stages**	**Modes and analysis**	
Atkinson et al. (24); Freebairn et al. (15, 25) Australia	Epidemiology, health promotion and disease prevention	Agent-Based Modeling	Alcohol-related harms, violence, ED presentations, and hospitalisations	Policymakers, PIs, Providers. N = 10–15 (planned)	Purposive sampling	Problem formulation, Conceptual MB, Model Verification, Experimentation/ Implementation, Parameterisation, Participant recruitment	Discussion/ dialogue, Meetings, Workshop Structured Direct model interaction	**Model design:** Model quality, Data identification, Multiple perspectives **Participants:** Productive discussion, Learning, Problem-solving **Implementation:** Model acceptance, Implementation
Baldwin et al. (26, 27) UK	Health and care systems operation	Discrete event simulation	Cost-effectiveness of liver transplant patients wait list prioritization models	Providers, Purchasers/ Payers. N = ns	Purposive sampling	Problem formulation, Conceptual MB, Model Verification, Experimentation/ Implementation	Discussion/ dialogue ns Direct model interaction	**Model design:** Problem relevance, Multiple perspectives **Participants:** Productive discussion
Barbrook-Johnson et al. (28) UK, USA, EU	Epidemiology, Health Promotion and Disease Prevention	Agent-Based Modeling	Influenza infections, vaccination-seeking, individual adoption of other protective behaviors	Policymakers, PIs, Providers, Purchasers/ Payers. N = 48	Purposive sampling	Conceptual MB, Model Verification, Experimentation/ Implementation	Questionnaire, Workshop ns Thematic analysis, Direct model interaction	
Bell et al. (29) UK	Health and care systems operation	Hybrid (System Dynamics, Discrete Event Simulation)	ED presentations, unplanned hospital admissions, hospital readmissions, bed occupancy	Providers, Purchasers/ Payers. N = ns	Actor inheritance	Problem formulation, Conceptual MB, Model Verification	Interviews ns Direct model interaction	**Model design:** Model quality
Bowers et al. (30) UK	Health and care systems operation	Discrete Event Simulation	ED Patient wait time	Providers. N = ns	Accessed through collaborative institution, As part of a larger project/ initiative	Conceptual MB, Model Verification, Experimentation/ Implementation	Discussion/ dialogue Unstructured Direct model interaction	**Model design:** Model quality **Implementation:** Model acceptance, Implementation
de Andrade et al. (31) Brazil	Health and Care Systems Operation	System Dynamics	ST-segment elevation myocardial infarction patient ejection fraction, length of stay	Providers. N = 6	Convenience sampling, Accessed through collaborative institution	Problem formulation, Conceptual MB	Interview Structured ns	**Model design:** Multiple perspectives

(Continued)

TABLE 1 | Continued

References and country	Model			Stakeholders		Stakeholder engagement		Impacts
	Topic area	**Type**	**Health-related outcomes**	**Type and number**	**Recruitment method**	**Stages**	**Modes and analysis**	
Freebairn et al. (15, 25, 32, 33) Australia	Epidemiology, health promotion and disease prevention	Hybrid (Discrete event simulation, system dynamics, agent-based modeling)	Gestational diabetes incidence and later-life type 2 diabetes incidence, offspring gestational diabetes and type 2 diabetes incidence	Policymakers, Providers, Purchasers/ Payers N = 10–15 (planned)	Purposive sampling	Problem formulation, Conceptual MB, Model Verification, Experimentation/ Implementation, Parameterisation, Process Evaluation	Discussion/ dialogue, Interview, Meetings, Workshop Structured Thematic analysis, Direct model interaction	**Model design:** Problem relevance, Model quality, Data identification, Multiple perspectives **Participants:** Productive discussion, Learning, Problem-solving **Implementation:** Model acceptance, Implementation
Giesen et al. (34) Netherlands	Health and care systems operation	Agent-Based Modeling	Provision of youth health care to difficult cases, wait list size, patient withdrawal from wait list, patient wait time, provider utilization	Providers. N = 4	ns	Conceptual MB, Model Verification	Discussion/ dialogue, Interviews ns Direct model interaction	**Model design:** Model quality
Glasgow et al. (35) UK	Extreme Events Planning Health and Care Systems Operation	Discrete Event Simulation	Exhaustion of red blood cell inventory, adherence to blood transfusion guidelines	PIs, Providers. N = ns	Accessed through collaborative institution	Conceptual MB, Model Verification, Parameterisation	Discussion/ dialogue, Questionnaire Unstructured ns	**Model design:** Model quality **Participants:** Problem-solving
Hassmiller Lich et al. (36) USA	Epidemiology, health promotion and disease prevention	System dynamics	Prevalence of youth with managed serious emotional disturbance	Patients/ Public, PIs, Providers. N = 103	Public advertising	Problem formulation, Conceptual MB, Experimentation/ Implementation	Webinar, Workshop Structured Value coding, Thematic analysis	**Participants:** Productive discussion **Implementation:** Refined terminology
Homa et al. (37) USA	Epidemiology, Health Promotion and Disease Prevention Health and Care Systems Design	Agent-Based Modeling	Average patient health (all patients; patients with chronic illnesses), clinician visits (total; due to poor health), primary care visits resulting in specialist referrals	Patients/ Public, Providers. N = 15	Purposive sampling	Problem formulation, Conceptual MB, Model Verification, Experimentation/ Implementation	Focus groups, Interviews, Workshop Structured Direct model interaction	**Model design:** Multiple perspectives
Hung et al. (38) Canada	Health and Care Systems Operation	Discrete Event Simulation	Pediatric ED patient wait time, length of stay	Providers. N = ns	As part of a larger project/ initiative	Conceptual MB	Interviews Unstructured ns	

(Continued)

TABLE 1 | Continued

References and country	Model			Stakeholders		Stakeholder engagement		Impacts
	Topic area	**Type**	**Health-related outcomes**	**Type and number**	**Recruitment method**	**Stages**	**Modes and analysis**	
Johnson et al. (39) UK	Health and care systems operation	Discrete event simulation	Total cost of treatment pathways for sepsis, pneumonia, chemotherapy	Providers, Purchasers/ Payers. N = ns	Purposive sampling, As part of a larger project/ initiative	Problem formulation, Conceptual MB, Model Verification, Parameterisation	Meetings ns Direct model interaction	**Model design:** Model quality, Data identification
Lane et al. (16) UK	Health and care systems operation	System dynamics	ED Patient wait time, elective cancellations, hospital occupancy; ED clinician utilization	Providers. N = 14	Accessed through collaborative institution	Conceptual MB, Model Verification, Experimentation/ Implementation, Parameterisation	Discussion/ dialogue, Meetings Unstructured Direct model interaction	**Model design:** Model quality **Participants:** Learning, Problem-solving **Implementation:** Model acceptance
Lattimer et al. (40) UK	Health and care systems operation	System dynamics	ED throughput, hospital bed occupancy	Providers. N = 30 (interviews) N = ns (discussion)	Accessed through collaborative institution	Conceptual MB, Computer MB, Experimentation/ Implementation, Parameterisation	Discussion/ dialogue, Interviews Unstructured Direct model interaction	**Model design:** Model quality **Participants:** Productive discussion
Leskovar et al. (41) Slovenia	Health and care systems operation	Discrete Event Simulation	Hospital administrative staff utilization	Ns. N = ns	ns	Problem formulation, Conceptual MB	Interviews ns ns	
Lote et al. (42) USA	Health and care systems operation	Discrete Event Simulation	Medical laboratory staff utilization across departments	Providers. N = ns	ns	Conceptual MB, Model Verification	Discussion/ dialogue ns Direct model interaction	
Mackay et al. (43) Australia	Health and care systems operation	Hybrid (System Dynamics, Discrete Event Simulation, Agent-Based Modeling)	ED patient wait time, hospital bed occupancy	Ns. N = ns	ns	Conceptual MB, Model Verification, Experimentation/ Implementation, Parameterisation	ns ns Direct model interaction	**Implementation:** Implementation
Matchar et al. (44) Singapore	Health and care systems operation	System dynamics	Proportion of population with complex condition, cost per person, patient satisfaction, doctor-patient relationship	Patients/ Public, Policymakers, PIs, Providers, Purchasers/ Payers. N = 50	ns	Problem formulation, Conceptual MB	Discussion/ dialogue, Workshop Structured Direct model interaction	**Model design:** Multiple perspectives
Mitchell et al., (45) USA	Epidemiology, Health promotion and disease prevention	System dynamics	Rates of adolescent screening for alcohol, tobacco and substance abuse problems, positive screenings, brief interventions	Providers. N = ns	As part of a larger project/ initiative	Problem formulation, Conceptual MB, Model Verification, Experimentation/ Implementation	Interviews, Meetings, Webinar ns ns	

(Continued)

TABLE 1 | Continued

References and country	Model			Stakeholders		Stakeholder engagement		Impacts
	Topic area	**Type**	**Health-related outcomes**	**Type and number**	**Recruitment method**	**Stages**	**Modes and analysis**	
Murphy et al. (46) Jamaica	Health and care systems operation	System dynamics	Gap between available and required registered nurses	Policymakers, PIs, Purchasers/ Payers. N = ns	As part of a larger project/ initiative	Problem formulation, Conceptual MB, Model Verification, Experimentation/ Implementation, Parameterisation	Discussion/ dialogue ns ns	
Roberts et al. (47); Freebairn et al. (15, 25) Australia	Epidemiology, health promotion and disease prevention	System dynamics	Prevalence of overweight and obese children	Policymakers, PIs, Providers, Purchasers/ Payers. N = 44	Accessed through collaborative institution	Problem formulation, Conceptual MB, Model Verification, Experimentation/ Implementation, Parameterisation	Workshop ns Direct model interaction	**Model design:** Multiple perspectives **Participants:** Productive discussion, Learning, Problem-solving **Implementation:** Model acceptance, Implementation
Rosmulder et al. (48) Netherlands	Health and care systems operation	Discrete event simulation	ED Patient length of stay, quality of care	PIs, Providers. N = 6	Accessed through collaborative institution	Problem formulation, Conceptual MB, Model Verification, Experimentation/ Implementation	Discussion/ dialogue, Meetings, Public Display, Workshop Unstructured Direct model interaction	**Model design:** Multiple perspectives **Participants:** Problem-solving **Implementation:** Implementation
Rwashana et al. (49); Semwanga et al. (50) Uganda	Epidemiology, health promotion and disease prevention	System dynamics	Neonatal mortality	Patients/ Public, Policymakers, PIs, Providers. N = 345	Random sampling, Convenience sampling, Purposive sample	Problem formulation, Conceptual MB, Computer MB, Model Verification, Experimentation/ Implementation, Process Evaluation	Interview, Workshop ns Thematic analysis, Direct model interaction	**Model design:** Problem relevance **Participants:** Productive discussion, Problem-solving
Uebelherr et al. (51) USA	Epidemiology, health promotion and disease prevention	Agent-Based Modeling	Cooling center coverage during extreme heat	Policymakers, Providers. N = ns	Snowball sampling	Problem formulation, Conceptual MB	Interviews ns ns	**Model design:** Multiple perspectives **Participants:** Problem-solving
Uriarte et al. (52) Sweden	Health and care systems operation	Discrete event simulation	ED patient wait time, length of stay	Ns. N = ns	Accessed through collaborative institution	Problem formulation, Conceptual MB, Model Verification, Parameterisation	Discussion/ dialogue, Meetings ns ns	**Participants:** Problem-solving **Implementation:** Implementation

(Continued)

TABLE 1 | Continued

References and country	Model			Stakeholders		Stakeholder engagement		Impacts
	Topic area	Type	Health-related outcomes	Type and number	Recruitment method	Stages	Modes and analysis	
Zimmerman et al. (53) USA	Health and care systems operation	System Dynamics	Evidence-based psychotherapy initiation and completion in veterans	Patients/ Public, Providers. N = ns	Accessed through collaborative institution	Problem formulation, Conceptual MB, Computer MB, Model Verification, Experimentation/ Implementation, Parameterisation	Meetings Structured Qualitative formative evaluation, Direct model interaction	**Model design:** Problem relevance, Data identification **Participants:** Productive discussion, Learning, Problem-solving **Implementation:** Implementation

UK, United Kingdom; USA, United States of America; EU, European Union; ED, Emergency Department; PIs, Principal Investigators; MB, Model Building; ns, not specified.

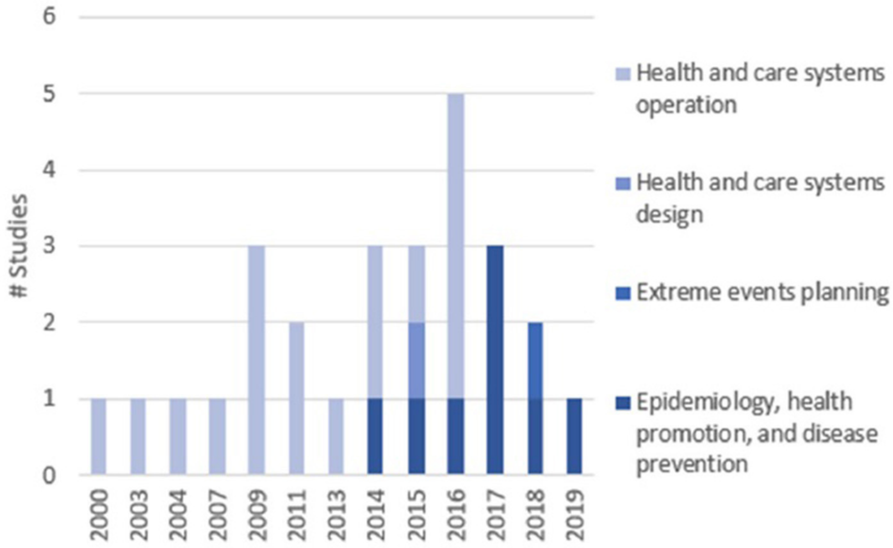

FIGURE 3 | Evolution of study topic areas over time.

model building). There were four primary modes employed by studies in the engagement of stakeholders: discussion/dialogue ($n = 13$, 48%), interviews ($n = 11$, 41%), workshops ($n = 8$, 30%), and meetings ($n = 7$, 26%), with some variation across SM stages. Specifically, interviews were most common earlier in the SM process while workshops were commonly used in the mid and late stages of the process. Workshops, discussion/dialogue and meetings generally involved direct model interaction, where the model acted as a communication vehicle ($n = 18$, 67%), allowing stakeholders to physically manipulate and "play" with the model design. Some studies provided descriptions about how they facilitated this input, which ranged from structured and active methods where stakeholders were asked specific questions (31) or engaged in purposeful storytelling exercises (32), to unstructured and passive methods where stakeholders provided feedback about or annotated an existing model (30, 40). More structured methods of facilitation were used in early stages when studies were engaging stakeholders in designing the model from scratch (24, 31, 32, 36, 37, 44, 53), and more passive methods were used when stakeholders were engaged at a later stage and a draft model had already been designed (16, 30, 35, 38, 40, 48). Further details about the Modes of Engagement & Facilitation are found in **Appendix C**.

Assessing the Impacts of Stakeholder Engagement

There were four types of impacts reported from stakeholder engagement on model design: (1) increased relevance of the problem addressed ($n = 4$, 14%), (2) better quality/accuracy of the model for its purpose ($n = 9$, 33%), (3) improved

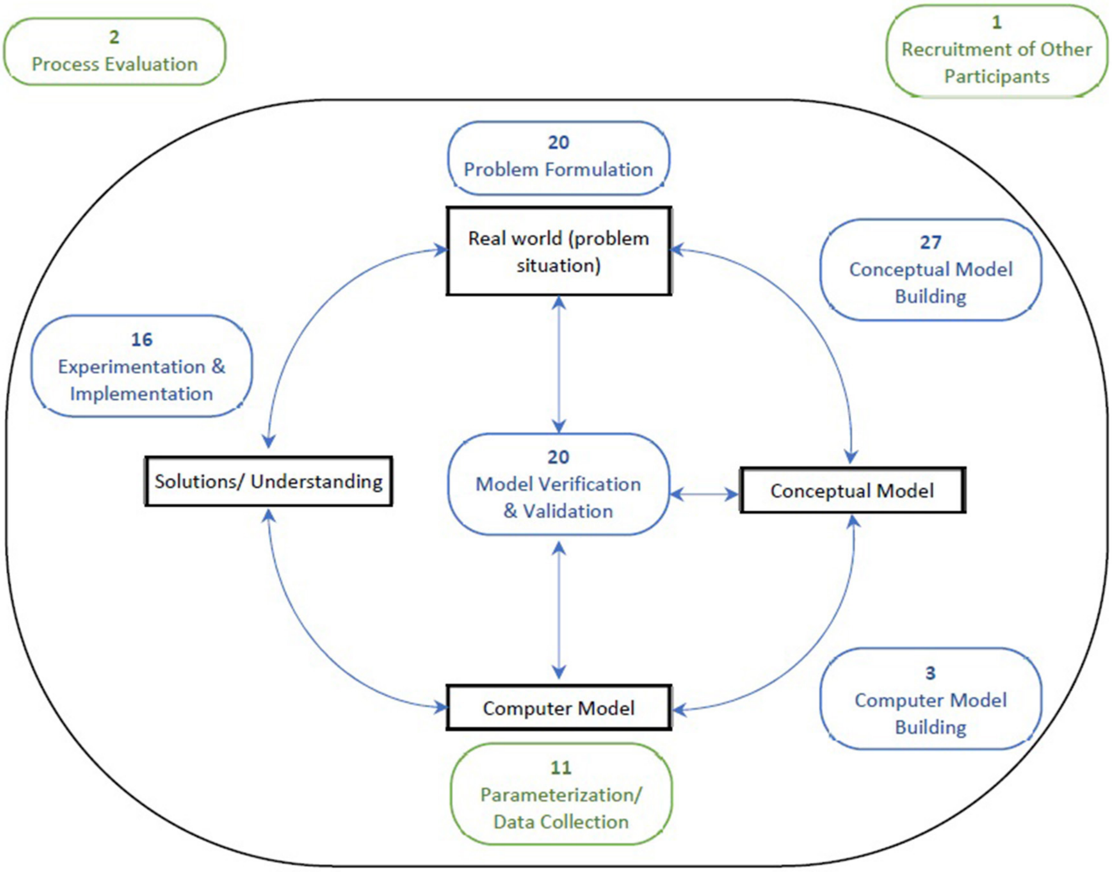

FIGURE 4 | Number of studies reporting stakeholder engagement during generic (blue) and openly coded (green) stages of SM. Common stages of engagement aside from conceptual model building were problem formulation (74%). model verification & validation (74%) and experimentation & implementation (59%). It was relatively uncommon for studies to engage stakeholders during the computer model building stage (11%). however, collecting data or parameters through the engagement of stakeholders was used by almost half the studies as a means of quantifying the computer model (41%). Only two studies (7%) engaged stakeholders in evaluating the participatory process in the simulation study.

identification or access to better data ($n = 4$, 15%), and (4) expertise from a range of perspectives ($n = 9$, 31%). Across the SM stages, increased relevance of the problem was most reported during problem formulation, while better quality/accuracy of the model was most reported during the conceptual modeling phase.

There were three types of impacts reported from the participatory process on the stakeholder participants: (1) productive discussion or shared understanding of the problem ($n = 8$, 28%), (2) "learning" ($n = 5$, 17%), and (3) better problem solving or decision-making ($n = 10$, 35%). The fact that models require perspectives and assumptions to be made explicit in a graphical representation which imitates the real system meant that several studies found that interacting with the model created productive discussion between stakeholders, particularly those from different disciplines (24–26, 49). There were also three types of impacts reported from stakeholder engagement on model implementation: (1) refined use of terminology ($n = 1$, 3%) (36), (2) greater acceptance or ownership of the model ($n = 5$, 17%), and (3) improved implementation or suitable use of the model ($n = 8$, 27%).

In the overlap between the participatory process and impacts, studies involving direct model interaction were more likely to report benefits for stakeholder ownership of the model (56 vs 11%) and productive discussion & shared understanding (61 vs. 22%), vs. studies without direct model interaction. Read more about the impacts of participatory process on model design, implementation and participants in **Appendix D**.

Specific Processes Used to Engage Stakeholders in Simulation Modeling

Some studies provided specific details about the process used to combine stakeholder engagement and SM and how to do this well (26, 29, 32, 33, 49). This can provide practitioners and decision-makers, as well as researchers, with useful guides for engaging in such processes. These processes included: the Collaborative Hybridization Process (29), an adapted dynamic synthesis methodology (49), and the Modeling Approach that is Participatory Iterative for Understanding (MAPIU) (26). Descriptions and examples of these processes are outlined in **Appendix E**.

DISCUSSION

We have systematically reviewed the ways in which studies using SM have engaged stakeholders through participatory processes. We reviewed these participatory processes on their reported abilities to improve the design and use of models in healthcare as well as produce desired impacts on stakeholder participants. The reported processes used to engage stakeholders in healthcare SM were heterogenous, but there were common characteristics in terms of the stages, modes and activities through which engagement is facilitated. Studies mostly commonly involved provider stakeholders, across multiple SM stages, using discussion/dialogue, interviews, workshops and meetings as key modes of engagement. In addition to conceptual modeling, many studies engaged stakeholders in the adjacent stages of problem formulation and model verification and validation, as well as during the later stages of experimentation and implementation. Interviews were mostly used earlier in the SM process while workshops were mostly used in the mid and late stages of the process. Key reported impacts of stakeholder engagement included improved model quality/accuracy, implementation, and stakeholder decision-making.

The Link Between Stakeholder Engagement Process and Impact

The communication gap between stakeholders and modelers has been identified as a primary causal factor driving consistently poor rates of model implementation in healthcare SM (9, 54). This review has identified two possible mechanisms by which engagement processes, *via* improved model design and stakeholder impacts, may lead to improved model implementation.

Firstly, we found that direct interaction between stakeholders and the model seemed to influence interpersonal communication (between stakeholders themselves and between stakeholders and modelers), leading to stakeholder impacts of more productive discussion and shared understanding, and implementation impacts of greater ownership and acceptance of the model. This is likely because the model operates as a "boundary object" (55), a visual "multi-interpretable, consistent transparent, and verifiable representation of reality" (56). To effectively use models in this way, Rose et al. recommend: using specific conventions to describe model components and interactions to create a common language; using an early simple model to teach stakeholders the model concepts; and allowing hands-on stakeholder exposure to the model user interface (57). As such, using models as "boundary objects" may provide structures around which to base effective communication, providing visual aids for stakeholders to view the whole problem system and better identify areas for solutions.

More structured methods of stakeholder engagement, i.e., the use of specific questions (31) or purposeful storytelling exercises (32), were also associated with improved quality of models for their purpose and helped to incorporate diverse perspectives and expertise into the model design. Freebairn et al. discussed a particularly effective example of using "storytelling" to facilitate communication of the model structure through clinical case histories of individuals–a thought process familiar to clinical stakeholders (32) During storytelling the modelers are better able to use language that the stakeholders can understand and relate to. Also, having the stories allows stakeholders to give the modelers an increased understanding of the complexity of "wicked" problems and complexities associated with populations affected by these problems. The use of storytelling can exemplify the individual trajectories of agents, communicating the ability of the model to capture the evolution of agents over time. During the process evaluation, participants reported that while the sophisticated and highly technical nature of the model remained a barrier in communicating easy to understand policy messages, the use of storytelling to compliment the model outputs was a "particularly valuable tool" to improve mutual understanding of the model (32). That greater understanding contributes to improving the modeling, confidence in the model and ownership. This example suggests that storytelling may provide a useful addition to the "boundary object" approach, allowing communication of highly technical model elements in a more easily understood way. It's also likely to contribute to successful design, confidence, model ownership and future implementation as stories seem to get the message across people from different disciplines.

Reporting and Evaluation of Stakeholder Engagement in SM in the Literature

Many of the methodological issues faced by this review were due to a lack of standardized or detailed reporting of stakeholder engagement, and insufficient reporting was one of the primary reasons for article exclusion. This lack of reporting comprised the details of the process itself and adequate evaluations of the engagement process. Only five studies provided specific details about the stakeholder engagement process (26, 29, 32, 33, 49), and a mere four studies reported on a process evaluation from the stakeholder perspective (15, 30, 49, 53). For the remaining studies, it was difficult to distinguish between intended and reported impacts that were observed or realized during the process as the reporting was based solely on the authors' reflections.

A recent framework from the environmental model building field provides a possible solution to the lack of standardized reporting of stakeholder engagement that may be equally applicable to healthcare SM. Gray et al. propose a four-dimensional reporting framework (4P) which includes: (1) the Purpose for using a participatory SM approach (i.e., intended impacts), (2) the Process by which stakeholders were involved in model building or evaluation; (3) the Partnerships that were defined and participants that were chosen; and (4) the Products that resulted from these efforts (i.e., actual impacts) (58). A detailed breakdown of each of these dimensions is provided by the authors in addition to 4 exemplar case studies. This could be supported by the adaptation of one of the engagement processes identified in our review. The MAPIU is easily generalizable and provides several frameworks for designing a participatory SM process, including a classification system for stakeholders, and frameworks for how different stakeholder contributions fit into the MAPIU process and what types of communication should be considered (26). Guidance on process evaluation is sparser, with Esmail et al.'s systematic review identifying only two studies reporting quantitative results, with most formal evaluations relying on qualitative, self-reported retrospective accounts of the engagement experience (59). Future research should focus on the development and validation of measures and methods for rigorous evaluation of engagement in healthcare SM which should be an *a priori* embedded component of the research design.

A limitation of this review is the timeframe, which included studies published until March 2020.The crisis and transformation occurring in health care since February 2020 due to the COVID-19 pandemic is deliberately not captured here. The COVID-19 pandemic has resulted in rapid changes inside health systems including changes in direct care procedures and the adoption of remote care through new technologies, with a corresponding global burden of high health care worker stress. Therefore, health care stakeholder involvement for SM during COVID-19 would involve different, crisis driven approaches, and is the subject of a separate subsequent project.

CONCLUSION

This review explored the process by which studies engaged stakeholders in healthcare SM and the impacts of the engagement process on model design, model implementation and stakeholders. We found that engagement of stakeholders in the SM process was common during multiple stages, involved informal discussion as well as more formal one-to-one interviews or group workshops, and was facilitated by a range of more or less structured activities for model building, with structured activities associated with improved model quality and ability to capture diverse perspectives and expertise. Key enablers reported by authors and stakeholder participants were the use of the evolving model as a "boundary object" to facilitate communication and storytelling to communicate the model logic, complexities and interactions in a non-technical way. We suggest the adoption and clear reporting of structured engagement and process evaluation methodologies/frameworks to enable high-quality stakeholder involvement, improve SM confidence and ownership by healthcare staff and decision-makers, and ultimately lead to implementation of optimal interventions identified by SM that contribute toward better health care systems.

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

TZ, KL, IM, and JE devised the research and developed the research questions in collaboration with DS and JH. Search strategy was devised by TZ with assistance by KL and JE. Articles were screened by TZ and KL and fulltext extraction performed by TZ with technical guidance and assistance by KL and JE. Manuscript was drafted by TZ. All authors provided inputs into subsequent revisions.

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SUPPLEMENTARY MATERIAL

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Commentary: Engaging healthcare staff and stakeholders in healthcare simulation modeling to better translate research into health impact: A systematic review

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A Commentary on

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Introduction

As simulation modeling is increasingly embraced for implementation research, Zabell et al. offer a very timely and thought-provoking systematic review. The review comprehensively synthesizes the field's knowledge regarding the processes and impacts of engaging in simulation modeling those who are affecting or affected by an innovation's implementation [henceforth, implementation “associates”; please note this use of an alternative term for “stakeholders” for this commentary, per (1)]. Notable strengths of the review article include its identification of potential mechanisms through which specific processes used for engagement affect successful model development and usage, as well as its guidance on existing frameworks that can be leveraged for improved reporting and evaluation of engagement processes. The article urges future research around validated measures-driven evaluation of engagement for simulation modeling, and it also appropriately recognizes the likely changes to engagement process considerations since the COVID-19 pandemic (the timeframe of which is not included in the review). By highlighting and expanding on these visions for future work that the article discusses, this commentary aims to set the stage upon which the field can contextualize and debate the necessity and importance of the envisioned future work for advancements in associate engagement for simulation modeling.

TABLE 1 Key questions for conducting and evaluating associate engagement, adapted from (4).

Who will benefit from the implementation effort?
Who are the appropriate associates to engage?
What is the current nature/extent of associate engagement?
What is the desired nature/extent of associate engagement?
What processes should be developed and used for reaching and sustaining the desired nature/extent of associate engagement?
If multiple associates participate and only a subset benefits, was the engagement meaningful or perfunctory?
How will the quality and quantity of associate engagement be evaluated?
Does associate engagement improve the evidence-based practice's fit with the implementation setting(s)?

Evaluation of associate engagement for simulation modeling

For enhanced reporting of associate engagement processes for simulation modeling, the authors discuss the potential combined use of Gray et al.'s four-dimensional reporting framework (4P) for standardized reporting of associate engagement (2) and Baldwin et al.'s Modeling Approach that is Participatory Iterative for Understanding (MAPIU) for associate-engaged simulation modeling (3). For addressing the authors' call for future work on devising systematic approaches to evaluating the processes that are specified (for instance, using 4P and MAPIU), an additional framework to consider may be the list of key evaluation questions (Table 1) that Goodman and Sanders Thompson recommend in their 2017 commentary on the science of associate engagement in research (4). The questions include asking which associates will benefit from what engagement processes, and how the implementation research team would know the quantity and quality of associate engagement. Goodman and Sanders Thompson posit that considering these questions enables research teams to pursue meaningful associate engagement that creates "an amalgam for research synergy allowing the partnership [e.g., between the research team and associates] to obtain outcomes that no one constituent member could have produced on their own (4)." Hence, considering these questions for evaluating associate engagement processes may enable gauging the extent to which the processes contribute to establishing such synergy around simulation modeling. Importantly, Goodman and Sanders Thompson encourage teams to begin considering these questions early in their planning of associate engagement, which precisely aligns with Zabell et al.'s recommendation that evaluation of associate engagement for simulation modeling "should be an *a priori* embedded component of the research design."

Considerations for associate engagement under COVID-19

The authors acknowledge that approaches to and considerations surrounding associate engagement processes are expected to be different for simulation modeling efforts under COVID-19. The differences are likely to be in both how the processes are conducted (e.g., virtual components replacing face-to-face components) and the nature of the implementation tasks at hand (e.g., crisis management of a public health emergency). Not specific to simulation modeling, a considerable collection of literature is developing around associate engagement for implementation efforts that target underserved communities that the pandemic disproportionately affected. For example, particularly for community engagement, den Broeder et al. propose specific features of engagement that are crucial for health promotion success during COVID-19 (5), and Corbin et al. report on a global multiple-case study that identified engagement activities that can help mitigate the consequences of public health emergencies and other crises (6). Especially as Zabell et al. mention that examining associate engagement for simulation modeling in the COVID-19 context "is the subject of a separate subsequent project," it will be of great interest to learn from their subsequent work whether how engagement processes account for COVID-19 is different for simulation modeling efforts vs. for implementation-related efforts more generally that involve associate engagement.

Reviews of central aspects of simulation modeling beyond associate engagement

Findings of the systematic review—namely, that associate engagement processes used for simulation modeling "are heterogeneous and often based on intuition rather than clear methodological frameworks"—suggest the potential benefit of conducting analogous comprehensive reviews of other central aspects of simulation modeling beyond associate engagement. Especially of interest may be aspects of simulation modeling for which this review found limited examples of associate engagement, such as computer model building. The various and dynamic real-world contexts and implementation efforts that use simulation modeling may necessitate heterogeneous approaches to computer model building. However, it may still be worth examining how modelers select the appropriate computational representation of a conceptualized model, handle uncertainties in the model, and visually represent or methodically document the model. For instance, to what extent do modelers align to established principles and best practices for each of these steps in building the model (7), including looking to other fields outside of healthcare for which modeling has historically been more widely used? Variations in approaches regarding these steps, as do variations in associate engagement processes, may affect the validity, utility, and impact of simulation modeling in translating research into health impact.

Discussion

Zabell et al.'s systematic review comes at a time when there is a growing and urgent call for knowledge translation efforts to better meet the needs of unique contexts into which evidence-based practices are implemented. As implementation research actively incorporates innovative applications of promising methods (such as simulation modeling), to help answer this call, careful assessments of the methods' value added (including the preparatory steps needed to allow for such assessments) must be delineated and shared across the field. For associate engagement, which is deeply rooted in theories and practices of organizational, management, and behavioral sciences, there is an opportunity for implementation science to learn from how those fields have incorporated associate engagement into applying innovative methods in their research. An example of such learning is Elwy et al.'s approach to selecting specific engagement strategies for different types of associates (e.g., supportive and non-supportive) when disseminating research information that is central to successful implementation (8), which draws on Freeman's theory that an organization's success depends on its ability to create value for all of its associates (9).

Through the aforementioned strengths of their systematic review and the directions for meaningful future work that the review encourages, the authors provide a useful roadmap that similar efforts can follow to synthesize existing knowledge regarding, and prepare for rigorous assessments of, innovative methods for implementation research. Heterogeneity of evidence-based practices and their implementation contexts likely require applications of innovative methods to be heterogeneous as well, pointing to the need for standardized yet flexible structures and guidelines that make their applications and assessments both comparable across implementation efforts and adaptable to specific cases of implementation. Similar to the field's focus on determining not only what works for implementation but also for whom and how, informative assessments of innovative methods should elucidate the circumstances under which the methods are more or less applicable.

Author contributions

BK conceptualized and wrote the commentary, inspired by Zabell et al.'s article and valuable implementation research collaborations.

Conflict of interest

The author declares 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 Implementation Process of Two Evidence-Based Protocols: A Spatial Neglect Network Initiative

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Introduction: Spatial neglect, a neurocognitive disorder of lateralized spatial attention, is prevalent among stroke survivors especially in inpatient rehabilitation facilities (IRFs). The ultimate goal of the project was to improve spatial neglect care in inpatient rehabilitation and trained as many OTs as possible using both tools in their regular practices as the means to achieve our overall objective. Therefore, we conducted a project aimed at implementing two evidence-based protocols, one for assessment (KF-NAP®) and the other for treatment (KF-PAT®), and share the implementation process, which included barriers and facilitators identified during and after the process, and implementation outcomes.

Methods: Sixteen IRFs were involved. The Knowledge-To-Action Cycle was used to describe the process of knowledge inquiry (training), translating knowledge (implementation) and evaluating the use of knowledge in clinical practice (outcomes). Barriers and strategies were reported using the Consolidated Framework for Implementation Research and identified through a survey, after the study concluded.

Results: Thirty-two therapists at the participating sites were trained to some level of the KF-NAP and KF-PAT. Throughout the project and also once after it finished, different barriers were identified by researchers and clinicians, who then determined together actions to eliminate or minimize the barriers. For example, multiple sites reported: "not having time to train other staff at their hospital due to high patient volume and other responsibilities."

Discussion: The project shared our implementation process which demonstrated the importance of using implementation methods and incorporating a researcher-clinician partnership, not only for knowledge generation but also knowledge translation. Frequent communications and exchanging information with stakeholders at different levels, may be determinant to the success of each implementation phase. Further research is needed.

Keywords: spatial neglect, Prism Adaptation Treatment, knowledge translation, Kessler Foundation Neglect Assessment Process, Consolidated Framework for Implementation Research

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INTRODUCTION

Spatial neglect is a neurocognitive disorder that is characterized by the inability to attend to, perceive, and orient to the space that is contralateral to the injured or damaged cerebral hemisphere (1). It affects 20–40% of stroke survivors (2) and individuals with other acquired brain injuries (3). Since the 1980 s, devastating impacts of spatial neglect on rehabilitation progress, functional recovery, community reintegration, and caregiver burden have been demonstrated in various studies conducted by independent research groups around the world (4–10). Furthermore, spatial neglect prolongs inpatient rehabilitation and increases the risks of falls and injuries (5, 8, 10, 11). Treatments and assessments have been developed, examined, and recommended as guidelines, by organizations such as the American Heart/Stroke Association (12), Canadian Stroke Association (13), and the Australian Stroke Foundation (14). Nonetheless, in practice, it has been arbitrary whether individuals with spatial neglect are provided the recommended evidence-based treatment and assessment services. The problem may be related to the hurdles to achieve knowledge translation, dissemination, and implementation (15–18).

The ultimate goal of the wider research project was to improve spatial neglect care. To achieve this wider goal, we sought to implement two evidence-based standardized protocols, one for assessment and the other for treatment. The assessment protocol was the Kessler Foundation Neglect Assessment Process (KF-NAP®), and the treatment protocol was the Kessler Foundation Prism Adaptation Treatment (KF-PAT®). In this article, we aim to report the implementation process, which included barriers and facilitators identified during and after the process, and share implementation outcomes using quantitative and qualitative information.

In order to report the implementation process systematically, we incorporated methods from the implementation science literature (19). First, we followed the Knowledge-to-Action (KTA) cycle (20) to describe the progression from knowledge dissemination, protocol implementation, to outcome evaluation. The KTA cycle provides a "map" for how to move knowledge into action and encouraged revisiting phases of the action cycle as many times as necessary (**Figure 1**). The KTA cycle has been widely used in practice because it captures the complexities of real-world application and encourages transformation of knowledge that has been generated in research settings to promote use of evidence-based practices in the clinic (21).

Second, we used the Consolidated Framework for Implementation Research (CFIR), a framework of constructs related to implementation (22), to report barriers identified during the implementation process and the subsequent strategies used to address each barrier (23, 24). The CFIR is organized into five domains (intervention characteristics, outer setting, inner setting, characteristics of the individuals involved and the process of implementation) which provides organization and specificity to evaluate the project's impact (25). There are multiple examples of pragmatic research projects that use the KTA and the CFIR in a rehabilitation setting. Studies suggest that using the CFIR may increase the replicability and generalizability of study findings (26–28), and the KTA cycle can contribute to positive changes in stroke rehabilitation practices (21).

This project implemented the KF-NAP and the KF-PAT. The KF-NAP is a standardized method to administer and score the 10-item Catherine Bergego Scale (CBS) during daily activities (29). The items include gaze orientation, limb awareness, auditory attention, personal belongings, dressing, grooming, navigation, collisions, meals, and cleaning after meals. The scoring uses a scale between 0 and 3 for each item, with the total score ranging between 0 and 30 (the higher the number, the more severe the neglect is). The KF-PAT is a standardized protocol to deliver prism adaption treatment (PAT) (30). PAT is one of the treatment approaches recommended for stroke rehabilitation by the latest guidelines of the American Heart/Stroke Association (12). Both the KF-NAP and KF-PAT, and related materials such as clinician-oriented manuals and equipment, were developed through clinical research and trials over the past decade by our research team (31–35) and thus were the preferred choices in the present implementation project.

The discipline that participated in this project was occupational therapy (OT). Conventionally, in the United States, OT is the discipline in neurorehabilitation providing care related to visuospatial deficits, and is the discipline known to document the observable symptoms of spatial neglect, such as head and eye deviation. Thus, the present project was focused on integrating the two evidence-based protocols into inpatient OT (31–35). In addition, both the KF-NAP and KF-PAT were developed in and for the inpatient rehabilitation care through studies and clinical trials with much involvement of occupational therapists (OTs) (31–35). In the present project, we trained as many OTs as possible using both tools in their regular practices as the means to achieve our overall objective (i.e., to implement both tools) and move closer to our ultimate goal (i.e., to improve spatial neglect care).

MATERIALS AND METHODS

Participants and Setting

Sixteen inpatient rehabilitation facilities (IRFs) across 11 different states in the United States participated in this assessment and treatment implementation project through an agreement with the research center in New Jersey. The agreement included OT training and de-identified clinical information sharing. Twelve sites were on the East Coast (New Jersey, Ohio, Florida, Pennsylvania, Georgia, Maryland, New York), one on the West Coast (California), two in the Southwest (Texas, Arizona) and one in the Midwest (Missouri). The project was approved by the research center's Institutional Review Board (IRB) and the local IRB of each hospital that had a research infrastructure. IRFs without a research infrastructure were attached to the research center's IRB protocol through a federal assurance agreement. Directors of rehabilitation at each site nominated one or two lead OTs (i.e., implementation champions) for project participation. A total of 32 champions were trained to use the KF-NAP and KF-PAT throughout the project. They implemented the protocols in their practice, participated in monthly calls, tracked information regarding implementation,

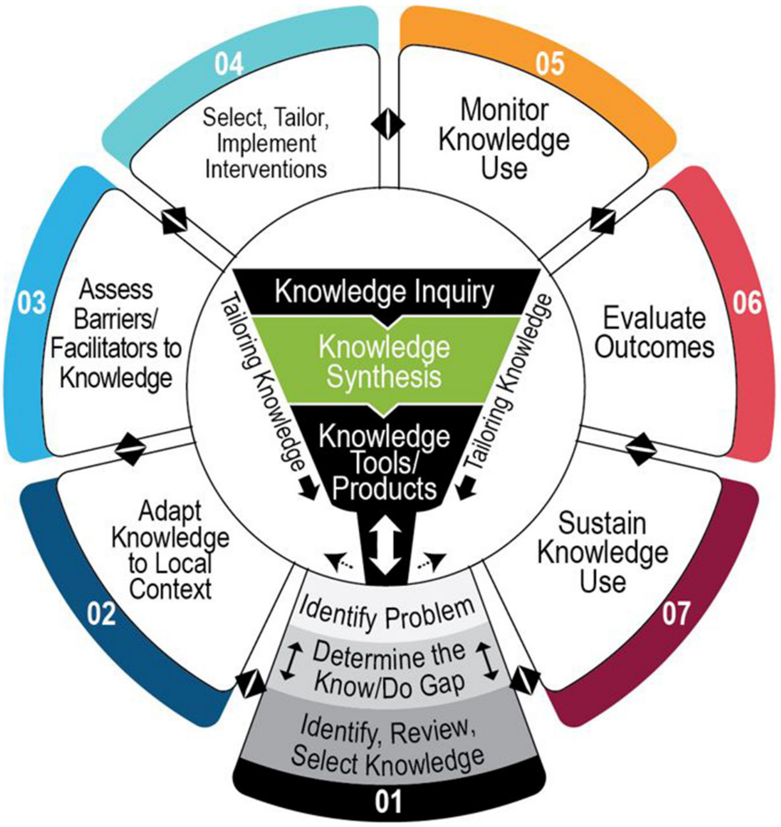

FIGURE 1 | Knowledge-to-action cycle. Adapted from Graham et al. (20) and phases are numbered in this version was our iteration.

provided feedback to the research center, and were encouraged to train their peers. The implementation information being tracked included de-identified patient clinical records. Patient outcomes were reported separately (36, 37).

The project was initiated in June 2017, and the therapist user feedback completed in March 2021 marking the end of the project. OTs at three sites that had participated in our previous research (31–35) and KF-NAP and KF-PAT development were more familiar with either tools than OTs at other sites. OTs at sites that joined the project earlier might be more experienced with either tool than OTs at sites that joined the project later over the years. While the project was not designed as a research study, lead OTs served as "study participants," representing their sites, in the user feedback survey at the end of project, and the consent form was waived. Evaluation of the implementation outcomes was based on responses to the survey and information shared about de-identified clinical records.

Procedures

Following the KTA cycle (**Figure 1**), the research team led and was actively involved with hospital management leaders and clinicians in the knowledge dissemination (center of the KTA cycle), protocol implementation (Phase 1 to Phase 5), and outcome evaluation (Phase 6). ***Knowledge*** here refers to the two protocols of the KF-NAP and the KF-PAT. Phase 6 required the research team to step back and conduct outcome evaluations. This project did not move into Phase 7.

Knowledge Dissemination

Knowledge dissemination involved the lead OTs participating in a formal 2-day training. The training took place at either the research center, the IRF where the OTs worked, or a specified IRF that would host a few groups of OTs at the same time. Sixty percentage of the lead OTs received the training at their sites, and the remaining 40% traveled to the location where the training was provided. Completing the training would enable them to reach Level 2 of competency on both protocols (**Table 1**), and they were instructed and encouraged to fulfill the requirements for the highest level of competency (Level 3) on their own. Level 3 competency would qualify the therapists to be able to teach their colleagues how to administer the KF-NAP or KF-PAT. This entailed using **Table 1**'s criteria to guide the training process. For example, the trainer scheduled time for each therapist to first observe them completing each protocol, and then had the trainees perform the assessment and treatment protocols under supervision.

The 2-day training was taught by the same members of the research team, who developed the protocols and have

TABLE 1 | Competency levels and criteria.

Level	KF-NAP	KF-PAT
Level 1	Competence to administer the KF-NAP. • Observing Trainer's administration with at least 1 patient. • Creating the environment for KF-NAP. • Assessing the 10 functional activities in no more than one visit.	Competence to administer the KF-PAT. • Having read the KF-PAT Manual. • Observing Trainer's administration with at least 1 patient. • Under Trainer's instruction and supervision, performing at least 1 session with an actor patient.
Level 2	Competence to score the CBS following the KF-NAP. • Observing Trainer's scoring with at least 1 patient. • Scoring at least 2 patients with Trainer's supervision.	Competence to treat patients using the KF-PAT. • Under Trainer's supervision, performing at least 2 sessions with patients.
Level 3	Competence to train other therapists to use the KF-NAP. • Having assessed and scored at least 10 patients independently. • Creating the environment for KF-NAP in a novel environment (e.g., examination room).	Competence to train other therapists to use the KF-PAT. • Having treated at least 5 patients independently.

therefore extensive knowledge on the topic of spatial neglect. The curriculum started with didactics about spatial neglect and then the two protocols, hands-on practice using both protocols under the trainer's supervision and ended with discussions on implementation. The lead OTs were provided training materials including the Manuals, lecture handouts, and pre-recorded video tutorials. Fidelity of both the assessment and intervention were discussed when these materials were being distributed. This discussion included that the Manuals were mandatory to use, the training of other staff members must include the lecture handouts, video tutorials should be reviewed prior to the in-person supervision and hands-on-training, and competency forms should be used. The lead OTs were also instructed about how the ways in which to communicate with the research team.

In addition, the research team offered lectures to other disciplines of therapists, medical staff, case managers, and trainees during new employee trainings, regular staff meetings, and schedule meetings outside of working hours. The lectures focused on the mechanisms, clinical presentations, and consequences of spatial neglect. These knowledge dissemination activities were developed to help coworkers of the OTs understand why the KF-NAP and KF-PAT were being implemented in their facilities. Thus, consistent with "culture," a construct of the inner setting domain within the CFIR framework, an environment friendly for spatial neglect care was cultivated, potentially beneficial for the implementation project.

Implementation Process

Daily Practice and Frequent Communications

After the training, the lead OTs returned to their daily clinical activities and started to gain experience by completing the protocols independently with their own patient case load. They were instructed to assess all neurological patients for spatial neglect using the KF-NAP within 4 days after admission, regardless of whether patients' symptoms were clearly observable or not. In addition, the lead OTs were also instructed to treat patients using the KF-PAT Portable Kit[1] when spatial neglect was confirmed through the KF-NAP, and assess these patients using the KF-NAP again after completing 10 sessions of PAT or before IRF discharge.

In addition to implementing both the KF-NAP and the KF-PAT in their clinical practice, the lead OTs were asked to document why the assessment and treatment sessions were not performed or performed in a way deviated from the standardized manuals. The research team provided a spreadsheet template to the lead OTs and required that it be filled out with de-identified clinical records of patients who were assessed using the KF-NAP and who were treated using the KF-PAT. The spreadsheet was submitted to the research team every quarter. This spreadsheet was one way that the barriers to implementation and strategies trialed were communicated. The other way was during the monthly calls.

The research team hosted monthly 1-h conference calls with all participating IRFs, represented by the lead OTs. This is an example of the KTA cycle being used to monitor outcomes. A total of 37 conference calls were conducted from June 2017 to September 2020, and they were recorded to document the meeting and later used to create meeting minutes. These minutes were shared via email to all attendees and the lead OTs who were not able to attend. During the calls, the OTs and the research team had the opportunity to share progress related to the training and implementation. The OTs shared any facilitators or barriers implementing either protocol that they may have listed in their spreadsheet or that were new and therefore being reported for the first time. For example, a facilitator was that OTs exchanged experiences about obtaining leadership support when integrating both protocols into their clinical practice. Barriers often shared were related to managing time and resources. When a barrier was shared, other OTs on the call would offer suggestions that worked or did not work for them, and the research team would help determine a resolution. However, if no resolution was suggested during the call or if the solution suggested was not agreed upon, the research team would follow up with the clinicians and sometimes their supervisors after the call. The OTs were encouraged to contact the research team via email at any time for further questions and comments. The calls also allowed the research team to clarify details in the assessment or treatment protocols that might have been forgotten from the training. In addition, starting at the June 2018 meeting, the research team

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[1] KF-PAT Portable Kit, Stoelting, 620 Wheat Lane, Wood Dale, IL, USA 60191.

would ask an OT to share a patient case to the group. The cases presented usually included a short medical history and details of either protocol used with that patient. The attendees could offer their comments and asked questions. The sharing of cases facilitated engagement during the meetings as well as encouraged discussions and comradery.

Engaging Other Stakeholders

While the project was focused on integrating the evidence-based protocols into the OT's clinical practice, there were other stakeholders who played significant roles. Because the OTs were involved in the implementation project, there were increased discussions about spatial neglect during care team meetings attended by all disciplines that provided medical and therapy services. In addition, other disciplines were able to easily and informally observe how the KF-NAP and KF-PAT were administered in spaces shared by all disciplines. Also, at several participating sites, the OTs conducted in-services with physicians, nurses, and nutrition staff to share information about this implementation project. This involvement of multiple disciplines could be one action that facilitated the implementation progress, especially in Phase 3 and Phase 4 of the KTA cycle (**Figure 1**). Also, the IRF administrative leadership were engaged in discussions with the Chief Executive Officers and supported the implementation of both protocols after reviewing implementation goals of the project. Directors of Rehabilitation were informed with the project progress and were encouraged to offer comments and suggestions throughout the project.

Addressing Barriers

The implementation procedures evolved and adapted to different hospital contexts as we continuously learned from OTs' experience using either KF-NAP or KF-PAT protocol with patients and interacting with their colleagues, and from administrators' guidance on hospital regulatory and operational standards. From time to time, a situation would occur that was not expected, or a solution was not immediately available, and we classified the situation as a ***barrier***. When barriers were identified, via verbal or written report, then strategies were carefully customized based on the needs of the setting, and then implemented. A strategy and related actions were decided and executed based on the available resources and contextual situations at the time, usually right after the barrier was identified, rather than based on a pre-determined decision-making roadmap. We followed the CFIR framework (22) to organize the identified barriers and summarize strategies and actions taken to eliminate the barriers (**Table 2**). Barriers were identified in 4 of the 5 CFIR domains. In these domains, there were no identified barriers in some constructs, but a number of barriers in other constructs. Throughout the process, two limiting factors—time and staff—emerged frequently across different constructs and domains. Time was limited against the administration of the KF-NAP and KF-PAT. Shortage of trained staff trained on the two protocols was a common barrier to assessing all patients with neurological conditions and treating patients with spatial neglect. Collaborating with clinicians and their managers, we offered potential solutions. Some of the barriers identified were resolved shortly such as those identified in the Intervention Characteristics domain (Domain I, **Table 2**), some barriers ultimately required multiple strategies to fully address the problem such as those identified in the Inner Setting domain (Domain III), and others remained challenging such as several barriers identified in the Process domain (Domain V).

Implementation Outcomes

We evaluated the implementation outcomes using quantitative and qualitative information that was collected during the 4-year period. The study also included collecting patient outcomes, which was reported separately (36, 37).

Numbers of Therapists Trained and Patients Receiving the Care

We used the number of OTs trained to indicate the success of knowledge dissemination and the number of patients receiving spatial neglect care through either the KF-NAP or KF-PAT to indicate the success of knowledge implementation. In April 2020, the research team asked the lead OTs to report the number of therapists they trained on both protocols, and what competency level they reached. In November 2020, we completed the collection of de-identified clinical records shared by participating sites. Note that patient outcomes (i.e., improvement in spatial neglect and rehabilitation outcomes) were reported in separate articles (36, 37).

Lead OTs were interviewed to provide context of the number of therapists trained and the number of patients receiving spatial neglect care. Responses to the interviews were summarized in writing with no audio records. Interview responses were reviewed by Authors PC and CGS.

User Feedback Survey

After the last monthly call (September 2020), a survey was sent to the lead OTs via an online platform, Survey Gizmo. The OTs were asked to report on the IRF that they represented, based on their own experience. See the survey in **Appendix 1**. The goal was to identify any sustaining barriers and additional facilitators to implementing either protocol now that the research team stepped back. Categorical responses were summarized and described in percentages. The qualitative answers were reviewed by Authors KH, PC, and CGS to enable the identification of emerged categories. We each separately read the data to determine reoccurring information, discussed and compared notes via conference calls and came to an agreement on how to code the data into similar groups or categories.

RESULTS

Number of Therapists Trained

Table 3 reports that overall, 169 OTs at the participating sites were trained to some level of the KF-NAP, and among them, 81 (47.9%) reached the highest level (level 3) of competency. One hundred forty-one OTs were trained for the KF-PAT, and 110 (78.0%) reached the highest level of competency. Site 9 reported that they only implemented the KF-NAP at the beginning of

TABLE 2 | Barrier assessment by the Consolidated Framework for Implementation Research (CFIR) with actions to remove the barrier.

Domain I: Intervention characteristics (Key attributes of interventions, i.e., KF-NAP® and KF-PAT®, that influence the success of implementation).
No barrier was identified in four constructs including **intervention source** (stakeholder perception about whether the intervention is externally or internally developed), **evidence strengthen and quality** (stakeholder perception of the quality and validity of evidence supporting the belief that the intervention will have desired outcomes), **relative advantage** (stakeholder perception of the advantage of implementing the intervention vs. an alternative solution), and **trialability** (the ability to test the intervention on a small scale in the organization, and to be able to reverse course if warranted).

Construct (definition)	Barrier	Strategy and actions to remove the barrier
Adaptability (The degree to which an intervention can be adapted, tailored, refined, or reinvented to meet local needs)	• KF-NAP assessment: ○ Time limitation against adding a new assessment protocol ○ Determining best time to complete the assessment during the admission and before discharge • KF-PAT treatment: ○ Set-up time ○ Patients with varied medical, physical, cognitive, and neuropsychological conditions (also see Domain II: Outer Setting, the construct of Patient Needs and Resources)	• KF-NAP assessment: ○ Suggestions made to integrate KF-NAP with conventional ADL assessment in the morning to increase the efficiency of time allocation ○ Instruction added to complete the assessment by Day 4 from admission date (giving patients time to be acclimated to the facility) and give enough time for treatment to be complete ○ Suggestions made to prioritize KF-NAP assessment after KF-PAT completion or the day before discharge • KF-PAT treatment: ○ Solutions provided to reduce the set-up time, such as allowing assistance of therapy aides to set up the equipment and laminating the stimulus sheets. ○ Instructions refined and clarified in the manuals for how to provide commands and when to skip a task and move on. ○ Suggestion to consult with optometry if the person was prescribed with optical lenses. Reading glasses can be used under the prism lens, if necessary.
Complexity (Perceived difficulty of implementation, reflected by duration, scope, radicalness, disruptiveness, centrality, and intricacy, and number of steps required to implement)	• KF-NAP assessment: ○ Time limitation against completing all 10 items. • KF-PAT treatment: ○ Hesitance of some neuro-optometrists who were unfamiliar with the intervention. ○ Time limitation against fitting the treatment into an OT therapy session	• KF-NAP assessment: ○ In-person instructor-guided assessment practice to demonstrate how to complete all 10 items in one session. ○ Suggested actions to take in order to decrease assessment time based on the facilities' unique needs. • KF-PAT treatment: ○ Invitations to neuro-optometrists to discuss the treatment mechanisms and why the KF-PAT is within the scope of OT ○ In-person instructor-guided treatment practice to demonstrate how to fit the treatment into regular OT sessions
Design quality and packaging (Perceived excellence in how the intervention is bundled, presented, and assembled)	• KF-NAP assessment: ○ The booklet of the manual was not easy to carry around when administering the assessment. • KF-PAT treatment: ○ Equipment assembly not always intuitive. ○ Device not fit on patients with a much smaller or larger body size. ○ Frequent wear and tear of the equipment	• KF-NAP assessment: ○ A two-page double-side-printed shortened 'cheat sheet' was developed. • KF-PAT treatment: ○ Added pictures to the manual and production of short video clips showing how to set up the equipment. ○ The visual field occluder (the wearable shelf) was modified to accommodate a wider range of body sizes. ○ Device repairs and replacement were provided.
Cost (Costs of the intervention, and costs associated with implementing the intervention, including investment, supply and opportunity costs)	• KF-NAP assessment: ○ Limited budget for staff training • KF-PAT treatment: ○ Did not have the equipment	• KF-NAP assessment: ○ Provision of 100% discount to the online tutorial ○ Free email and phone consultation ○ Support from the management to provide travel funds for therapists to attend in-person hands-on trainings • KF-PAT treatment: ○ The equipment was loaned to the sites by the research team, as part of the research agreement

Domain II: Outer setting (The economic, political, and social context within which an organization resides).
No barrier was identified in three constructs including **cosmopolitanism** (the degree to which an organization is networked with other external organizations), **peer pressure** (mimetic or competitive pressure to implement an intervention), and **external policies and incentives** (a broad construct that includes external strategies to spread interventions).

Construct (definition)	Barrier	Strategy/action used to remove the barrier
Patient needs and resources (The extent to which patient needs, as well as barriers and facilitators to meet those needs, are accurately known and prioritized by the organization)	• KF-NAP assessment: ○ Not all 10 items were scored in certain patients due to physical disabilities or cognitive impairment.	• KF-NAP assessment: ○ Solutions and in-person demonstrations regarding how to build a rapport with patients, observe neglect symptoms, and score as many items as possible

(Continued)

TABLE 2 | Continued

Construct (definition)	Barrier	Strategy/action used to remove the barrier
	○ Some patients refused to comply with the assessment protocol. For example, not feeling comfortable being observed when having a meal • KF-PAT treatment: ○ Unable to follow commands due to severe neglect symptoms ○ Unable to follow commands due to language barriers in non-English-speaking patients ○ Unable to use certain equipment components as intended due to physical disabilities ○ Unable to tolerate the prism goggles (e.g., feeling dizzy or seeing doubles due to optical shifts, too much physical pressure on the head by the goggles for patients who wear a helmet)	• KF-PAT treatment: ○ Solutions and in-person demonstrations regarding how to work with patients with severe neglect symptoms ○ Simplified directions and gesturing to work with non-English-speaking patients ○ Device modifications and alternative ways of putting on goggles to allow most patients to participate in the treatment

Domain III: Inner setting (Features of structural, political, and cultural contexts through which the implementation process will proceed).
No barrier was identified in one construct, which was **structural characteristics** (the social architecture, age, maturity, and size of an organization).

Construct (definition)	Barrier	Strategy/action used to remove the barrier
Networks and communications (The nature and quality of webs of social networks, and the nature and quality of formal and informal communications within an organization)	• Miscommunication and confusion with the implementation process • Research documentation including activities completed by the therapists were disorganized • Outdated knowledge on the mechanisms and presentations of spatial neglect. For example, the disorder was often referred by clinicians as "visual neglect" and thus PAT was incorrectly considered a vision therapy	• Standardization of both protocols to establish what must be followed and what can be modified • Solutions provided to improve the organization of information and the quality of the communication • Provision of additional education sessions from the researchers to clarify the principles of KF-NAP and KF-PAT and what spatial neglect is, from neurological and neuropsychological mechanisms to clinical presentations
Culture (Norms, values, and basic assumptions of a given organization)	• Profitability unknown	• Production of an information brochure about spatial neglect and KF-PAT treatment, targeted at potential clients (patients and their family members) • New research projects designed to examine to what extent the implementation of KF-NAP and KF-PAT reduces cost while improving quality of care

Implementation climate
(The absorptive capacity for change, shared receptivity of involved individuals to an intervention, and the extent to which the use of the intervention will be rewarded, supported, expected within their organization).
No barrier was identified in three sub-constructs including **compatibility** (the degree of tangible fit between meaning and values attached to the intervention by involved individuals, how those align with individuals' own norms, values, and perceived risks and needs, and how the intervention fits with existing workflows and systems), **goals and feedback** (the degree to which goals are clearly communicated, acted upon, and fed back to staff, and alignment of that feedback with goals), and **learning climate** (a climate in which: leaders express their own fallibility and need for team members' assistance and input; team members feel that they are essential, valued, and knowledgeable partners in the change process; individuals feel psychologically safe to try new methods; and there is sufficient time and space for reflective thinking and evaluation).

Sub-construct (definition)	Barrier	Strategy/action used to remove the barrier
Tension for change (The degree to which stakeholders perceive the current situation as intolerable or needing change)	• Competing demands in the therapy departments, self-initiative of the therapists to use the protocols consistently	• Frequent communications with the IRF management highlighting that these protocols would provide guidance for staff, and the potential impact of the implementation on quality of care
Relative priority (Individuals' shared perception of the importance of the implementation within the organization)	• KF-NAP assessment: ○ Some therapists prioritized the administration of KF-NAP in patients who already showed neglect symptoms • KF-PAT treatment: ○ Some therapists did not provide KF-PAT to patients with "very mild" neglect	• KF-NAP assessment: ○ Frequent reminders during staff training and monthly calls that it was of great importance to assess all patients with neurological conditions because certain symptoms were not apparent. It was also important to confirm the absence of spatial neglect.

(Continued)

TABLE 2 | Continued

Sub-construct (definition)	Barrier	Strategy/action used to remove the barrier
	○ Some therapists prioritized other treatment than KF-PAT in patients whose length of stay was pre-determined to be shorter than 10 days	• KF-PAT treatment: ○ Frequently discussed during monthly calls regarding the factors to be considered in initiating and completing the treatment.
Organizational incentives and rewards (Extrinsic incentives such as goal-sharing awards, performance reviews, promotions, and raises in salary, and less tangible incentives such as increased stature or respect)	• No competency measure existed as well as no specific incentive to participate in the research project	• Free meal if training lectures were offered during the lunch hour • Development of competency certification processes for both KF-NAP and KF-PAT such that certificates could be added to therapists' profiles, which may help promotion • Participation in the research was an approved task that counted toward clinical promotion

Readiness for implementation (Tangible and immediate indicators of organizational commitment to its decision to implement an intervention).
No barrier was identified in one sub-construct, which was **access to knowledge & information** (ease of access to digestible information and knowledge about the intervention and how to incorporate it into work tasks).

Sub-construct (definition)	Barrier	Strategy/action used to remove the barrier
Leadership engagement (Commitment, involvement, and accountability of leaders and managers with the implementation)	• A few sites were slow in executing the collaborative agreement with the research team, delaying the initiation of the project • Some sites were under leadership changes during the project • Several sites were at the relatively early stage of hospital development	• Increased frequency of communications with the IRF management • Seeking assistance from the Reginal management team
Available resources (The level of resources dedicated for implementation and on-going operations)	• Limited budget for outside staff training • Limited time allocated for lead OTs to train other OTs • No budget to acquire KF-PAT equipment additional to the initial one provided by the research team	• Provision of 100% discount to the online KF-NAP tutorial • Free email and phone consultation • Support from the management to provide travel funds for therapists to attend in-person hands-on trainings • Collaboration between researchers and IRF leaders to improve the staff training capacity for the goal of assessing all neurological patients and treating all patients with spatial neglect with prism adaptation • Working with the IRF management to understand the threshold for capital purchase requests

Domain IV: Characteristics of individuals (Characteristics of OTs implementing KF-NAP® and KF-PAT®).
No barrier was identified in all five constructs including **knowledge and beliefs about the intervention** (individuals' attitudes toward and value placed on the intervention as well as familiarity with facts, truths, and principles related to the intervention), **self-efficacy** (individual belief in their own capabilities to execute courses of action to achieve implementation goals), **individual stage of change** (characterization of the phase an individual is in, as he or she progresses toward skilled, enthusiastic, and sustained use of the intervention), **individual identification with organization** (a broad construct related to how individuals perceive the organization, and their relationship and degree of commitment with that organization), and **other personal attributes** (a broad construct to include other personal traits such as intellectual ability, motivation, values, competence, capacity and learning style).

Domain V: Process (Essential activities of implementation process).
No barrier was identified in one construct, which was **planning** (the degree to which a scheme or method of behavior and tasks for implementing an intervention are developed in advance, and the quality of those schemes or methods).

Construct (definition)	Barrier	Strategy/action used to remove the barrier
Executing (Carrying out or accomplishing the implementation according to plan)	• Initial lead OTs left the position or were on medical leave • Not all OTs were trained to administer the KF-NAP or KF-PAT	• Collaboration between researchers and IRF leaders to improve the staff training capacity ○ Training experienced and enthusiastic therapists to become lead OTs and trainers ○ Developing remote education modules
Reflecting and evaluating (Quantitative and qualitative feedback about the progress and quality of implementation accompanied with regular personal and team debriefing about progress and experience)	• Infrequent feedback provided from therapists who did the frontline work of implementation	• Centralizing the information related to the progress and outcomes of the KF-NAP and KF-PAT implementation at the research team, who summarized and shared the information periodically to lead therapists and their supervisors of all campuses

Engaging (Attracting and involving appropriate individuals in the implementation and use of the intervention through a combined strategy of social marketing, education, role modeling, training, and other similar activities).
No barrier was identified in two sub-constructs including **formally appointed internal implementation leaders** (individuals from within the organization who have been formally appointed with responsibility for implementing an intervention as coordinator, project manager, team leader, or other similar roles) and **champions** (individuals

(Continued)

TABLE 2 | Continued

Sub-construct (definition)	Barrier	Strategy/action used to remove the barrier
who dedicate themselves to supporting, marketing, and driving through an implementation, overcoming indifference or resistance that the intervention may provoke in an organization).		
Opinion leaders (Individuals in an organization who have formal or informal influence on the attitudes and beliefs of their colleagues with respect to implementing the intervention)	• KF-NAP assessment: No barrier identified • KF-PAT treatment: ○ Hesitance of some neuro-optometrists who were unfamiliar with the intervention.	• KF-NAP assessment: Not applicable • KF-PAT treatment: Invitations to neuro-optometrists for discussing the treatment mechanisms
External change agents (Individuals who are affiliated with an outside entity who formally influence or facilitate intervention decisions in a desirable direction)	• Length of stay may be shorter than anticipated	• Therapists were instructed to start the treatment very soon after admission, to be able to have as much treatment as possible provided

This qualitative analysis was based on verbal reports and informal observations during (rather than after) the implementation process. Each identified barrier may represent one therapist's experience, a few participating site's situation, or a general observation of almost all participating sites. ADL, activities of daily living; IRF, inpatient rehabilitation facility; OT, occupational therapist.

the project and decided not to continue because an ongoing study was using the CBS following the original non-standardized questionnaire format (38). Nonetheless, Site 9 continued using the KF-PAT in their care.

Number of Patients Receiving Care

OTs assessed a total of 4,454 patients for spatial neglect using the KF-NAP, and 2,491 (56%) of them had the syndrome. 1,078 (43%) of the patients with spatial neglect were treated using the KF-PAT for at least one session.

To understand why more than half of the patients with spatial neglect did not receive PAT, we had discussions with the lead OTs during the conference calls and reviewed the OT's field notes in the de-identified clinical records in order to determine categories. Also, while the COVID pandemic led to a long pause in 2020 of no treatment using the KF-PAT Portable Kits across all participating sites, there were various factors that contributed to different implementation rates of either protocol in different sites, and therefore We classified the 15 participating sites (excluding Site 9) into three categories: early adopters, additional trained staff needed, and developing facilities.

Five sites (Sites 1, 2, 3, 4, and 6) were the first sites to be trained (aka early adopters). Therefore, many staff OTs, in addition to the implementation champions (lead OTs), were trained during the project. Although the rate of lead OT changes was 50% among these first trained sites, the other OTs were able to step up and take on the lead OT roles. These five sites collectively assessed 3,698 (83%) of all assessed patients and treated 783 (73%) of all treated patients across 16 sites. Based on the shared clinical records, the median CBS scores of PAT-untreated patients at these sites ranged from 2.5 to 3.75, which is a mild level of severity. In the de-identified clinical records and field notes, OTs reported that other deficits such as upper extremity impairment, rather than spatial neglect, was prioritized in OT sessions because the neglect was not severe.

Eight sites (Sites 5, 7, 8, 10, 12, 13, 15, and 16) were classified as "additional trained staff needed." The median CBS scores of PAT-untreated patients at these sites ranged from 7.5 to 17.38, which is a wide range covering all levels of neglect severity. These sites relied on their lead OTs to implement both protocols while other OTs may or may not have integrated either protocol in their practice. Thus, only patients under lead OTs' care were assessed for spatial neglect, and other OTs who were not trained on the KF-NAP themselves, had to refer patients with neglect signs on their caseloads to the lead OTs for KF-NAP assessment. This indicated that patients whose neglect symptoms were less apparent may have not been identified and therefore not referred. Furthermore, not all patients who were confirmed with spatial neglect received PAT because the work load was too high for the lead OTs. Sites reported in field notes: "we do not have time to train other therapists in these protocols because of other responsibilities." In addition, when a lead OT left, there was a lag in time during the transition and thus the average 45% change rate of implementation champions among these sites became a significant barrier. These eight sites planned to have additional staff trained early in Year 2020, which however was soon on pause due to the COVID pandemic. The pandemic caused particular challenges for Sites 15 and 16 who had joined the project a few months prior to the shutdown of research activities.

Lastly, four sites fell into the category of "developing facilities." The management team was at the early stage of development in Sites 15 and 16 (also classified as "additional trained staff needed") and Sites 11 and 14. These sites were having a hospital-wide staffing call, in order to recruit more therapist to work at their hospitals. Therefore, the combination of situations resulted in low numbers of identified individuals with neglect. That is, the infra-structure was not ready to fully support the implementation project.

User Feedback Survey

Fifteen sites (93.75%) responded to the User Feedback survey. The quantitative aspect of the survey results was summarized in **Figure 2**. Multiple responses to open-ended questions were able to be categorized. First, the top three barriers related to the KF-NAP not being administered 100% of the time were: (1) lack of time to train the rest of staff on unit to perform the assessment, (2) patients being discharged earlier than expected, and (3) patients requiring other considerations at discharge such as extensive family training. It was also reported by multiple individuals that patients at multiple sites did not always receive

TABLE 3 | Participating rehabilitation hospitals and occupational therapists (OTs) trained.

Site ID	Location (State)	Trained on site	Number of patients assessed using the KF-NAP®	Number of patients with spatial neglect	Number of patients treated with the KF-PAT® for at least one session	Number of OTs trained (over the period from June 2017 to April 2020)								Lead OT change rate (number trained divided by number of therapists who left)	Monthly call attendance rate
						Competency level of the KF-NAP®				Competency level of the KF-PAT®					
						Any level*	1	2	3	Any level*	1	2	3		
1	NJ	x	1,002	610	168	17	0	10	7	17	0	0	17	100%	73%
2	NJ	x	528	314	149	12	1	8	3	12	0	0	12	50%	73%
3	NJ	x	856	276	31	32	0	2	9	14	1	3	6	0%	73%
4	NJ	x	647	466	240	23	0	4	20	22	0	3	19	100%	86%
5	OH		82	79	30	6	0	0	6	4	0	0	4	100%	73%
6	PA		666	294	195	10	0	0	10	9	0	1	8	0%	86%
7	FL	x	239	77	64	6	0	2	1	3	0	2	1	0%	70%
8	MO		159	129	51	13	0	11	2	13	0	0	13	0%	81%
9	NY		17	16	14	4	0	0	4	4	0	0	4	100%	62%
10	MD	x	55	54	41	9	0	3	6	9	0	3	6	0%	91%
11	AZ		41	37	30	9	0	6	3	9	0	6	3	100%	95%
12	CA		13	11	6	2	0	0	2	2	0	0	2	67%	91%
13	GA	x	29	29	14	5	0	5	0	5	0	0	5	50%	78%
14	TX		49	29	9	6	1	4	1	3	2	0	1	0%	79%
15	OH		67	66	34	11	2	4	5	13	3	3	7	50%	47%
16	OH		4	4	2	4	2	0	2	2	0	0	2	0%	100%
	Total	7	4,454	2,491	1,078	169	6	59	81	141	6	21	110	45% (average)	79% (average)

*Sites that were not trained on site sent lead OTs to training sites. *Any level trained included therapists at level 1, 2, or 3 and therapists whose competency records were not available.*

all 10 KF-PAT sessions because of three reasons, categorized as: (1) short length of stay, (2) other clinical goals being prioritized, and (3) a lack of trained staff to assist with carrying out all 10 sessions. Besides the implementation of the two protocols, responses on the other aspects of the project included categories: (1) time consuming research documentation, (2) helpful monthly conference calls, and (3) supportive leadership.

DISCUSSION

There is still work to be done related to translating research into practice and decreasing the research-to-practice gap in the rehabilitation settings despite many efforts being made by many teams (26, 28). The shorter time it takes for the latest evidence to be applied to clinical practice, the greater chance for patients to receive better care (39). This manuscript highlights an implementation project that used the KTA cycle as the process model to assist the transfer of scientific knowledge into clinical practice. Specifically, the KTA cycle helped to guide the project development, report the results and provide specific information for future reproducibility. The CFIR was another implementation tool that was used in this project to assist with the categorization of barriers identified as well as provided a way to organize strategies that were trialed. Similar to others conducting rehabilitation implementation research (26), we found the use of the frameworks to be a strength of the study because the researcher-clinician team had a "road map" to guide implementation of the protocols as well as evaluate outcomes of the implementation.

The close collaboration between researchers and clinicians was key to achieve knowledge translation. The research team and the OTs had frequent communications through the de-identified clinical records and the monthly conference calls. This suggests that rather than a one-way, top-down instruction provision from the research team to the OTs, participants worked together and modified certain aspects on how to administer the KF-NAP and KF-PAT at specific sites. This is one example of how we used the KTA cycle and made an adaptation to fit the local context. However, it was important to the researchers that the core elements of both protocols remained unchanged, in other words, fidelity was maintained. For instance, regarding the KF-NAP protocol, as long as the therapist assessed tasks that relate to skin care or hair care (including facial) then they could be creative to what they ask the patient to complete (e.g., applying makeup instead of washing their face, which is the task suggested in the manual).

Most barriers identified during the implementation process were aligned with previous studies that offered reasons for the difficulties in knowledge translation and evidence-based practice (EBP) implementation in stroke care and rehabilitation (16, 40). One barrier, however, was unexpected. This was when consulting neuro-optometrists questioned whether administering PAT was within the scope of OT practice. The strategy addressing this barrier was to be collaborative, transparent, and be open to inter-professional learning. More specifically, the research team-initiated discussions with the neuro-optometrists about the mechanisms of prism adaptation and offered treatment demonstrations to share the procedures of the KF-PAT. Both KF-NAP and KF-PAT protocols were in use as part of clinical practice by the end of the implementation period. This suggests the tools were accepted by the OTs and adopted into the standard of care (41).

Another interesting finding was that focusing on a single discipline has the potential to change the overall quality of care in the multidisciplinary inpatient rehabilitation system. Shown in a prior study, only 31% of spatial neglect cases were mentioned in care team meetings, which potentially impeded provision of comprehensive care to all patients with spatial neglect (42). In the present project, the change of OT practice via the implementation of both spatial neglect assessment and treatment protocols increased the awareness of spatial neglect care among other disciplines. The CBS scores via the KF-NAP (indicating severity of spatial neglect) and improvements observed after PAT were discussed during care team meetings attended by all disciplines that provided medical and therapy services. Other disciplines could observe the procedures of both protocols easily as OTs worked in the same space with them. Thus, a new vocabulary was created and understood by all the care team members. This became an inner-setting facilitator (22) that emerged during the implementation process, different from facilitators provided by the research team and hospital administrative leaderships. Thus, the researcher-clinician collaboration is critical to initiate knowledge translation, and clinician buy-in and subsequent spontaneous inter-disciplinary communications are essential to strengthen the translation.

The therapists' time to complete the assessment and treatment was a limitation and was the most reported barrier. For the KF-NAP, the difficulty was related to the second (i.e., "post-treatment") assessment, which is essential in order to measure changes in spatial neglect severity from before to after treatment. The second assessment which was to occur before the patients' discharge was difficult to administer when scheduling conflicts occurred more often at discharge than at admission. Time limitation with the assessment also affected treatment delivery. As recommended by the KF-PAT protocol, patients should complete the full treatment course which includes 10 sessions. In the present project, OTs at several sites shared that they prioritized other therapy activities over PAT when knowing that there was insufficient time to provide the recommended 10 sessions of PAT. This is due to the fact that the length of stay is usually estimated and pre-determined by insurers. Extending approved length of stay in an inpatient rehab solely for the purpose of completing the KF-NAP protocol may be applicable for a small percentage of patients with private insurers. For patients covered by Medicare's prospective payment plan, the hospital may elect to extent a patient's length of stay if the interdisciplinary team feels the additional days to complete the protocol would outweigh benefits of the projected discharge date. Among 2019 Medicare beneficiaries, for example, the average length of stay is 17, 16, and 15 days for patients with stroke, traumatic brain injury, and non-traumatic brain injury, respectively. Even if patients are assessed using the KF-NAP within the first few days of admission, there may be <10 full treatment days for a therapist to provide the recommended 10 once-daily PAT sessions. This factor in addition to many other

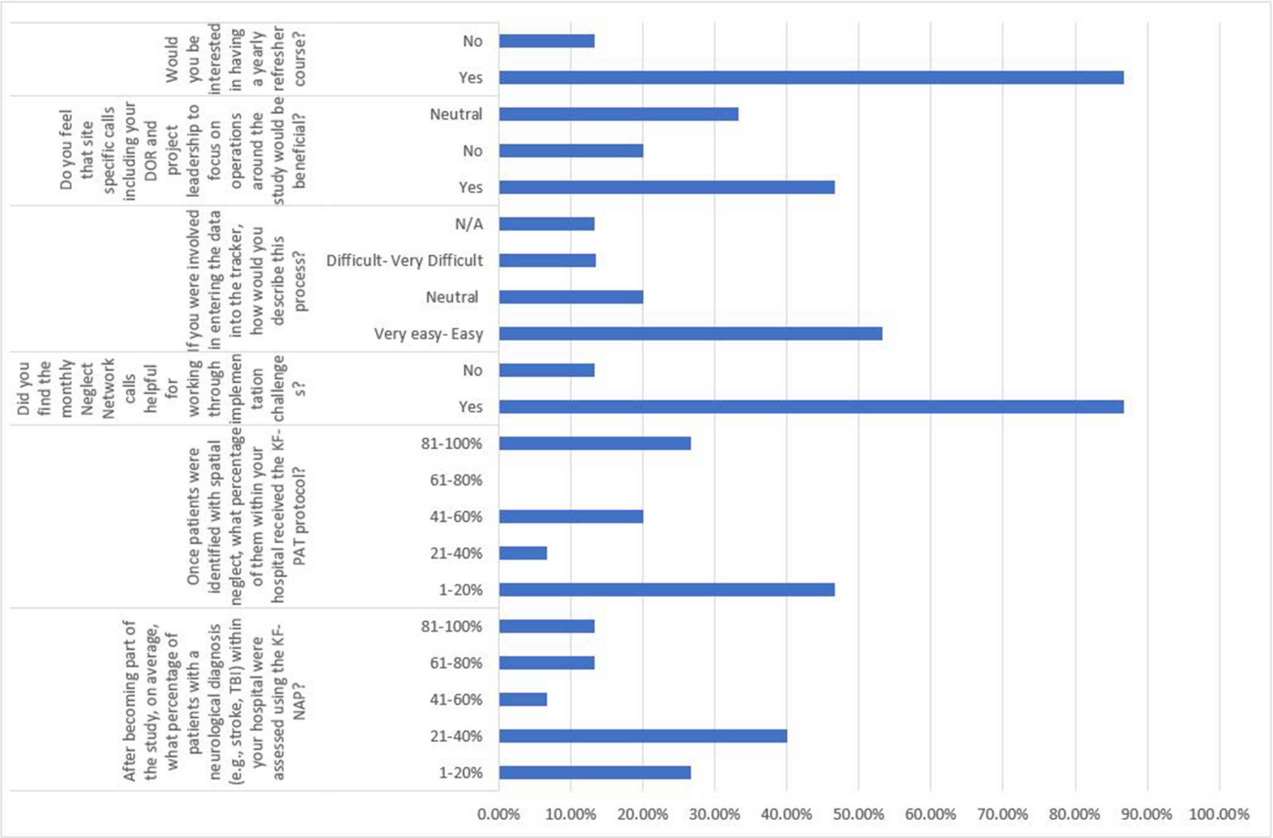

FIGURE 2 | Summary of quantitative survey results in percentage.

factors may contribute to a decision not to provide PAT to certain patients.

The limited number of trained OTs in either protocol was another major barrier. This seems inconsistent with the fact that about 170 therapists were trained to integrate the KF-NAP and about 140 therapists were trained to use the KF-PAT in their practice across 16 IRFs. However, 10 participating sites primarily relied on lead OTs in administering the protocols, Who were unable to train other OTs due to time constraints, other clinical duties, and factors related to readiness of certain hospitals. The overall 45% change rate of lead OTs created lags of researcher-clinician communication and further slowed down the implementation progress. Regarding user feedback, 46.7% of survey respondents reported that it would be beneficial to have meetings or calls with their individual leadership, so they could share any continued barriers and determine strategies together. Almost 90% of the survey respondents mentioned that they would be interested in a yearly refresher course, on both protocols. This may help sustain implementation and also ensure fidelity (43). Thus, after collectively providing spatial neglect care to more than 4,500 patients in the context of this implementation project, OTs saw the need of continuing implementing KF-NAP and KF-PAT in their practice.

Study Limitations

The project was initially driven by researchers and fueled by a collaborative effort shared by researchers and clinicians (including hospital administrative leaders). This is a strength but also the limitation of the project such that the outcomes may not be generalizable to facilities that have little access to researchers, especially researchers knowledgeable about implementation science. Another limitation was the inability to evaluate which strategies that were used toward eliminating a given barrier during the implementation process, had the best success rates vs. other strategies. It was not our priority to determine the best strategy but to offer solutions at the time when a barrier was present. Therefore, we cannot comment on the recommended strategies or which strategies should be trialed first. Further investigations formally testing outcomes such as feasibility, adoption and acceptability of delivering the protocols are needed to identify all the challenges to maintaining the implementation, and to determine how to overcome those challenges (43).

CONCLUSION

The project demonstrated a researcher-clinician partnership in not only knowledge generation but also knowledge translation (e.g., dissemination and implementation of knowledge to be applied clinically). Evidence-based protocols can be implemented through multiple, tireless iterations of barrier reduction and problem solving with active participation of practitioners and practical support from leaders. There were no unintended consequences of the implementation efforts. Frequent communications and exchanging information with stakeholders at different levels, may be determinant to the success of each implementation phase. The results of the present project appeared promising in EBP implementation for spatial neglect care. However, further efforts are needed to promote the persistent inclusion of EBP for spatial neglect as the standard of care in inpatient rehabilitation. We also suggest the following future implementation efforts: (1) a pre-trial consultation with organizational leadership could ensure that sufficient clinician time can be blocked out, and (2) enabling all staff to receive training and deliver the intervention with higher levels of fidelity.

DATA AVAILABILITY STATEMENT

The data is not available to be shared.

ETHICS STATEMENT

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

AUTHOR CONTRIBUTIONS

KH and PC designed the study, analyzed and interpreted the data, and then wrote the manuscript. PC, KH, and CG-S interpreted the qualitative component of the study. JM contributed to editing the manuscript and was essential in data collection efforts. CG-S was essential to study member recruitment and edits to the entire manuscript. AB was key to study design and edited the entire manuscript. RG edited the manuscript. All authors read and approved the final manuscript.

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SUPPLEMENTARY MATERIAL

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/frhs.2022.839517/full#supplementary-material

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Better safe than sorry: Evaluating the implementation process of a home-visitation intervention aimed at preventing unintentional childhood injuries in the hospital setting

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Background: Child home injuries prevention interventions have rarely been implemented in hospitals. The SHABI program ("Keeping our Children Safe"; in Hebrew: "SHomrim Al BetIchut Yeladenu") recruits at-risk families arriving with child injury to the Emergency Department. Medical/nursing students conduct two home visits four months apart, providing safety equipment and guidance. One hundred thirty-five families had a first visit and 98 completed the second. Fifty percentage of families were ultra-Orthodox Jews, 11% Arab, and 28% had $\geq$3 preschool children. We investigated SHABI's implementation using the Consolidated Framework for Implementation Research (CFIR).

Methods: Between May 2018 and March 2021 SHABI was implemented in the Emergency Department of a hospital in Israel's northern periphery, an area with high child injury rates. The Implementation process was examined through Emergency Department medical records and tracking registries, hospital management, nurses', and home visitors' meetings notes ($n = 9$), and a research diary. Hospital's inner setting and SHABI's characteristics were evaluated through interviews with hospital management, nurses, and home visitors 8 months after baseline ($n = 18$). Home visitors' characteristics were evaluated through interviews, post-visit questionnaire on challenges encountered ($n = 233$), families' perceptions of SHABI and home visitors' skills through telephone interviews ($n = 212$); and home visitors awareness of dangers at home ($n = 8$) baseline and 8 months later. Qualitative data were analyzed through explanatory content analysis according to CFIR constructs. Quantitative data were analyzed using X2 and Wilcoxon test for dependent subgroups.

Results: Despite alignment between SHABI and the hospital's mission, structural hospital-community disconnect prevented implementation as planned, requiring adaptation and collaboration with the medical school to overcome this barrier. Recruitment was included in the initial patient triage process but was only partially successful. Medical/nursing students were recruited as home visitors, and following training proved competent. Children were a distraction during the visits, but home visitors developed strategies to overcome this.

Conclusions: Injury prevention programs in hospitals have significant benefits. Identifying implementation barriers and facilitators allowed implementers to make adaptations and cope with the innovative implementation setting. Models of cooperation between hospital, community and other clinical settings should be further examined.

KEYWORDS

hospital-based intervention, pre-school children, home safety, injury prevention, home visit, implementation science, Consolidated Framework for Implementation Research

Introduction

Unintentional childhood injuries are a major worldwide health and healthcare concern (1–3). In the United States, almost two million children <5 years old are admitted annually to the Emergency Department following an unintentional injury (4). A sibling's previous admission due to an injury poses additional risk for a child's arrival at the Emergency Department for an injury (5). Yet, many of the injuries occurring in the home environment could have been prevented by improving home safety and increasing parental supervision (6, 7).

Over the years, a leading strategy for unintentional injury prevention employs parental guidance through home-visitation (8). Such interventions have been implemented mainly in community settings, such as primary care clinics (9, 10) or early childhood centers (11, 12). Interestingly, despite Emergency Department admittance rates and hospitals being central stakeholders for reducing child injuries, their role in injury prevention has been minimal and remains unclear.

Hospitals' perceptions on recurrent visits due to disease differ. Traditionally, interaction between the patient and hospital starts with seeking care for an illness, continues with treatment provided by the hospital, and results in recovery and discharge; once a patient is discharged, hospital responsibilities cease (13). In recent years, there have been efforts to reduce recurrent hospital visits for both adults (14) and children (15). This includes an expansion in hospital care models involving the community setting through staff home visits or follow-up phone calls after discharge (16). Although recurrent visits due to child injuries remain a pressing matter, little has changed regarding hospital outreach to prevent avoidable hospital visits due to child injury.

Evidence regarding hospital leadership in designing and implementing home-visitation interventions for reducing child injury is particularly lacking. A literature search reveals only one study reporting a hospital-led intervention where families were approached 3 days post-hospital discharge following a child's injury (17). One thousand one hundred and seventy-two families received two home visits 1 year apart and two follow-up phone calls in the interim by a home visitor whose professional qualifications were not reported. While the control group received only a general safety pamphlet, the intervention group received an information pack on injury prevention; instructions by a home visitor on how to correct unsafe practices observed in the home, e.g., child's reaching small objects or lack of a smoke detector; instructions on how to prevent similar injuries to what was reported; and coupons to purchase safety devices including installation information. Findings showed no change in child injury rates between the control and intervention groups, nor significant change in parents' awareness and knowledge about child injury. Parents succeeded in improving, on average, only two unsafe practices out of the 11 measured (17). Another study recruited families to a home-visitation program from a hospital pediatric continuity clinic and focused on parental guidance on child injury prevention (18). However, recruitment from the clinic's logs included arrivals for any reason-an illness or an injury. Two further studies reported recruiting families to a home-visitation intervention *via* hospital medical records (19, 20), however their focus was improving child development and parenting practices, and home safety and child injury reduction were only secondary outcome measures.

Interestingly, a common thread in all the studies reviewed is that while the hospitals provided contact details of families *via* electronic medical records, the extent of their responsibility and involvement remained vague. Moreover, these studies are limited in their reporting of the design and implementation process of hospital-led interventions, and none to date have evaluated the possible reasons for success or failure in achieving the desired outcome in injury reduction. The implementation

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Abbreviations: SHABI, "Keeping our Children Safe"; in Hebrew: "SHomrim Al BetIchut Yeladenu"; CFIR, Consolidated Framework for Implementation Research.

process of such interventions remains a “black box”. There is a need for understanding processual levers and barriers that can assist in successful implementation in a variety of contexts and settings, and which in turn could contribute to reducing recurrent hospital visits due to child injury.

In the past decade, Implementation Science has emerged as a new field of inquiry to better understand the complexities of translating evidence-based interventions into every-day practice in real-world settings (21, 22). Complexities manifest also when implementing an intervention in different contexts and settings (22). Implementation Science helps in scaling-up successful interventions, and in choosing the best approach by understanding the factors that influence the implementation process (23, 24). Further, when interventions are implemented two potentially conflicting forces may act simultaneously-fidelity vs. adaptability. Fidelity is the degree to which an intervention is implemented according to the original design, and adaptability is the extent to which an intervention may need adjustment according to setting, context, or facing barriers (25).

To date, few published studies have used the lens of implementation science to examine implementation efforts focused on reducing child injury through home visits (26, 27). Nicks et al. (26) examined the implementation process of altering a computer-based intervention into home-visitation design. The software identified home injury dangers according to the data inserted by families. In their study they evaluated the facilitators and barriers encountered, but their findings were limited to the process of altering a computer-based program into a home visit design, and not on the levers and barriers in conducting the home visits. Smithson et al. (27) conducted a systematic review for identifying facilitators and barriers for injury prevention from the perspective of community leaders, counselors, implementers, and families. While their study contributed to the identification of levers and barriers affecting the implementation process, this study did not specifically examine home-based interventions, and therefore its insights are limited.

The present study aimed to understand the barriers and facilitators to implementing a novel hospital-led intervention for reducing child injury through home visits.

The SHABI program

SHABI (“Keeping our Children Safe”; in Hebrew: “SHomrim Al BetIchut Yeladenu”) is a program delivered in a hospital setting. Families are recruited by the pediatric Emergency Department nursing team when attending with an injured pre-school child. They are then assigned to a home visitor-a nursing or medical student, for two home visits-the first immediately following the hospital visit and the second 4 months later. The visits include a tour through the home accompanied by the parents, joint discussion on child safety in each area of the home with a checklist developed from “Beterem-Safe Kids Israel” (28), and installation of provided safety equipment. Two months later, the home visitor calls the family and offers further injury prevention guidance. The second home visit includes an additional home tour and guidance.

The students are trained in five sessions led by various experts conducted over 11 months, involving an injury prevention expert, a local ultra-Orthodox Jewish Rabbi, and the head of social services in a local Arab village. The training includes topics such as child injury epidemiology and prevention, relationship-building, cultural competence skills, and guidance on adapting the visit to the family’s culture.

The conceptual framework used in this study

To evaluate the factors affecting the implementation process, such as organizational factors and the effect implementers had, we used the Consolidated Framework for Implementation Research (CFIR) (29). CFIR was chosen as it is one of the foremost conceptual frameworks in the field of Implementation Science due to its integration of relevant theories into one unified model (29). CFIR was contextualized to assist in exploring the factors that influenced SHABI’s implementation in the hospital setting, namely: (1) *Implementation process*-Assessing the intervention’s planning and execution, followed by feedback and evaluation process (e.g., pre-implementation meetings); (2) *Inner setting*- Identifying the organizational factors that affect the intervention implemented (e.g., the organizational vision); (3) *Intervention characteristics*-Understanding the implementers’ perceptions about the intervention (e.g., advantages or difficulties in execution); (4) *Individual characteristics*-Implementers’ knowledge, opinions and skills; (5) *outer setting*-Examining the contextual factors such as regulations or policies (e.g., federal or national policies) (29). This last domain was not investigated as it was outside the study’s scope.

Methods

Study design and setting

The study was conducted from May 2018 to March 2021 in the Pediatric Emergency Department of a hospital with 330 beds, located in Israel’s northern social-geographic periphery. The hospital’s surrounding towns and villages rank low in socio-economic status (SES), with 170,000 residents from diverse Jewish and Arab communities, of whom 10% are 0–4 years old (30). The area is characterized by higher rates of admissions, mortality, and attendance for unintentional childhood injuries compared with the national average (31). Intervention design and pre-implementation meetings were conducted from May 2018 to April 2019, and SHABI was delivered from May 2019 to June 2020. A significant improvement in home-safety items was observed 4 months after the first visit [14 (IQR 12–16)] vs. [17 (IQR 15–19); $p < 0.001$], accompanied by an overall increase in home safety (Mean ± SD 71.9 ± 9.5% vs. 87.1 ± 8.6%; $p < 0.001$) (32). We have reported SHABI's impact on home safety previously (32).

Participants and procedures

The study involved the following participants:

- The hospital team-The hospital director, head of nursing, head nurse of the Emergency Department, nine Emergency Department nurses, and SHABI coordinator appointed from the hospital supervision staff.
- Home visitor team-Eleven trained nursing and medical students who conducted the home visits were paid a modest stipend per visit.
- Families who participated in SHABI-Families with adequate spoken Hebrew living in the hospital's catchment area who arrived at the Emergency Department with a <5 year old child following a home injury. One hundred thirty-five families received at least one home visit. Of them, 50% were ultra-Orthodox Jews and 11% Arab. A high proportion had <12 years education and a third were unemployed. Only 6% of parents lived in separate households. Thirty-eight families had three or more children under the age of five.

Helsinki approval was obtained through the Hospital Ethics Committee (0029-19-ZIV).

Data collection

Data collection included analysis of documents, questionnaires developed for this study since aside from one existing relevant questionnaire no relevant tools were found in the literature, in-person semi-structured interviews adapted from CFIR's interview guide tool (https://cfirguide.org/) with both hospital and home visitor teams, and through brief telephone interviews with the participating families:

- *Implementation process*: Meeting notes of pre-implementation meetings conducted with hospital management as well as feedback meetings held with hospital management, nursing staff, and home visitors ($n = 9$); a diary documenting the implementation process compiled by a researcher (LS); and Emergency Department attendance for child injury as well as participation in SHABI extracted from hospital medical records and tracking registries ($n = 5{,}105$).
- *Inner setting*: Meeting notes from pre-implementation meetings held with hospital management; hospital's mission statement; hospital management's views on SHABI and its decision-making process, and nurses' perceptions on SHABI's recruitment and operating evaluated through semi-structured interviews conducted 8 months from baseline ($n = 13$).
- *Intervention characteristics*: Hospital management, nurses, and home visitors' views on SHABI's design and delivery evaluated through semi-structured interviews ($n = 18$).
- *Implementers' characteristics*: Nurses' recruitment skills and home visitors' skills in engaging families and conducting home visits were evaluated through semi-structured interviews; home visitors' post-visit questionnaire on the challenges faced during the visit ($n = 233$); families' views on home visitors' skills were evaluated through telephone interviews conducted after each visit ($n = 212$) by a researcher (LS); home visitors' confidence in conducting the visits were assessed through semi-structured interviews; and home visitors' awareness of dangers in the home was assessed through a questionnaire asking to list the potential dangers in each home area administrated before the first training and 8 months later ($n = 8$), adapted from Kendrick (10).

Data analysis

Semi-structured interviews along with families' post-visit telephone interviews were recorded and transcribed. All data were analyzed through explanatory content analysis (33) based on CFIR constructs (29). To achieve interrater reliability, two researchers validated the analysis (LS and SS) to ensure the trustworthiness of the results. In case of disagreement, further discussions were held until agreement was reached.

Potential dangers at home were categorized into injury categories and counted for potential dangers reported. Descriptive statistics were used to describe Emergency Department attendance and participation in SHABI. Comparisons of percentages between different groups were analyzed using X^2. Non-normally distributed data were analyzed using Wilcoxon test for dependent subgroups (using SPSS version 27.0).

Results

Analysis of the data showed a variety of factors affecting SHABI's implementation through the prism of CFIR: the implementation process, the hospital's inner setting, SHABI's characteristics and nurses and home visitors' perceptions and skills. Data is presented in Table 1 according to the themes that emerged and exemplified through relative quotes from hospital management, nurses, home visitors, and families.

SHABI was designed as a hospital-led program, and its implementation faced several barriers and likewise, facilitators. Analysis indicated that despite the compatibility between SHABI's mission in preventing child injuries and the hospital mission in increasing community health, the hospital found it difficult to operate SHABI outside of its own setting as planned as well as hiring Emergency Department nurses as home visitors. As a result, the medical school took over SHABI's operational aspects and recruited medical/nursing students as home visitors. This collaboration between the hospital and the medical school helped bridge the gap.

SHABI's implementation was facilitated by the top-down decision-making process and nurses perceived SHABI's importance in preventing child injury. Despite the inclusion of recruitment to SHABI in the initial patient triage process, it was still only partially successful. Nurses approached only 63% of eligible families and failed to recruit foreign body or animal injury cases.

Medical and nursing students were recruited as home visitors. Both medical and nursing student cohorts had very few Arabic speakers and none applied for the position. This lack of Arabic speakers may have influenced attrition of Arab families, who were more likely to drop out after the first home visit than Jewish families (7 of 15 Arab families completed both visits vs. 91 of 120 Jewish families; $p = 0.02$). During SHABI's operation and following training sessions, home visitors increased their awareness of dangers at home from baseline and 8 months later [6 (IQR 5–7)] vs. [8 (IQR 7–8); $p < 0.05$]. They also improved their confidence in conducting home visits and enhanced their understanding of cultural and religious groups with whom they had little familiarity. Finally, children's presence in the visits often drew parents' attention, and home visitors involving them in the visit helped reduce distractions.

Discussion

SHABI is a home-visitation program that aims to prevent unintentional childhood injuries through delivery of a hospital-based service. This study's goal was to evaluate the barriers and facilitators of implementing SHABI using the theoretical and conceptual framework of CFIR (29), exploring different stakeholders' experiences-families and implementers, to better understand the implementation process and outcomes.

Hospitals are an important setting for child injury prevention considering the high arrival and admission rates. Review of hospital-led interventions revealed only two home-visitation studies focused on home safety and injury rate (17–20), however the hospitals' responsibility and involvement remained unclear. This case study contributes to the literature by demonstrating and evaluating the ambiguity regarding the hospital's role and responsibility in implementing SHABI. In the early implementation stages the hospital expressed structural difficulties in operating SHABI outside of its setting as well as in hiring nurses as home visitors. Unlike health systems in other countries, in Israel, hospital and community care settings operate separately using different computerized documentation systems and lacking the mechanisms to mediate between the two (34, 35). To mediate this in SHABI, the collaboration between the hospital and medical school served as a bypass for that structural barrier between hospital and community.

The use of this bypass to overcome the disconnect between the hospital and community was implemented in the ETGAR program (36) aimed at reducing recurrent admissions following discharge from hospital. ETGAR, also developed by the medical school, uses medical students to visit patients and provide guidance following discharge (36). As demonstrated by ETGAR, there is a need for improved coordination and collaboration between hospital and community. Literature suggests that there is specific value for bridging hospital-community silos to the field of child injury prevention. Towner and Dowswell (37) reviewed child injury prevention interventions and found that collaboration between organizations can create an environment in which multiple players, such as municipalities or voluntary agencies, contribute their resources, namely knowledge, experience, or ability, and assist each other when encountering a barrier (37). Despite the benefits of collaborations, as demonstrated in the SHABI program, the bypass created by the hospital and medical school provides only a temporary solution. The structural difficulties of hospitals' involvement in community-hospital prevention programs emphasize the need for designing a sustainable solution that will enable hospitals to become major actors actively contributing to various prevention fields.

Albeit SHABI's recruitment being successful to an extent, one of the organizational catalysts for its implementation was the hospital's top-down decision-making process. Top-down decision-making characterizes hierarchical and clinical implementation settings such as hospitals and Emergency Department (38). Decision-making of this kind can be an influential element in implementing new programs and was found as a motivator for implementers, yet it can also lead to resistance (39, 40). Implementers' beliefs about an intervention serve as an additional significant facilitator for implementation success (41), including staff attitudes regarding hospital-based interventions (42). For example, Garbutt et al. (43) evaluated implementers' beliefs regarding a US national program for papilloma virus vaccines among at-risk girls. They found that implementers who achieved high vaccination rates were those who held a strong belief on the vaccine's importance, who felt self-efficacy and confidence in the vaccine contribution, and were personally committed to the mission. Efforts must therefore be invested in educating implementers about a

TABLE 1 Principal findings regarding the facilitators and barriers in implementing SHABI in the hospital setting.

CIFR domain and themes	Barriers	Facilitators	Quotes ([+]=facilitator, [-]=barrier)
Implementation process			
Families and home visitors' recruitment process and adherence to the program	773 eligible families arrived at the Emergency Department due to child injury; only 63% were approached by nurses to participate in SHABI Families often failed to agree to participate or be contacted as they felt they had no need for the intervention Less Arab families completed both visits (7 of 15 Arab families completed both visits vs. 91 of 120 Jewish families; $p = 0.02$)	Separation between families' recruitment (done in hospital by nurses) and the home visit components (coordinated by the medical school)	[-]"The mother said there is no safer home than her own and no need for a visit" (Home visitors' post-discharge recruitment phone call to a Jewish mother of two preschoolers from a low SES city)
Inner setting			
Compatibility of the hospital's vision with SHABI's mission The hospital's barriers in operating in the community	Despite its mission statement and the hospital director's views on responsibility to the community, in reality, hospital management encountered difficulties in extending its role to the community and operating outside of the hospital setting While recruitment was partially successful in the hospital, concerns about staff insurance outside the hospital precluded hospital nurses conducting home visits as originally intended	SHABI's mission in promoting health in communities located in the hospital catchment area aligned with the hospital's declared mission In the light of hospital barriers, the medical school stepped in and took responsibility for delivery of the home visitation service, and recruited medical and nursing students as home visitors	[+]"I look at the hospital as a community hospital... As a worldview, I would not reduce my responsibility only to what happens within the hospital. I see a broader responsibility within the community as well" (Hospital director) [-]"We work in the hospital, and cannot provide family medicine, community care. It is two different worlds... Hospital is one thing and community is another" (Head of nursing)
The hospital's top-down decision-making process	Nurses perceived that the head nurse daily reports on recruitment was a form of criticism, and that the SHABI coordinator was hardly involved	The top-down decision-making process obligated the nurses to recruit ensuring that it was part of their job	[+]"We received an explanation at the staff meeting with all the managers. We were given an explanation about the program- what was required of us. It is clear to me that this is not democracy, I do not choose what to do at my workplace, it is part of the job" (Nurse #4).
Strategy and available resources	The lack of time in a busy Emergency Department and burdensome nursing tasks affected nurses' ability to recruit	Including recruitment as an additional task in the initial patient triage process facilitated recruitment	[-] "The problem is that SHABI takes time-this is another form that needs to be filled out, and there are many other things that need to be done. There are more people waiting" (Nurse #1)
Intervention characteristics			
Recruitment following an injury	Nurses perceived some families were too agitated about their child injury to be approached	Recruitment immediately after a child's injury was perceived to be a definite motivator for parents to consent to SHABI and to actively make changes to their homes	[+]"The parents were very happy that I arrived and wanted to schedule the visit. Both parents were present. They encountered a serious incident [injury] with their daughter, and now are dedicated to prevent similar incidents in the future" (Home visitor #5)

(Continued)

TABLE 1 (Continued)

CIFR domain and themes	Barriers	Facilitators	Quotes ([+]=facilitator, [-]=barrier)
SHABI as a bridge between the hospital and the community		In Israel, the hospital and community interfaces operate independently. Hospital management perceived SHABI as an appropriate bridge between hospital care and preventative community efforts	[+] "I think it is the connection, the connection point, between what we do in the hospital when a child arrives after a home injury, and what happens in the community" (Head of nursing)
Home-visitation intervention design	Home visitors perceived that at times the home tour was felt to be invasive by families	Hospital management, home visitors and families generally perceived that the visit was effective in improving home safety. This drove the home visitors to invest in the intervention The checklist helped to guide the visit and home visitors to discuss safety in each home area	[-] "I felt it (house tour) was an invasion of their privacy. I mean, if the bedroom is messy and the parent does not feel comfortable with it, then it hurts his/her ability to open up to me or listen to the things I want to say. A tour through the home has disadvantages… It can create antagonism" (Home visitor 4#)
Implementers' characteristics			
Perception of SHABI's importance	Nurses prioritized their efforts in recruiting families arriving with fall injuries (345 of 508 families with fall injuries were recruited vs. 163 who were not recruited; $\chi2 = 15.3$, $p < 0.001$) in comparison to a foreign body (58 of 119 families with foreign body were recruited vs. 61 who were not recruited; $\chi2 = 12.2$, $p < 0.001$) or due to animal injuries (e.g., dog bite; 23 of 67 families with animal injuries were recruited vs. 44 who were not recruited; $\chi2 = 25.8$, $p < 0.001$)	Nurses perceived SHABI as important which was a significant driver to recruiting families in the Emergency Department	[+]"The [nursing] team members need to build the passion for it [recruitment]... and it also depends on the team member. If they are passionate, it will be more successful" (Nurse #1)
Communication skills	Paucity of Arab speaking home visitors may have influenced communication with Arab families	While nurses and home visitors worried that SHABI's visits might be perceived as judgmental and critical, their sensitivity and explanations that injuries are common allowed constructive engagement	[+]"I explain again and again that it is not a matter of you being a bad parent. There is not a single child that goes through childhood without something happening to him. And it is good to avoid next time" (Nurse # 4) [+]"[The home visitor] was very pleasant, gave a good feeling and did not give a critical and judging feeling, but a sense of sharing and togetherness" (A Jewish mother of three preschoolers from a low SES city)

(Continued)

TABLE 1 (Continued)

CIFR domain and themes	Barriers	Facilitators	Quotes ([+]=facilitator, [-]=barrier)
Home visitors' training	Home visitors had difficulty in encounters with culturally diverse families	Through training and encountering families, home visitors increased their understanding about cultural and religious groups with whom they had little familiarity	[+]"The program completely changed my stereotype. I came from the center of the country to a city like Safed, a low socio-economic city and people with a different background than mine… and it changes something. You suddenly see the person. You do not see he is ultra-Orthodox" (Home visitor #3)
Home visitors' awareness of potential dangers in the home		Increasing awareness influenced home visitors to recognize potential dangers in the home from baseline and 8 months later [6 (IQR 5–7)] vs. [8 (IQR 7–8); $p < 0.05$]	
Home visitors' self-confidence in conducting the visits		The improvement in home-visitors' self-confidence, which was low at the beginning but improved with experience, influenced the visits' effectiveness	[+] "It took a while until I learned how to conduct the conversation [first family phone call] and gain confidence. At first, I would only do it in front of the computer, with the text in front of me and only when there is no noise around me. Now I do it on the go... I initially had the challenge of my insecurity" (Home visitor #1)
Home visitors' skills in conducting the visits	The presence of children distracted from home visitors' ability to conduct the visit	Focusing on building relationships, rather than immediately discussing home safety, enhanced parents' engagement Involving the children in the visit kept them occupied and secured parents' attention	[+]"I kept trying to involve the kids in the visit. I say to the kids: who knows what a door stopper is' [door slamming prevention accessory]? And put it on their noses. 'Who can guess what this product does?' " (Home visitor #3)

program's importance in order to create a sense of ownership and achieve sustainable change. Despite some difficulties in accepting the hierarchical decision process, our nurses perceived SHABI as a valuable program, and made efforts to persuade parents to participate.

SHABI's implementers included Emergency Department nurses and home visitors comprised of medical and nursing students rather than only Emergency Department nurses as originally planned. We found that home visitors increased their self confidence in conducting home visits, as well as their awareness toward dangers at home. Along with the significant improvement found in home safety, it seems that professional qualification is not an essential component, and home visitors with adequate training do not harm the program's outcome measures. In the child injury field, several home-visitation studies have used both professional (10, 18) and non-professionals (17, 44, 45) as home visitors. Conflicting findings were found as to home safety increase and/or injury rates decrease, but the literature is unclear as to the necessity for professional qualifications. Further research is needed regarding implementers' required qualification, characteristics, and skills.

Arab families have relatively high levels of injuries in the home (31, 46) and were therefore key targets. Recruitment was lower and there was greater drop out after the first SHABI home visit. This might have been mitigated if the home visitors had among them Arab speaking students. Smithson et al. (27) found that a major barrier to preventing child home injuries is messages that are often not culturally adapted. However, home-visitation interventions where locals were employed as home visitors failed to show significant improvement in home safety and/or injury rate (44, 45). Further research is needed to understand the distinctive skills and characteristics child injury prevention implementers require.

Two opposing forces act simultaneously in the implementation field (21, 22). Fidelity is the need to maintain uniformity according to the original research protocol, compared to adaptability which is the need for protocol adaptation in new settings and contexts to increase implementation success (25, 47, 48). In SHABI, for example, adaptive mechanisms were applied on several occasions. During SHABI's Emergency Department implementation, families' recruitment component was included as part of the patient triage process to ensure that eligible families are included. Additionally, the home visitors developed a strategy for including the children to keep parents' attention during the home visit. Yet the process changes described had no major structural implications to SHABI's core program, did not affect the programs' aspired outcome measures, but maybe increased SHABI's implementation success. Adaptive mechanisms are important as by applying them failure of the implementation process may be prevented (48).

Another aspect in child injury is the vast and diverse existing data on injury prevention. This variability is expressed in several ways, such as dangers in different home areas (kitchen vs. the bedroom), or different injury mechanisms (poisoning vs. burns). This also leads to differences in safety guidelines provided, such as improving the physical environment vs. changing parental behavior or recommending safety devices vs. moving objects out of the child's reach (28). The variance creates diversity in research tools that evaluate effectiveness (8, 49, 50). The lack of uniformity of injury prevention messages, measurement and evaluation tools creates difficulty in developing standards and quality indicators. This difficulty is particularly evident in the attempt to scale-up successful interventions to other settings or larger population groups (24).

Home safety checklists are a common research tool used in child injury prevention, but they generally have not undergone a validation process (17, 44, 45). In SHABI we used a checklist developed by "Beterem" (28), which although based on the literature, has not been formally validated. The HOME inventory (The Home Observation for Measurement of the Environment) (51) appears to be the only validated tool, however only eight out of the 219 items assess home safety, while the rest examine topics such as child physical and emotional development or parent-child attachment. In SHABI we chose the "Beterem" checklist since it has been used widely in Israel. There is no doubt that there is a need to develop validated research tools and standards of quality indicators in the field of child injury.

There are several limitations to this study. The insights gained result from study of a specific clinical setting in the Israeli health system. Further studies are needed in other hospitals in Israel and beyond using various methods and theoretical frameworks in order to extend the conclusions. There was a disparity between the numbers of Arab and Jewish families included in the research population, although the figures reflect the sociodemographic of the hospital's catchment area where the population is 20% Arab. Nonetheless, the lack of Arabic speakers among the home visitors may have reduced SHABI's accessibility to Arab families. It would have been of interest to explore home visitors' attitudes toward local population groups prior to the intervention particularly as the focus on cultural sensitivity was a strength and home visitors claimed that their cultural competence had increased. Lastly, due to the lack of suitable validated research tools, we developed the tools for the current research. This limitation was mitigated by triangulation of the findings from the hospital management's, implementers', and families' perspectives.

Conclusions

This is the first time that the Implementation Science lens has been used to explore a hospital-led home-visitation intervention aimed at preventing child injury. The conceptual CFIR theoretical framework focused on the entire implementation process, hospital inner setting, SHABI's characteristic, and nurses and home visitors' characteristics. We found that a sustainable solution is needed to bridge the disconnect between the hospital and the community, so that hospitals can become a key player in preventing child injuries. Nurses and home visitors applied adaptive means to increase SHABI's implementation success in the recruitment process at the hospital and during the home visits. Finally, our work further highlights the need to further explore settings for implementing interventions using home visits to prevent child injury.

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

Helsinki approval was obtained through the Ziv Medical Center Ethics Committee (0029-19-ZIV; 22 October 2017). Written informed consent to participate in this study was provided by the participants' legal guardian/next of kin.

Author contributions

LS was involved in study planning and intervention design, collecting, analyzing data, and drafting the manuscript. MR was the initiator of the study, involved in study planning and intervention design, and reviewing the manuscript. SS was involved in study planning and intervention design, analysis, and reviewing the manuscript. 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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Patient engagement to examine perceptions of perinatal depression screening with the capabilities, opportunities, motivation, and behaviors (COM-B) model

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Background: Perinatal (during pregnancy and up until one year after birth) depression is one of the most common medical complications of pregnancy and is a major public health issue. The common early detection method to identify depression is to systematically administer depression screens to patients during their usual care clinic encounters. This study investigates how prenatal patients perceive depression screening and how screening informs their treatment to meet the specific needs of different racial and ethnic groups within both community and health care settings.

Methods: Between June 2019 and August 2019, semi-structured in-depth interviews were conducted to explore participants' experiences of depression screening with the Edinburgh Postnatal Depression Scale (EPDS). Perinatal women ($N = 29$) consented to participate in-depth, one-on-one qualitative interviews. Trained patient-researchers ($n = 6$), women who had previously experienced a perinatal mental health problem, were trained as research team members and facilitated the interviews alongside a research assistant. All interviews were recorded and transcribed verbatim. Data was analyzed with the use of Nvivo12. Thematic network analysis was used to analyze the data.

Results: Through the in-depth patient engaged qualitative interviews this study uncovered several specific motivators and behaviors related to perinatal depression screening. Using directed content analysis, several themes within a COM-B frame emerged and could be reduced to themes and further divided into two different stages: the depression screening stage and the post-screening stage.

Conclusions: The results of this qualitative study provide information for health care providers to improve, adjust, and assess the process of conducting perinatal depression screening among women. The data also provide information for health care facilities to identify a better screening tool and develop and measure their screening process. These findings are essential to design comprehensive patient-centered screening protocols given the increase in state and federal policies urging universal depression screening.

KEYWORDS

perinatal depression, COM-B, qualitative interviews, depression screening, pregnancy, postpartum depression

Introduction

Depression during the perinatal period is the most common complication of pregnancy and childbirth, affecting 1 in 8 women in the United States (1). Untreated perinatal depression can result in adverse outcomes for both postpartum women and their infants (2, 3). Moreover, the experience of untreated depression can be severe, resulting in suicidal ideation and/or suicide (3, 4), and maternal suicide is a leading cause of maternal mortality in the U.S. (5). Some studies report that treating depression during pregnancy is complicated by risks to the fetus (6, 7). At the same time, untreated depression during pregnancy is associated with substantial risks for adverse birth outcomes, such as low birth weight, preterm birth (2, 8), and postpartum depression (9). Given the considerable number of potential adverse physical and behavioral health outcomes for women and their offspring, it is essential to detect perinatal depression early and connect women to treatment and support. Several new models, such as psychiatric referral and consultation protocols, offer promise for assessing and treating perinatal depression (10, 11).

One promising approach to identifying perinatal depression is the practice of universal screening for depression during a health-care visit. Screening for depression during pregnancy is a clinical approach to identifying women in need of mental health diagnoses, treatment, and referrals (12, 13). It remains unclear if screening for depression during pregnancy results in better or poorer health outcomes for women and their infants (14). Currently, the United States Preventative Services Task Force (12), the American College of Obstetrics and Gynecology (15), and the Canadian Task Force on Preventive Health Care (16) have introduced screening standards in an effort to improve the detection of perinatal mental health problems. The American Psychiatric Association released a position statement on improving the quality and use of perinatal depression screening (4). The benefits of using a validated screening instrument, as well as the optimal time to screen, have not yet been determined (17). An individual's actions after completing a depression screen and motivations to seek treatment remain unknown. It also remains unclear if the act of screening results in behavior changes for the individual being screened. Few studies have involved patients in the design or delivery of research studies.

This present study is focused on the aspects of patient-engaged implementation research that includes authentic factors and conditions to scaffold intended behavioral changes resulting from the implementation of perinatal depression screening. Authentic factors, in the context of this study, represent situational factors and conditions that might facilitate or hinder the intended implementation of perinatal depression screening. In the health-care context, the Capability, Opportunity, Motivation – Behavior framework (COM-B) was proposed to articulate components and processes for intended behavioral changes of individuals upon interacting with organizations and agencies (18, 19), and can be generally interpreted as follows. *Capability* can be either physical or psychological and could be considered in terms of psychological capabilities as the result of receiving relevant training or education. *Opportunity* deals with physical and social environments within which behavioral changes occur. *Motivation* relates to perceptions, feelings, emotions, habits, and self-planning of individuals upon interacting with factors and conditions afforded by *capability* and *opportunity*. Similar to other behavioral change frameworks, the outcome of COM-B is the behavioral change of individuals within an organization or system. Therefore, this present study seeks to reveal the patient perceptions of effective depression screening processes for behavioral change purposes at the individual level in response to a system-level process.

Behavioral changes resulting from implementation of the innovation should be observed at two levels: organizational and individual. As an example, at the organizational level, incentives and obstacles could influence organizations' routines and processes for managing an individual's knowledge capital and their capabilities to make intended organizational behavioral changes (20). In other words, organizations need to absorb pertinent knowledge, skill, and ability capacities before commencing any organization-level and strategic behavioral changes. To date, few investigations have centered on people with lived experience (i.e., patients) in the discovery of motivating factors for behavioral change. For this study the COM-B framework is used to explore a qualitative research question: *What are the facilitators and barriers in depression screening and post-screening stages of mental health care for perinatal women to carry out intended behaviors?*

Methods

Sample

During the study period from June 2019 to August 2019, a total of 29 women consented to the study and participated in in-depth, one-on-one interviews. The participants of this study were recruited from a single public health district in Central Illinois in the context of an existing patient-centered outcome research engagement project (21–25). This study builds upon our previous work by examining what happens in the weeks to months after completing a depression screening (22). A purposive sampling approach was used in this study to better inform the research question described in the previous section. All participants provided informed consent before participation in this study. There were several inclusion criteria for participants in the study: (a) currently pregnant or within 12 months postpartum, (b) self-reported perinatal depression screening experiences, (c) 18 years of age or older, (d) English-speaking, and (e) residing in the public health district's county. Participants' eligibility was assessed through a brief telephone screening. Patients that met eligibility criteria were scheduled for individual meeting sessions followed by phone screenings. In the sample, the average age of participants was 29.5 ($SD = 6.05$). This sample was 51.7% Black ($n = 15$), 37.9% White ($n = 11$), 6.9% Asian ($n = 2$), and 3.4% multiracial ($n = 1$). More than half (55.2%) of participants had more than 12 years of formal education. On average, participants had 2.21 children ($SD = 1.34$).

Setting

Recruitment for this interview study came from two clinic locations (one rural, one suburban) within a county public health district in the State of Illinois. The clinics provide family case management; home visits; administration of supplemental nutrition for women, infants, and children (WIC) program benefits (e.g., food vouchers for pregnant or breastfeeding women and children birth to 5 years of age); immunizations; and counseling (e.g., lactation, genetic, and nutrition) to low-income women. In order to receive most services, women must have an income <185% of the U.S. poverty line ($13,590 annual income for a single adult) and be pregnant or have children under the age of 5. In accordance with a state policy depression screening mandate, Maternal and Child Health Bureau case managers screen all pregnant women for depressive disorders using the Edinburgh Postnatal Depression Scale (EPDS) during the antenatal and postnatal periods. In addition, all outpatient and inpatient obstetric providers are mandated to perform depression screenings during pregnancy and the postpartum period in the State of Illinois.

Procedures

An innovative patient-engaged data collection framework was adopted for the present study. This involves patient engagement at all stages of the research process from study conception through dissemination (26). The definition of a patient is a person with lived experience of a perinatal mental health disorder. The research question originated from research question–generating sessions where advisory members wanted to know if screening for depression results in behavior changes and whether patient partners might serve as researchers in interviewing other patients to learn about their experiences completing perinatal depression screenings. Six patient partners who identified as parents and had previously experienced perinatal mental health issues and/or completed depression screenings were recruited from a patient advisory board affiliated with the patient-centered outcomes research engagement projects. These patient partners served as patient consultants and attended monthly meetings on a patient-centered outcomes research advisory board. Before participating in the current study, patient partners were required to complete two qualitative interview trainings facilitated by the lead authors of this study on how to conduct human subject activities as part of the research team.

The semi-structured interview protocol in this study was developed by the advisory board members to explore participants' perceptions and experiences of receiving perinatal depression screenings and subsequent treatment decision-making. Invitations for participants were distributed by clinical staff at a partnered public health district in Illinois. Written consent was obtained from all study participants. All participants received the interview protocol at the beginning of each interview session. Participants were interviewed by the trained patient partners in English. Interviews were conducted at study participants' preferred locations, which included but were not limited to the public library's private study room, participants' homes, the clinic examination rooms of the partnered public health district, and a classroom at the local university. All interviews were conducted face-to-face, and free on-site childcare was provided to both interviewers and interviewees to promote the mother-centric nature of this study. Interviews averaged 40 minutes per participant. Each participant was compensated $50 for their participation. Data collection ended after the recruitment of 29 participants, which met a strong level of saturation in the data. Interviews were audio recorded and transcribed verbatim. All procedures were approved by the Institutional Review Board at a university in Illinois.

Analysis

All interviews were analyzed using directed content analysis (12), which is a common method in health-care research

(13), and supervised by the senior author. Our analysis process started with determining the theoretical background and categorization matrix of the COM-B framework. The coding under "motivation" follows the definitions of "reflective motivation" (increasing knowledge and understanding, eliciting feelings about behavioral targets) and "automatic motivation" (learning that induces feelings and impulses relevant to the behavioral target, imitation, habit forming, or direct influence on automatic motivational process via medication) (18). The mentioned three codes all fall under one of the motivation categories. Further, a guideline for coding rules and anchor examples was established among research team members. The research team members read all transcripts from each interview and, based on first impressions, coded text using the predetermined codes of the COM-B framework. Each interview was independently coded among research team members. To increase the rigor of the analysis, all coders cross-checked emerging themes and ratings during regular analysis meetings.

After working through 50% of the data, an intercoder reliability (ICR) test was conducted to ensure adequate ICR and establish the credibility of the findings. Coding results from two transcripts selected by the study principal investigator were used in calculating ICR and generated Cohen's kappa coefficients to verify the level of agreement between coders in qualitative text. Research indicates that the closer the kappa value is to 1, the better agreement has been reached, and values above 0.8 suggest perfect agreement (14). The Cohen's kappa values were 1.0 and 0.8 for the two selected transcripts in the study, indicating the establishment of perfect agreement among research team members.

After the re-interaction process of ICR, to further ensure quality control and enhance the trustworthiness of findings, reanalysis of existing coding was performed, which included revision of the categories and subcategories, recognition of missing texts related to the predetermined codes, and identification of newly emerged codes. Based on the finalized categorization, two coders then completed coding for all transcripts. Each step of the analysis was reviewed and organized collaboratively by the coders and the study principal investigator. The final category frequencies and interpretations based on the COM-B framework are presented in the Results section.

Results

The results from the qualitative analysis are presented in Tables 1, 2 along with illustrative quotes corresponding to each stage. As shown in Tables 1, 2, the findings are divided into two different stages: the depression screening stage and the post-screening stage. If the patients' experiences are related to their interactions with health providers or the instruments involved in the screening stage, they are listed under the depression screening stage in Table 1. If the patients' experiences are related to resources (usually after the first screening), they are listed under the post-screening stage in Table 2. By dividing the patients' experiences into these two different phases, we can identify which parts of the screening stage influence the post-screening stage. This analysis is critical, as the screening stage either initiates or hinders patients' efforts to address depression screening outcomes, which is the intended behavior.

Emerging themes in the reflective motivation factors are patients' perceptions, critiques on the screening questionnaires, absence of the screening results, and feedback from the providers. The majority of the patients reported that the screening questionnaires were not specific enough to diagnose their depression symptoms or were not able to capture their emotions. For example, in order to draw attention to the need for help, a patient shared: *"When... they gave me that... the other day, I'm like, I know I need help right now. I have to mark things high."* Some patients thought that having a conversation with providers would have made them feel more welcome than filling out a form. Scores and screening results were usually not delivered to patients, and as a result, not many patients were able to receive feedback and resources on the screening day. Upon closer inspection, if the patients had previous experiences with depression, they were concerned more about the quality of the screening questionnaires, while the patients who did not have previous depression were concerned more about the lack of feedback from providers.

The second significant factor at the screening stage was physical opportunity. Patients were concerned about both the time interval between screenings and the appropriate timing of the screening. As described by one patient: *"I think that there needs to be more done [screening] toward the end of the pregnancy because... the end of the pregnancy is rough"*. Many postpartum screenings were performed right after the birth (i.e., within 48 h of a woman's delivery) when women were still experiencing pain, exhaustion, and nauseousness from anesthesia. Many patients expressed that they were not able to process the questions and just wanted to "get done with it" so they could rest. Allowing a certain amount of time for women to recover and settle after birth would enhance the effectiveness of screening and increase patients' access opportunities. The quality of communication between patients and providers as well as providers' warm attention during the screening are found to be influential factors for patients. The majority of patients reported that the provider's lack of attention made them feel like the screening was just a part of a checklist rather than an opportunity.

In the patients' post-screening stage, physical opportunity was emphasized. The physical opportunity includes some factors at the system level (e.g., lack of affordability; see Table 2), which is outside of the patients' control. Most of the other factors of the patients' physical opportunities in the post-screening stage are related to their psychological capability factors during the screening. If patients lacked comprehension of screening

TABLE 1 Applying COM-B factors to patient's depression screening stage.

Factors	Criteria	Emerging themes	Frequency	Quotes
Capability	Psychological Comprehension of assessment and/or cognitive functioning related to the screening stage	• Language of the EPDS screening • Comprehension of what is depression screening/knowledge regarding screening	23	• *"I just feel like the questions were straight for me."* • *"If I didn't know anything about the screen from working with pregnant women on a regular basis I probably wouldn't have understood that they were screening me for depression."*
	Physical Physical capability to adapt to lifestyle changes related to the depression screening stage	• Unable to focus on screening	8	• *"I'm pretty sure I was given one of them (screening questionnaire) but I had a C-section and I was very drugged up on medication. Also, my kids were in the NICU…"*
Motivation	Reflective Perception of illness, belief about treatment related to the depression screening stage	• Perception of the screening tool • Results/feedback were not delivered to patients • Screening led to/did not lead to resources • Patient's perception of Self-reliance Ineffective screening questions to diagnose depression	201	• *"I think the questions are too general, too broad…I would prefer if someone would, like, talk to you one-on-one with the questionnaire."* • *"I mean, I never got a score so it would have been nice to at least have those results… but really they didn't follow up with it at all."* • *"When… they gave me that… the other day, I'm like, I know I need help right now. I have to mark things high."*
	Automatic Stimuli or cure for action, mood state/disorder related to the depression screening stage	• Felt being judged by the provider • Felt being blamed by the provider • Screening caused fear	79	• *"I don't know how that's going to affect my personal life. What if I'm ever going through a custody battle with something that gets brought up…"* • *"What if you say the wrong answer maybe something may happen you have to deal with they make you go to counseling… or maybe if you have other children, they may feel like you're not stable enough to take care of them. So… I didn't know whether to answer the questions truthfully or not."*
Opportunity	Physical Cost, access, social support, doctor and patient relationship/communication related to the depression screening stage	• Screening interval timing • Doctor-patient relationship/ communication • Screening seemed more about self-serving purpose than serving patients	82	• *"I think that there needs to be more done (screening) toward the end of the pregnancy because… the end of the pregnancy is rough."* • *"She took more time with me, explain[ed] to me… the different things that I could do…"* • *"I think that often it can be kind of skimmed over like this… is just a part of our routine, and people don't take it as seriously as they should and don't really ask questions and take the time."*
	Social The stigma of the disease, fear of disclosure, religious and cultural beliefs related to the depression screening stage	• Lack of privacy	31	• *"It seems like maybe it would have been more appropriate to do it individually."*

TABLE 2 Applying COM-B to patient's post-screening stage.

Factors	Criteria	Emerging themes	Frequency	Quotes
Capability	Psychological Comprehension of assessment and/or cognitive functioning related to post-screening stage	• Too depressed to reach out • Stress/can't process information • Having suicidal ideation	9	• *"…like I said, when you're depressed you don't want to reach out for help…"*
	Physical Physical capability to adapt to lifestyle changes related to the post-screening stage	• Lack of physical capacity • Unable to take psychiatric medication	18	• *"I was already medicated for ADD, and I couldn't take my medications when I got pregnant or while I was breastfeeding so that kind of, like, was hard and what led to me kind of getting depressed."* • *"Finding someone to keep my child [was a problem], or most of the time therapists are Monday through Friday. So when I was going to do it before, it was like, I have to take off work to go to the therapist. I can't take off work."*
Motivation	Reflective Perception of illness, belief about treatment-related to post-screening stage	• Lack of mother-centric services • The resource was/was not helpful	7	• *"Nothing was really offered to me. The list of resources that they gave me I never referenced after I had initially been given that list, and I wasn't really offered anything."* • *"I didn't really look at them [resources] …I think most of the things they gave us was more like social groups…"*
	Automatic Stimuli or cure for action, mood state/disorder related to post-screening stage	• Prefer to ask friends (trust) • Comfortability	16	• *"I was having a problem, but I don't know if I would feel comfortable necessarily just reaching out to some random..."* • *"It wasn't the resource list that motivated you to go there. It was a friend."*
Opportunity	Physical Cost, access, social support, doctor and patient relationship/communication related to post-screening stage	• Lack of resources for fathers • Prompt and flexible process • Help from mother's support group • Lack of affordability (finance, insurance, and citizenship issue) • Lack of transportation • Prior involvement in services • Unwanted medication & treatment • Providers take initiatives to make the linkage	92	• *"I think dads are totally skipped in this process and it can affect them."* • *"I really need to talk a little bit more, and he opens up a schedule for me. So I'm really blessed in that aspect…I can get some therapy and counseling while I'm doing my Med checks…"* • *"The first thing that was said to me…options were never given. It was pretty much like…try these pills and if that doesn't work, we'll try something else"* • *"Two months after giving birth, I don't have more Medicaid to have more insurance. So now I can't see a therapist."* • *"It's because I'm not a US citizen, so I could have it during the pregnancy and up to 60 days after giving birth."* • *"I feel like they probably would have followed up with me after that since I did score high then it probably would have been different."*
	Social The stigma of the disease, fear of disclosure, religious and cultural belief related to the post-screening stage	• Stigma about perinatal depression • Experienced racism at hospital	5	• *"I really feel like I didn't get the quality care that I needed…and I felt like sometimes it was based on my race…"* • *"…my family of origin, like going to seek assistance for depression and anxiety is not something that's accepted, so I think that is something that I still hold even though I've done it on my own as an adult."*

and described lower or impaired cognitive functioning levels (e.g., feeling too stressed/depressed to process information or showing suicidal ideation), they were much more likely to either refuse or not actively seek physical opportunities. In this study, opportunities for both reflective motivation and automatic motivation could be easily lost. For example, patients who were able to understand the depression and screening stage were either already involved in the support groups or actively looked for the resources after screening, as compared to those who were in need of support but perceived too many barriers. Loss of Medicaid insurance coverage was another reported barrier to opportunity in the post-screening stage. Moreover, the options provided often did not meet the expectations and needs of the patients, as described in one interview: *"The first thing that was said to me…options were never given. It was pretty much like…try these pills and if that doesn't work, we'll try something else."*

Another factor that influences patients' physical opportunities in the post-screening stage was the patients' prior experience with depression. If the patients had previous experiences with depression, many of them were either psychologically or physically not able to seek available resources (e.g., due to stress, inability to process information received, or inability to take psychiatric medication; see Table 2). Therefore, for them, the providers' initial approach (physical opportunity) was a critical factor in helping them adhere to the upcoming appointments and treatments. On the other hand, patients who did not have previous depression did not report notable capability factors in the post-screening stage. An example of this experience is described as follows: *"I was already medicated for ADD, and I couldn't take my medications when I got pregnant or while I was breastfeeding, so that kind of, like, was hard and what led to me kind of getting depressed."* And in another example of capability post-screening, a patient reported: *"Finding someone to keep my child [was a problem], or most of the time therapists are Monday through Friday. So when I was going to do it before, it was like I have to take off work to go to the therapist. I can't take off work."* These findings suggest that the patients' reflective motivation and physical opportunities in the screening stage should be designed for patients to achieve intended behaviors in the post-screening stage.

Discussion

This study investigated how 29 perinatal patients perceived depression screenings and how screening informed their treatment while meeting the specific needs of different racial and ethnic groups within both community and health-care settings. Screening for and treating depression during pregnancy presents substantial dilemmas for both patients and stakeholders. Novel to this study, we used a patient-engagement framework where patients with lived experience and training in research methods conducted interviews with current patients (i.e., pregnant and postpartum people). As documented in past studies, for many patients, pregnancy is the first time they are assessed for depression (27, 28). As mentioned, some research shows that depression screening provides clinicians with a tool to speak with patients about depression (14, 22), but few studies examine patients' perceptions of screening and how they use the information to make informed treatment decisions (3). Thus, the findings of this study present the individual-level responses within the context of a larger system.

The versatility of COM-B in guiding health-care intervention design and pertinent implementation research is upheld in prior studies. Huang and colleagues applied the COM-B framework in their review of the literature on medication adherence (6). Their findings reported on the feasibility of COM-B in categorizing factors associated with medication adherence and non-adherence. They concluded their argument with a discussion of the advantages of the COM-B framework over existing theories of adherence. Grounded in the context of customizing a technology-enabled health communication program to promote Diabetes Prevention Program (DPP)–aligned behaviors among postpartum Latina women with recent gestational diabetes, Suri and colleagues applied COM-B to analyze focus group data ($n = 22$) provided by multiple stakeholder groups (7). Their study verified the feasibility of COM-B as a qualitative thematic analysis framework for understanding the targeted technology-enabled DPP communication program in facilitating intended behavioral changes. In our study, COM-B provides a useful framework for the implementation of perinatal depression screening as a motivating factor that either initiates or hinders patients' efforts to address treatment-seeking or related actions after completing a depression screening.

Depression screening can positively affect service use behaviors. In one study, women screened for depression subsequently used more health services for their infants compared to women who were not screened (29). In this study, to address the perceived influences, patients' reflective motivation in the screening stage can be improved in the following ways: First, the patients' perceptions about the screening can be improved through interventions such as providing patients with prior training or information regarding prenatal depression before the screening. It would be helpful in countering patients' impaired psychological capability (i.e., too depressed to reach out) and increase the automatic motivation factor in the post-screening stage (i.e., trust and comfortability). Second, the manner in which feedback/scores/resource delivery are provided on the screening day can be achieved through interventions such as clarification of the steps of this process as part of mandatory screening protocols. This can increase patients' physical opportunities in the post-screening stage (e.g., prior involvement in services, or providers taking initiatives to make the linkage), which can lead to changes in behaviors.

This study has several strengths, such as the inclusion of patients (i.e., people with lived experience) throughout each step of the study design and data collection. The inclusion of patient perspectives for meaningful engagement and to help make sense of quantitative results empowers patients with opportunities to share their voices. From this study, where former patients interviewed current patients, we learned that the physical opportunity in the screening stage can be improved in the following ways: First, improved communication between providers and patients at the screening can be achieved through interventions such as enhanced communication with providers (e.g., communicating with providers regarding how high-quality communication can prevent patients from experiencing disconnections from providers and preventive care). This could reduce patients' psychological incapability (e.g., too depressed to reach out) and increase their physical opportunities in the post-screening stage (e.g., comfortability). Second, the appropriate time frames for the screening can be achieved through interventions such as increased promotion of the available screening services and information through different media. This would increase patients' physical opportunities in the post-screening stage (e.g., prior involvement in services, or providers take initiatives to make the linkage).

This study also has some limitations. For one, the study only sought to gather the perspectives of people who completed the depression screening and did not include the perspectives of those administering the screenings. Past studies have found that providers perceive a need for more training and preparation to detect mental health needs in usual care settings (22). However, provider motivation and reasoning for their own screening practices was not included in this study and remains unknown. As another limitation, considering that the conceptualization of COM-B framework was based on nine intervention functions and seven policy categories (18), the research team adopted the COM-B framework with the intention to understand individuals' behavioral barriers induced by local organizational structure, processes, and resources. In addition, the selection of the COM-B framework allows the research team to inform organizational health-care policy development implementation with empirical evidence (30). The limitation of the COM-B framework could be its lack of granularity in deciphering study participants' experiences based on the framework's initial conceptual constructs. However, recent qualitative inquiries grounded in COM-B framework have demonstrated its applicability in studying individual behaviors in health-care contexts (31–33). Despite this limitation, COM-B provides a strong starting point to gather how depression screening relates to individual behaviors.

The abovementioned patient-centered outcome research project is considered an example of implementation research because it designed and carried out various processes and events to cultivate stakeholders' commitment to "innovation" (1) to improve the quality of mental health care for perinatal women, our primary stakeholders, in the community. The efficacy of such implementation research, however, depends on many interacting factors. In articulating the effectiveness of implementation, Klein et al. (34) proposed a process framework that consists of the climate for implementation, skills, incentive structures, obstacles, innovation-value fit, and commitment of individuals and organizations (34). In this framework, the mediating role of implementation effectiveness is essential to the ultimate effectiveness of this innovation. Taking a more dynamic perspective to articulate the fluidity of implementation research, Century et al. (35) contended that implementation research is less about the extent to which the innovation could be enacted based on its original design and intent (i.e., the fidelity of the innovation implementation) (35). It is more about understanding factors, conditions, and contexts that can influence the enactment of intended actions, namely following through with depression treatments. They identified several factors: spheres of influence, characteristics of individual end users (of the innovation), organizational and environmental factors, attributes of the innovation, implementation support strategies, and implementation over time. While the two frameworks on implementation research are decades apart, they share some common ground on organizational climate, motivations, and implementation support.

The COM-B framework in this particular study illustrates how various factors and conditions relevant to intended implementation might interact with each other at the organizational level. In another qualitative inquiry, the COM-B framework was applied to reveal facilitators and barriers for general medical practitioners to adopt a web-based telemedicine solution for depression diagnosis and patient empowerment (36). The findings suggested various time-related factors for practitioners to introduce the intervention to patients as well as overcome any difficulty in interfacing with the web-based telemedicine system. In terms of the overall reliability and validity of the COM-B framework, Keyworth et al. (37) developed and validated a 6-item questionnaire derived from the COM-B constructs (Capability, Opportunity, Motivation, and Behavior). Based on a sample of 1,387 health-care professionals working in the National Health Service in the UK, the self-evaluation questionnaire exhibited acceptable levels of reliability, content validity, discriminant validity, predictive validity, and acceptability. This study revealed some ways patients use depression screening to make informed decisions based upon beliefs of available treatment options and their motivations. Future studies are needed to further detect how health-care providers implement depression screening and decisions in the post-screening stage.

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 Illinois at Urbana-Champaign IRB. The patients/participants provided their written informed consent to participate in this study.

Author contributions

KT and W-HH designed the study protocol and obtained funding support. W-JH, JS, and TH transcribed the data and conducted the analysis. MDH, EL, and W-JH wrote the initial draft. All authors provided substantial contributions and reviewed the final draft.

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Conflict of interest

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

Publisher's note

Supplementary material

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/frhs.2022.845441/full#supplementary-material

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Harnessing the Single-Session Intervention approach to promote scalable implementation of evidence-based practices in healthcare

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Effective implementation of evidence-based practices often involves multi-level strategies targeting individual-, organizational-, and system-level determinants of change. Although these multi-level implementation approaches can successfully facilitate EBP uptake, they tend to be complex and resource intensive. Accordingly, there is a need for theory-driven, generalizable approaches that can enhance efficiency, cost-effectiveness, and scalability of existing implementation approaches. We propose the Single-Session Intervention approach as an unexplored path to developing low-cost and scalable implementation strategies, especially those targeting individual-level behavior change. We argue that single-session strategies (S3) for implementation, which can simultaneously target myriad barriers to individual behavior change, may promote clinicians' EBP uptake and sustainment in a manner that is low-resource and scalable. We first overview the evidence-base supporting the Single-Session Intervention approach for patient-level outcomes; situate this approach within the implementation science literature by outlining its intersections with a leading framework, the Theoretical Domains Framework (TDF), as an exemplar; and illustrate how the TDF might directly inform the design and evaluation of single-session strategies for EBP implementation. Overall, single-session strategies (S3) for implementation reflect a promising but yet-to-be-tested means of streamlining and scaling individual-level behavior change efforts in healthcare settings. Future partnered research is needed to gauge the potential of this approach across diverse clinical and community contexts.

KEYWORDS

implementation science, implementation strategy, Single-Session Intervention, Theoretical Domains Framework, behavior change

Background

Per the widely-touted 17-year gap between the identification and application of evidence-based clinical practices, the so-called research-practice gap reflects a canonically "wicked problem" in healthcare (1, 2). This care gap undermines access to effective treatment across health service sectors, including all levels of care (e.g., acute, ambulatory) and across disease areas (e.g., psychiatry, oncology, primary care). In response to this challenge, implementation science has emerged as a discipline focused on systematically studying methods to increase the adoption, use, and sustainment of evidence-based practices (EBPs) in settings where care is delivered. Implementation approaches often deploy multi-level strategies targeting individual, organizational, system, and sociopolitical determinants (i.e., barriers and facilitators) to individual behavior change (3). In many cases, these multi-level and multi-faceted implementation approaches have facilitated increases in use of evidence-based clinical care (4). However, they are often costly and complex to sustain—and past implementation science efforts have struggled to support individual, clinician-level behavior change absent expensive and often-infeasible implementation plans (5). When they have been deployed, they are often not theoretically derived, minimizing their potential impact (6) and preventing identification of change mechanisms (7), which has been highlighted as key to strengthening implementation strategies across levels. These gaps highlight the need for approaches that improve the efficiency, cost-effectiveness, capacity for mechanism-identification, and scalability of effective implementation strategies that shape clinician-level change. Ideally, such approaches could easily integrate with implementation strategies at other levels, across diverse settings and contexts. To enhance their broad usability, such approaches should also be generalizable, offering theory-driven guidelines for scaling implementation strategies for widely-varying practice goals.

We argue that the Single-Session Intervention approach (8)—typically applied to increasing the scalability of patient-level clinical interventions—presents an untapped opportunity to improve the scalability of implementation strategies targeting individual clinician behaviors. We propose that single-session strategies (S3) for implementation may efficiently support clinicians' adoption, implementation, and sustainment of EBPs. Although some brief implementation strategies have been developed and examined previously (e.g., a "pre-implementation enhancement strategy" to strengthen the utility of school-based consultation (9); a brief program leveraging parent opinion leaders to support caregivers to pursue evidence-based mental health care for their children (10), prior efforts have not prioritized the scalability and generalizability of brief, targeted implementation strategies. Below, we overview evidence supporting the Single-Session Intervention approach; highlight its natural intersections with a widely-applied implementation science framework, the Theoretical Domains Framework (11); and outline how the development of mechanism-targeted single-session strategies, built for and with specific populations of clinicians and optimized for scalability, may streamline the development and deployment of flexible, low-cost, and targeted implementation strategies that work.

The Single-Session Intervention approach

Single-Session Interventions (SSIs) are "structured programs that intentionally involve just one visit or encounter with a clinic, provider, or program" (8). To date, they have focused on patient-level clinical interventions and associated outcomes. Often, they target core mechanisms of longer-term healthcare interventions, such as a program teaching a single evidence-based treatment strategy for depression (cognitive reappraisal; behavioral activation). However, their brevity and flexibility augments their immediate, cost-effective scalability. SSIs may be offered as stand-alone interventions or adjunctive supports within broader healthcare systems; they may be delivered by trained providers or *via* digital, self-guided programs; and *via* diverse settings, from classrooms to clinics to smartphones.

SSIs have improved individual-level outcomes spanning many disciplines, including education, medicine, and public health. SSIs have increased motivation to empathize, empathic accuracy, and the number of friendships in college students (12); decreased alcohol consumption among individuals with alcohol use disorder (13); mitigated rates of HIV infection among high-risk adolescents (14); increased distress tolerance and endorsement of positive parenting practices among high-anxiety parents of young children (15); decreased self-hatred and increased intentions to stop self-harming in youth with histories of non-suicidal self-injury (16, 17); produced clinically significant improvements in pain catastrophizing, pain intensity, and pain interference in adults with chronic lower back pain, with non-inferior effects to 8-session cognitive behavioral therapy (18); and significantly reduced 3-month depression, anxiety, hopelessness, and restrictive eating behaviors in a nationwide sample of adolescents ($N = 2{,}452$) during the COVID-19 pandemic, vs. a supportive-therapy control (19). In a meta-analysis of 50 randomized trials, SSIs significantly reduced youth mental health problems, relative to their respective controls, with effect sizes only slightly smaller than those observed for longer-term and more expensive youth mental health treatments (20, 21).

How do SSIs work? Broadly, they target theory-driven principles and proximal factors that underlie general behavior change—regardless of the distal outcome of interest. For

FIGURE 1
Conceptual model illustrating how Single-Session Interventions (targeting patient-level outcomes) and single-session strategies (targeting clinician EBP implementation) may shape distal outcomes of interest (patient health; clinician EBP use) by proximally shaping shared determinants to individual-level behavior change. Notably, mechanisms theorized to underlie the effects of SSI and S3 are shared, but S3 may be evaluated as a means of improving uptake of any EBP, including and beyond SSIs.

example, Schleider et al. (8) describe a four-component process to designing SSIs capable of spurring behavior change, grounded in basic research in social psychology, education, and marketing. These design features involve (1) including scientific evidence and social-norming data to normalize the users' experiences and boost message credibility; (2) empowering users as "experts;" (3) allowing users to share back what they learn during the intervention, to help others in their community navigate similar challenges; and (4) including narratives from others facing similar challenges. Many SSIs also guide users to develop an "action plan" for using the new skill, to strengthen motivation and self-efficacy in future strategy use (19, 22, 23). These design principles reflect insights from participatory action research, which highlights the benefits of empowering individuals to "expert" positions (24), which is consistent with implementation science approaches; self-determination theory, which suggests that boosting feelings of competence, agency, and relatedness can motivate adaptive behavior change (25, 26); and meta-analyses suggesting that narratives increase persuasiveness of health-related messaging (27, 28). Indeed, self-guided SSIs adhering to this design framework have shown consistent, sustained impacts on myriad factors that motivate adaptive behavior change, including hope (17); self-efficacy and perceived agency (19, 29); and expectancies that changes in emotions and behaviors are possible (12, 30, 31). Moreover, evidence from SSI trials suggests that short-term changes in these outcomes (e.g., perceived control and agency) predicts larger improvements in long-term clinical outcomes (e.g., depression, anxiety), suggesting these targets as likely mechanisms of SSI effects (29). Notably, all four of these design principles may be integrated into even the briefest of SSIs, including those that have required just 5–8 min of users' time (e.g., *via* inclusion of a single peer quotation, a single free-response item, or a two-sentence description of a psychoeducational concept). The SSI design features highlighted here reflect recommendations for framing SSI content, which may be built-out as briefer or longer interventions, per context-specific needs. At the same time, it is not necessarily required that an SSI encompass all four design features; they are presented as one of potentially many approaches to constructing single-session programs that spur improvements in relevant outcomes.

Because the mechanisms underlying SSI effects reflect generalizable drivers of behavior change, and given SSIs' consistent impacts on myriad outcomes, it stands to reason that SSIs may be helpfully reconceptualized as single-session strategies (S3) for implementation: Targeted, theory-informed activities aimed at promoting the uptake and sustainment of evidence-based clinical practices among clinicians. In other words, by tailoring the content of SSIs to address clinicians rather than patients, these brief, potent activities may be harnessed to motivate clinician EBP uptake and use (see Figure 1 for conceptual model).

Mapping overlaps between SSI capacities and widely-used implementation science frameworks may streamline tests of their utility and provide insights on development of strategies. Below, we describe how the single-session approach may be usefully integrated with the Theoretical Domains Framework (TDF), highlighting opportunities for the TDF to guide design and evaluation of single-session strategies (S3) to efficiently disseminate efforts to support clinician-level behavior change.

Notably, S3s would differ substantially in their goals and structures from existing provider-directed EBP training programs, which generally aim to establish mastery and uptake of complex, multi-pronged interventions (e.g., trauma-focused cognitive behavioral therapy) (32). Likewise, S3s would differ considerably from existing online continuing education (CE) courses for providers, which are often didactic, impersonal, lengthy (multiple hours) and often focused primarily (or exclusively) on knowledge-building (33, 34). Unlike these existing provider-directed supports, S3s would likely target uptake of highly specific EBPs (as no 15-min program can reasonably teach providers to deliver entirely new forms of treatment); and they would be designed as streamlined, interactive, and user-informed activities, in contrast to existing, highly-didactic online CE programs. Therefore, viewing S3s as activities that might be embedded within or alongside more extensive CE programs or provider trainings, along with system-level approaches to facilitating individual-level change, might be more fruitful than viewing S3s as alternatives to existing, provider-directed training programs.

Understanding single-session strategies for implementation using the Theoretical Domains Framework

The TDF is a leading implementation determinant framework that incorporates 128 constructs spanning 12 domains, derived from 33 different theories of behavior change (11). The TDF organizes myriad constructs known to motivate individual-level behavior change. For the purposes of this Perspective—and given the known best-uses for SSIs—we focus here on individual-level factors within the TDF (35). Individual-level TDF domains include knowledge (e.g., of scientific rationale for implementation); skills (e.g., ability); social/professional role and identity (e.g., group norms); beliefs about capabilities (e.g., self-efficacy); beliefs about consequences (e.g., outcome expectancies); motivation and goals (e.g., intention); memory, attention, and decision processes (e.g., attention control); emotion (e.g., burnout); behavioral regulation (e.g., feedback); and nature of the behavior (e.g., routine). These factors may be considered as individual, mechanistic targets for implementation strategies for mitigating individual-level barriers to behavior change—any of which might be tested as possible change mechanisms in future implementation research, per recent calls by leaders in the field (7).

Based on the SSI literature, it stands to reason that S3 for implementation—built as brief, streamlined programs for clinicians to complete—may be able to target multiple TDF-identified targets for individual behavior change. Table 1 overviews how previously developed SSIs (targeting patient-level outcomes) have targeted each of the TDF's individual-level barriers.

Notably, several examples in Table 1 reflect SSIs that primarily target one (or just a few) TDF-derived barriers. However, it is also possible for an SSI to simultaneously address multiple TDF-identified barriers, without substantially increasing intervention length. One example is the ABC ("Action Brings Change") Project: a 20-to-30-min, self-guided digital SSI based on principles of behavioral activation, an evidence-based depression intervention [the ABC Project was recently redesigned as a 5-to-8 min self-guided program, without demonstrating any reductions in proximal or distal effects—suggesting that its potency and capacity to target mechanisms of change does not depend on longer program duration (17)]. ABC was designed for adolescents experiencing depression; the program encourages users to "take action" in moments of sadness and amotivation by engaging in values-aligned activities (23). It has significantly reduced depressive symptoms in high-symptom teens relative to a placebo control (19). The follows the four SSI design features noted above (knowledge provision; user empowerment; personal narratives; advice-giving opportunities), which in this case easily map onto various TDF-derived barriers. First, the program addresses knowledge *via* psychoeducation about the nature of depression, and how taking values-based actions can boost mood in moments of low motivation or distress. It simultaneously targets social identity by providing users with norms regarding the many teens who experience depression—along with symptom relief after practicing values-based actions. It addresses skills and the nature of the behavior through a personalized "action plan," wherein users build a plan for engaging in specific, values-aligned activities in response to negative emotions. Further, it enhances memory for SSI content, empowering users to advise a peer in "taking action" to manage their mood [such "self-persuasion" writing activities promote internalization of novel beliefs (36)]. ABC has shown positive effects on beliefs about capabilities and consequences [e.g., increased confidence in one's capacity to cope with depression-related challenges (22)], and emotions [e.g., reduced hopelessness and depression symptoms (19)].

Overall, viewing the ABC Project within the TDF framework helps clarify the individual-level behavior change barriers, or mechanisms (7), through which the program might shape patient-level outcomes. By including assessments of proximal outcomes at immediate pre- and post-SSI along with distal clinical outcomes, prior SSI trials have identified the mechanisms (among those targeted) most likely to underlie effects on future symptom reductions (here, increased beliefs about capabilities and consequences and more positive emotions). Therefore, even when an SSI might be viewed as targeting multiple mechanisms simultaneously, it remains possible—through thoughtful and well-timed assessment—to parse which mechanisms matter most. The TDF also allows for parsing strengths and gaps in the broader SSI literature: Which TDF-derived barriers should an SSI target to maximize impacts on target outcomes? How do best-fit TDF targets vary across settings and behavior change goals? Future program development and evaluation may clarify these and related questions.

TABLE 1 Mapping individual-level TDF-defined behavior change determinants onto single-session implementation strategy (S3) targets.

TDF determinant	Targetable *via* S3?	Examples from evidence-based Single-Session Interventions targeting individual-level outcomes*
Knowledge	Yes	A parent-directed SSI provides psychoeducation about child anxiety, including a scientific rationale for reducing parenting behaviors that accommodate children's avoidance of anxiety-provoking stimuli, and encouraging approach-related ("brave") behaviors instead (15) SSI length: 30 min Format: Digital (self-guided) Primary outcome(s): Parent accommodation of child anxiety
Skills	Yes	An adolescent-directed SSI teaches, and embeds opportunities users to rehearse, "behavioral activation:" an evidence-based strategy for increasing positive affect by engaging in values-aligned activities (17, 23) SSI length: 5–20 min Format: Digital (self-guided) Primary outcome(s): Depressive symptoms; hopelessness
Social and professional role and identity	Yes	An adolescent-directed SSI includes survey results suggesting that >95% of their peers report *at least some* difficulty making friends at the start of a new school year, and that most report making *at least one close friend* by the end of that same year, normalizing and instilling hope among users (19). SSI length: 20 min Format: Digital (self-guided) Primary outcome(s): Depression, anxiety
Beliefs about capabilities	Yes	A college student-directed SSI is designed to instill the belief that empathy is a malleable skill that one can develop with practice, as opposed to a fixed trait that people "have or don't" (12). SSI length: 30–60 min Format: Digital (self-guided) Primary outcome(s): Empathy malleability beliefs; Empathic accuracy
Beliefs about consequences	Yes	An adult-directed SSI teaching that emotions are malleable through effort, as opposed to fixed and uncontrollable, increases expectancies that psychotherapy could be effective in treating mental health problems (31). SSI length: 5–8 min Format: Digital (self-guided) Primary outcome(s): Expectancies for the effectiveness of psychotherapy
Motivation and goals	Yes	An adolescent-focused SSI increased intentions to stop self-harming behaviors among youth with a recent history of non-suicidal self-injury (16, 17). SSI length: 5–30 min Format: Digital (self-guided) Primary outcome(s): Intentions to stop self-harming; Non-suicidal self-injury
Memory, attention, and decision processes	Yes	A Single-Session Intervention teaching users to practice mindful, non-judgmental awareness of chronic pain (i.e., supporting *attentional control*) significantly reduces pain catastrophizing, pain interference, and pain intensity among adults with chronic lower back pain (18). SSI length: 120 min Format: Provider-delivered Primary outcome(s): Pain catastrophizing, pain interference, pain intensity
Emotion	Yes	Multiple adolescent- and adult-directed SSIs reduce hopelessness, depression, and anxiety symptoms, both immediately and across multi-month follow-ups (15, 17, 19, 20, 23). SSI length: 5–60 min Format: Digital (self-guided) and provider-delivered Primary outcome(s): Depression, anxiety
Behavioral regulation	Yes	A parent-directed SSI provides immediate feedback (and opportunities to self-correct) during quizzes and vignette-based tasks, in which parents are asked to identify evidence-based strategies for reducing anxiety and promoting bravery in their children (15). SSI length: 30 min Format: Digital (self-guided) Primary outcome(s): Parent accommodation of child anxiety

(Continued)

TABLE 1 (Continued)

TDF determinant	**Targetable *via* S3?**	**Examples from evidence-based Single-Session Interventions targeting individual-level outcomes***
Nature of the behavior	Yes	An adult-directed SSI supports the creation of a personalized "action plan" to support the implementation of concrete, daily steps toward a values-aligned goal. Individuals select *when, where,* and *with whom* they will implement each goal-aligned step, resulting in a documented routine for them to follow in the future (22). SSI length: 45–60 min Format: Provider-delivered Primary outcome(s): Hopelessness; Perceived agency/self-efficacy

*All examples are drawn from clinical trials or randomized experiments of SSIs, in which the SSI was found to significantly improve the primary patient-/individual-level outcome of interest (e.g., parenting behaviors; expectancies for therapy effectiveness; mental health symptom severity).

Applying TDF to build, optimize, and test single-session strategies for implementation

What might a S3 for clinician EBP implementation look like, in practice, and how might the TDF inform its design? We offer an example of what an S3 might include, and how it might theoretically integrate with implementation strategies at other levels.

For illustrative purposes, a helpful context to consider is primary care: the first, and often only, healthcare access point for large portions of the population. One EBP for which primary care providers may benefit from implementation support involves providing patients with evidence-based mental health treatment recommendations, for those presenting with psychiatric difficulties. Although at least one implementation approach has been designed to support uptake of this EBP among primary care physicians (37), it is highly time- and resource-intensive—nearly 4 h long and designed for delivery by health professionals—and was not designed to target TDF-guided behavior change principles. Accordingly, we consider what a theory-driven, scalable S3 targeting this EBP might look like, if we rebuilt it based on the aforementioned SSI design principles and TDF-identified determinants.

First, the S3's delivery format is important to consider. Meta-analytic evidence suggests that effect sizes for clinician-delivered and digital (fully self-guided) SSIs for youth mental health do not significantly differ from one another, and several self-guided SSIs targeting TDF-guided behavior change factors have improved patient-level outcomes (12, 14–16, 19). Because digital, self-guided strategies are inherently easier to disseminate, technology-mediated S3s seem practical to prioritize and test. Many evidence-based, patient-directed digital SSIs require between 5 and 30 min to complete (see Table 1), suggesting an approximate target duration for novel S3s targeting clinician behavior change. Moreover, constructing S3s as self-guided digital activities would fit easily into many healthcare organizations' existing workflows for disseminating learning modules to clinicians (*via* digital platforms).

Second, we consider which TDF-guided behavior change targets to address, and how to address them within best-practice SSI design frameworks (as noted above, these design principles are not required to include in all SSIs or S3s; rather, they are applied here to exemplify one well-evidenced approach to designing SSIs that can spur individual-level behavior change). Toward the "providing scientific evidence" SSI design principle, the self-guided S3 might convey known benefits of making evidence-based mental health care recommendations. Drawing from the TDF, the S3 might target barriers linked to knowledge and professional/social identity by sharing data regarding norms among primary care physicians' mental health treatment recommendations to patients, along with the direct patient benefits that evidence-based treatment recommendations confer. Toward the "helping others/sharing back knowledge" and "users as experts" SSI design principles, the S3 might further address professional identity barriers by empowering physicians to write anonymous notes to others in their organization, sharing their personal and professional perspectives on the value of offering evidence-based treatment recommendations to patients with psychiatric needs. Third, toward the "testimonials from similar others" SSI design principle (and further addressing knowledge and professional barriers), the S3 might include testimonials from other physicians and patients, describing how making or receiving evidence-based mental health care recommendations benefited them personally. Through each of these approaches, targeting knowledge and professional identity-related barriers might enhance physicians' motivation to implement the new practice, as well as expectancies that doing so will benefit patients. Moreover, embedding an interactive "treatment recommendation plan" within the S3, wherein physicians select best-fit evidence-based treatment recommendations for common presenting mental health problems in their patient population (similar to the "action plan" embedded within existing SSIs (24), and resulting in a tangible resource for physicians to offer patients) might increase their perceived capability to implement the practice in real-time. Comparing S3 that target one or several of the above-mentioned TDF-identified behavior change targets and testing their relative effects on the behavior of interest (providing patients with evidence-based mental health treatment recommendations) might clarify which behavior-change barriers (and, in turn, which change mechanisms) are most important to target. Randomized factorial experiments might be useful methods for comparing the utility of targeting different combinations of behavior-change barriers *via* versions of the same S3.

It is also likely that S3 effects on clinician-level change will be enhanced if combined with implementation strategies at the organizational levels, given that implementation science focuses on clinician behavior within organizational constraints. Indeed, there will be many circumstances wherein organization-level strategies are essential to spurring initial EBP uptake—and in such cases, S3 approaches might enhance the capacity of those organization-level strategies to sustain clinician-level behavior change. This possibility opens a wide range of empirical questions to evaluate in diverse contexts of care. For instance, once an optimal S3 is developed for a given clinical context and EBP, one might compare the relative utility of implementing the S3 alone, vs. the S3 in combination with organizational- and system-level implementation strategies—for instance, providing primary care practices with intensive, expensive facilitation programs designed to support EBP uptake (38). Similar study designs have been used to test whether “nudges” are sufficient to change clinician EBP use, or whether more intensive, structural strategies are needed for nudges to sustain behavior change (39). Future research might compare the utility of an S3 relative to (or combined with) other implementation strategies—such as EMR-based reminders for physicians to recommend evidence-based mental health treatment options, yoked to individual patient diagnoses. Overall, the impacts of theory-driven S3 remain unknown—and hold considerable promise—across a wide variety of healthcare contexts, representing an important set of empirical questions to test in future research.

Discussion

We have proposed a novel approach to developing individual-level theoretically informed and brief and scalable implementation strategies for individual-level behavior change: Single-session strategies (S3) for EBP implementation. By targeting the same generalizable behavior change strategies that underlie evidence-based SSI for patient-level outcomes, single-session strategies for implementation may spur clinician-level EBP use at scale. The most novel aspect of this approach is the brevity in which it can achieve behavior change. Grounding and testing novel S3 based on established implementation frameworks, such as the TDF (as outlined here), or other common frameworks with similar elements (40) may optimize their impact on individual-level barriers to clinician behavior change. An advantage of theoretically grounded approaches, like S3, is that they clarify how implementation strategies might work, aligned with recent calls from thought leaders about mechanisms as the next frontier in implementation science (7). This aligns with other approaches used to develop implementation strategies, including implementation mapping (41). Here, we use the TDF to offer a roadmap for researchers interested in applying and evaluating different S3 approaches in diverse contexts.

Several caveats warrant consideration. First, implementing EBPs can be incredibly challenging—and for certain EBP implementation efforts, S3s for individual-level behavior change barriers will not be enough. In this vein, we are not suggesting that S3 should replace other implementation strategies already active within organizations; however, they may represent a scalable means of streamlining individual-level efforts within complex implementation plans. Likewise, in settings where no implementation plans are feasible to implement, S3 might offer sufficient support for certain types of EBP uptake. Both possibilities require future study. Additionally, any S3 will be unable to alter structural barriers that often strongly shape clinicians’ motivation and behavior (42). Thus, there is a need for research on contexts and structural factors that may catalyze or stymie S3 effectiveness.

In future examinations of TDF-guided S3s for clinicians, it will be critical to optimize program feasibility and acceptability. Patient-level SSIs are more feasible than longer-term psychotherapies for individuals to access and complete, but they still require some degree of effort and motivation from users. Across healthcare settings, clinicians have exceptionally limited time; therefore, new S3s must be brief and simple to ensure acceptability. Substantially-reduced versions of the same patient-directed, digital SSIs—from 25 to 5 min—produce comparable impacts on clinically-important outcomes [e.g., hopelessness, self-hate (17)]. Therefore, minimizing S3 user burden—and making S3 completion rewarding (e.g., offering compensation for S3 completion; integrating S3 completion into continuing medical education)—will be critical to sustaining programs.

Alongside prioritizing acceptability, co-design with clinicians in different settings will be critical to S3 success, as it has been for evidence-based patient-directed SSIs (23). Some patient-directed SSIs have shown equivalent effectiveness across diverse populations [e.g., LGBTQ+ youth (43)], but the same cannot be assumed for S3 for EBP implementation. Because salient behavior-change barriers are likely to differ across healthcare contexts, S3s that target the same EBP might require substantial adaptation across settings—and they might prove most acceptable and useful to providers at different points in long-term implementation processes. Thus, population-specific S3 co-design will remain key to effective design and dissemination.

Overall, single-session strategies (S3) for implementation represents a promising but yet-to-be-tested approach for streamlining and scaling individual-level behavior change efforts in healthcare settings. Future organization-partnered research may reveal the promise of this approach across diverse healthcare settings, contexts, and EBPs.

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

JS and RB conceptualized the manuscript. JS wrote the initial draft. Both authors reviewed, edited, and approved of the final manuscript.

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Conflict of interest

JS serves on the Scientific Advisory Board for Walden Wise and the Clinical Advisory Board for Koko, is Co-Founder and Co-Director of Single Session Support Solutions. Inc., and receives book royalties from New Harbinger, Oxford University Press, and Little Brown Book Group. RB is principal at Implementation Science & Practice, LLC, she receives royalties from Oxford University Press, consulting fees from United Behavioral Health and OptumLabs, and serves on the advisory boards for Optum Behavioral Health, AIM Youth Mental Health Foundation, and the Klingenstein Third Generation Foundation outside of the submitted work. In addition to the above potential conflicts, the authors would like to note that JS leads a research lab whose mission involves designing, evaluating, and disseminating single-session mental health interventions, including those discussed in the present manuscript.

Publisher's note

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Organizational readiness to implement a care model in primary care for frail older adults living at home in Sweden

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Background: The demographic change of an aging population constitutes a challenge for primary care organizations worldwide. The systematic implementation of preventative and proactive care models is needed to cope with increased care demands.

Objective: To investigate the organizational readiness in primary care to implement a new care model to prevent hospitalization among frail older adults.

Method: Individual qualitative interviews with health care staff investigated organizational readiness at seven primary care units in Sweden. A semi-structured interview guide was used during the interviews and included broad questions on individual and collective readiness to change. Directed content analysis and organizational readiness to change theory were used in data analysis.

Results: Positive beliefs among staff such as perceived benefits and compatibility with existing values contributed to a strong commitment to implement the new care model. However, perceptions such as unclear task demands, limited resources and concerns about new collaborative structures challenged implementation.

Conclusions: The findings emphasize implementation as an inter-organizational phenomenon, especially for holistic practices that span across multiple health care providers and disciplines. Furthermore, implementing care models in healthcare may require a change of culture as much as a change of practice.

KEYWORDS

implementation science, organizational readiness, primary health care, qualitative methods, care pathways

Introduction

The world's population is aging and the number of people over the age of 65 years is estimated to more than double by the year 2050 (1). As the population ages, the number of frail older adults will increase with changed health care demands as a result, for example, care of multi-morbidity, chronic diseases as well as acute conditions (2, 3).

Primary health care has been considered an ideal setting to address the needs of the frail older adults at risk of hospitalization (4). However, the health and care needs are not always identified in a timely manner because the health care system has a predominantly reactive orientation, i.e., acting when disease, injury or symptoms have occurred.

The importance of achieving a more standardized, individualized and proactive health care for frail older adults in Sweden provided the impetus for implementing a new primary care model called "Focused Primary Care" (FPC) during 2017-2019 (5, 6). The model includes a tool that identifies older adults that are at-risk of hospitalization and prompts primary care to systematically appraise medical status and health and social care needs among this population. The FPC model strives to be proactive (by identifying and reaching out to at-risk frail older adults); holistic (addressing social, psychiatric, functional, and medical concerns) and individualized (interactive care plans are created by a multi-professional team, patients, and family). There is an increased demand for shared responsibility and collaboration to meet overall needs. Older adults are over-represented with regarding both length of stay and frequency of hospital admissions (7). In addition, care has been found to be fragmented and poorly coordinated which may have further challenged the implementation of preventative care for this group (8).

Within implementation theory, several factors are typically proposed to determine implementation outcomes such as the characteristics of an innovation (e.g., the complexity of the care model); the individuals that implement the innovation (e.g., attitudes toward the care model among staff); contextual factors (e.g., financial resources) and the strategies that are employed (e.g., training offered to staff) (9). Furthermore, these determinants for implementation act on multiple levels of an organization, interact and together contribute to implementation success or failure. So-called organizational readiness to change has been recognized and shown to be a central aspect for successful implementation. Indeed, theory and empirical studies indicate that the readiness for change, to be central for subsequent implementation processes and outcomes (10–14) in terms of both individual staff members and collective group levels. The Organizational readiness to change theory conceptualize readiness to change as the shared experience of the ability and willingness to change in an organization. The theory further posit that this shared sense of readiness is determined by the extent to which individuals feel committed to change, confident in the collective ability to change, value the change as important and worthwhile as well as the extent to which they perceive that there are sufficient resources for change in the organization (11).

Aim

To investigate the organizational readiness to implement a new care model for frail older adults in nine primary care units in Sweden.

Methods

Study design

A qualitative interview study including interviews with physicians and nurses from nine primary care units. Directed content analysis (15) and the Organizational readiness to change theory was used in data collection and analysis (11).

Theoretical framework

Organizational readiness to change (ORC) has been argued to be a critical success factor for the implementation of new innovations (12). The ORC theory was developed by Weiner (11) and used to inform interview questions and data analysis. The theory conceptualizes implementation of change as collective, coordinated efforts carried out by organizational members. Thus, "organizational readiness" to implement change is the shared psychological state in which organizational members feel committed to change and confident in their collective ability to change. Determinants of organization readiness to change consist of change valence (how much organization members value the specific change and why) and situational assessment (task knowledge, resource availability and situational factors). These two determinants affect change commitment and change efficacy (the collective cognitive appraisal of the situational factors) taken together this predict the organizational readiness to change.

Setting

In Sweden, individual primary care units are responsible for offering preventative, primary and secondary care to the population living in their specific geographical area and registered patients. Primary care is also responsible for care in the home for older adults for example medical treatment and rehabilitation. Although primary care is not responsible for social services, the implementation of the new care model (Focused primary care) prompted collaboration with various actors outside of primary care for instance social services. Nine primary care units were invited and took part in interviews. All nine units were expected to within the FPC trial (5) implement a new care model in routine primary care. All nine units were located in Region Östergötland in the south of Sweden.

Participants

Purposive sampling was employed, inclusion criterion was health care professionals who were expected to adopt the new care model and had a critical role in the implementation process. Eligible individuals were identified in collaboration with the manager at each unit. The ambition was to recruit both physicians and nurses as these two professions were to have different roles in the implementation of the care model. Eligible individuals were invited through an e-mail that described the aim of interviews and information relating to participating e.g., confidentiality. A total of 18 individuals (nine physicians and nine registered nurses) were identified as eligible and invited to take part in interviews. Out of these, 12 individuals accepted to take part, and were interviewed (five physicians and seven registered nurses; one man and 11 women).

Data collection

Data collection was conducted at an early phase of implementation to capture key aspects of perceived readiness to change at the units. A semi-structured interview guide was used that aimed to capture (1) how the care model was perceived and understood. e.g., how new ways of working would affect current routines, (2) individual readiness to change, e.g., motivation and skills; and (3) organizational readiness to change, e.g., resources to implement the care model at the workplace. The interview guide was first piloted in an interview to determine its ability to capture data relevant to the study aims. The questions were perceived to be informative and valid, thus no major revisions were made, and the test interview was included in the analysis. Data collection was done by authors KT and PD (both PhD, female and postdoc researchers at the time with experience in qualitative methods) and two members of the larger FPC project group (both research assistants, female with experience in qualitative methods). Interviews were conducted in the workplace of each participant and lasted between 40 and 60 min. At the end of each interview, the interviewer asked if there was anything that had not been elucidated. All interviews were recorded and transcribed verbatim by a professional transcriber. Informed consent was obtained before each interview after the participants had been given written information about the study and informed that participation was confidential and voluntary, and that they could withdraw at any time during or after the interview. No compensation was given to participants and no relationship was established between interviewer and participants prior study commencement.

Data analysis

The interview data were analyzed using directed content analysis in accordance with Hsieh and Shannon (15). Content analysis is a method for analyzing texts based on empirical data that are explorative and descriptive. The use of a deductive category application and use of existing theory can help to focus the research question to predict variables of interest and the relationships between variables (15). Directed content analysis is a structured process for coding data using an existing theory or previous research (15). In this study, ORC theory (11) was used to analyze data.

As a first step, both authors read all transcripts repeatedly to gain an understanding of the whole dataset. The transcripts were then coded by the authors separately, which entailed coding and categorizing the data according to each construct of the ORC theory, both in terms of determining initial coding and relationship between the codes. In the next stage, the authors discussed the interpretation of the data in relation to ORC theory and compared their coding. The discussions continued until no inconsistencies existed and a shared understanding was reached to prevent researcher bias and strengthen the internal validity (16). Data that were deemed not to correspond to the OTC theory in the coding phase were coded later on in the analysis process and if relevant, labelled inductivelly (15). Representative quotations were identified to report the findings throughout the analysis. As a last step, quotations were translated from Swedish to English by the authors.

Results

The data showed that the new care model was perceived by nurses and physicians to include four standardized steps: identification of at-risk individuals, care planning, execution- and follow-up of care (Table 1). The data further indicated that the primary care units were at different stages of the implementation process at the time of the interviews. Some units had started to prepare for implementing the care model which was illustrated by for example allocating staff roles and responsibilities, whereas other units were at an earlier phase, perhaps only started to reflect on making organizational changes. However, all respondents were able to reflect and talk about the implementation of the care model at their unit.

The informants described that a single nurse or a small group of nurses were put in charge of implementing procedures. Designated nurses had the responsibility to book appointments with patients, coordinating the work on generating interactive care plans and monitoring patients over time. At the primary care units, mainly registered nurses and physicians actively worked with the care model. However, fully executing care plans also required liaising with stakeholders outside the primary care unit, e.g., municipality nurses (home care) and physiotherapists. Below follows results for each construct of the Organizational Readiness for Change theory (11): change valence, change commitment, situational assessment and change efficacy.

TABLE 1 A step-by-step description of the care model according to data.

Step	Actions	Actors
Identification		
Prediction	Identification of at-risk older adults based on algorithms/matching criteria using data from the regional care register	Project management team
Compilation	A list of at-risk adults is compiled for each participating primary care unit	Project management team
Distribution	A list of at-risk adults is distributed to the manager at each primary care unit	Managers (primary care units)
Review	Mapping of physicians responsible for each frail older adult who has been identified as at-risk Mapping of current care situation	Registered nurses (PC†)
Prioritization	Prioritizing how patients should be contacted	Registered nurses (PC†) and physician
Care planning		
Patient interview	The frail older adult is contacted via telephone where standardized questions is used to explore physical, mental and social health, general care needs and current medications	Registered nurses (PC†) and patients
Examination	Visit to the primary care unit for an examination. If the patient is not able to attend, home visits are carried out	Registered nurses (PC†) and patients
Assessment rounds	Generation of interactive care plans	Registered nurses (PC† and M‡ as needed) Physicians
Execution of care		
Treatment/action	Care is carried out according to the interactive care plans	Registered nurses (PC† and M‡) Physicians Rehabilitation professions
Follow-up of care		
Follow-up of treatment and actions	Health care professionals talk with patients and follow up care needs and outcomes	Registered nurses (PC†)
Revisions of care plans		Physicians Patients

† PC, primary health care; ‡ M, municipality (care in the home).

Change valance

Change valence refers to the extent organizational members perceived it necessary to implement the care model, expressed it to be important, beneficial, and worthwhile (11). The data showed that nurses and physicians were positive toward implementing the care model. Positive regard was expressed as beliefs that the new model will standardize the care process, increase work satisfaction among staff, and be beneficial for the patients. Furthermore, informants expressed the belief that the new care model would be highly relevant for frail older adults and that the new way of working would enable them to better meet the care expectations of this patient group.

> *"I have huge expectations, I felt that this way of working was needed when I worked in the municipality. The elderly is a large group. I love to work with elderly; it is the best thing I know . . . They don't need to explain their life story all over again; this way of working has huge advantages for the elderly"* Respondent 2, registered nurse.

Furthermore, informants expressed that the model enabled opportunities for patients to have a more central role in the healthcare process in terms of communicating their needs and preferences during care planning. The informants also expressed that they believed that patients would benefit from having an increasingly centered role in their care plan. Respondents expressed that the new care model required them to adapt a new approach whereby patient preferences were considered and addressed in a more systematic way compared to before.

> *"You have a more structured way of thinking and what to pay attention to. Previously, it was more fragmentary and not put into a wider context. The patients' response has not been the driving force, but rather what is written in the journal and my own and the nurses' experience. This method is more centered and based on the patients' response to the questions... it's different from how we worked before. Then there was more focus on medical assessment and what to do more or less in relation to that"* Respondent 5, physician.

The informants also expressed beliefs that implementing the care model could promote health care staff to employ a more holistic approach which was thought to be beneficial for patients. One example was working with the interactive care plans which required health care staff to consider multiple aspects of patients' situation including medical needs as well as home and social life. To fully employ a holistic approach to care thus required closer collaboration with, predominantly physicians, but also other health professions such as physiotherapists, occupational therapists or home care nurses.

> "*It is another type of collaboration. Before, you had specific questions (to the physician) but now we sit down together and discuss what I and the patient have talked about … It is rewarding; you feel that you are doing a good job … The patients are satisfied when they leave*" Respondent 6, registered nurse.

Furthermore, working holistically was expressed by nurses and physicians as something worthwhile and important. To understand the health and care needs from a holistic perspective was thought to not only benefit patients but also improve general work satisfaction among staff because these aspects were in accordance with core values and professional role expectations.

> "*You don't have so much time to work proactively. One thought I had was, will I generate more jobs when we already have trouble finding physicians. But if we work proactively, we might prevent people from getting sick and we will decrease the inflow in the long run; that is a good way to work*" Respondent 4, registered nurse.

Lastly, change valence was represented by the belief that the new care model would improve the care process for the patient group as a whole. The new care model was believed to enable continuity of care, including allowing patients to have one point of contact at their primary care unit. Respondents emphasized that a major strength of the new care model was providing primary care with structured way of working with frail older adults.

> "*It will be easier for the patient. They know that the nurse will call on Mondays and they can talk. It increases the feeling of safety and continuity. It also means you don't need to call an extra time. You can get to know your patient and that is extra important for this patient group*" Respondent 2, registered nurse.

Change commitment

Change commitment referred to organizational members' willingness and motivation to pursue the course of action involved in implementing the change (11). The level of change commitment is determined by the degree of change valence. Several primary care units had already started to plan for and improve their work with frail elderly persons. Thus, for them, the care model as a new way of working was legitimate and the purpose well sanctioned.

> "*We had made our own prediction list and then this research study came along. We lost some time because we already had our own plan and had to re-think; but we all wanted to do this*" Respondent 5, physician.

Change commitment was expressed among the respondents by the continuous effort to invest in implementing the new care model despite, e.g., limited resources or resistance among colleagues. Also, respondents described engaging in relational work with colleagues and patients to push for implementation or avoid resistance.

> "*Absolutely, we are positive and see this assignment as our responsibility to a very high degree*" Respondent 1, physician.
>
> "*You need to have time; we have that, we schedule this. It is me and one more nurse here who have half a day to work with this … It increases the pressure elsewhere, but that was there before this change too. It is always stressful, but we agreed to be involved and we want to prioritize this*" Respondent 6, registered nurse.

However, the data showed that negative experiences of previous implementation efforts or practice change to some extent compromised change commitment. For example, one nurse mentioned that she was tired of constantly being involved in new initiatives especially since several initiatives over the years had not been successfully implemented.

Situational assessment

Situational assessment is proposed to determine change efficacy and consists of task knowledge, perceived resource availability, and other situational factors (11). That is, did the informants know what it would take to implement the new care model and did they believe the care model could be successfully implemented at their unit given their current resources for change. The data showed that resources to implement change was perceived as both sufficient (experience in implementing change) and insufficient (staff resources). Specifically, resources to implement change were characterized in the data by the availability of time and staff and competency to implement change. Although respondents expressed a belief that there was sufficient competency and experience to implement change, they also voiced concern regarding the limited resources that were available in terms of staff and time.

> "*You find a concept that seems good and investigate how they have solved it somewhere else, with regard to finding resources, and find they put in a lot of resources. Then you are supposed to do the same thing but with no resources … that permeates what is expected from primary care*" Respondent 9, physician.

Regarding how nurses and physicians understood what was expected from them (task knowledge and demands), the respondents expressed the care model was somewhat unclear, for instance regarding roles and responsibilities. Sound knowledge about the model and what each step meant regarding workload and responsibility for staff was highlighted as important for successful implementation. Also, informants described how the timing of communicating roles and responsibilities were important, and clear from start.

> "*Knowledge about the model is required. If it this is not communicated properly, you don't know what is expected from you … Before you have the prediction list, it is not a good idea to talk too much about the model because that will create more anxiety than clarity. … If I were to ask if they [colleagues] know what is expected of them in the different steps today, 80-90% would say that they don't have a clear picture. It has to be totally clear if it is to work successfully in practice*" Respondent 1, physician.

Implementing the new care model entailed collaborating with new partners in a more structured way, including patients, family, and the municipality. The informants foresaw challenges with these new collaborative structures because of limited previous experience as well as limited resources and a rigid organizational structure. Collaboration beyond colleagues at the primary care unit was expressed as a central component of the care model to fully employ a holistic approach to care and to be able to monitor care outcomes over time. Respondents appraised how the new care model affected them and their work situation.

> "*I will work with five different physicians; that means it is going to be quite fragmentized and difficult. It feels like a more general organizational change might be needed for this to work well, but we'll see; collaboration I believe will be important*" Respondent 3, physician.
>
> "*We should collaborate more with the municipality and work differently but we don't have the resources … you could work full time with only this and still feel that you lack time. There are many elderly who are ill*" Respondent 10, registered nurse.

Change efficacy

Change efficacy refers to organizational members' cognitive appraisal of three determinants of implementation capability: task demands, resource availability, and situational factors (11). The data showed that the situational assessment in terms of poor understanding of the new way of working and perceptions of limited resources could limit change efficacy. Also, nurses and physicians expressed that collaborating with professions outside of the primary care unit or the municipality could be challenging. Although respondents expressed motivation and commitment to change, aspects that challenge their change efficacy were present:

> "*Many of these patients have home care, which makes things a little tricky; how do we do it? We can ask home care to do the interviews from the lists, but they have no obligation to do so; the interface between us is tricky*" Respondent 9, physician.

Poor understanding of the new care model among staff negatively influenced change efficacy. For example, one informant expressed concern regarding their limited experience working with the interactive care plans. Respondents also highlighted that their primary care unit was already under pressure even before embarking on implementing the new care model. Informants described limited organizational capacity.

> "*Today the situation is already strained in primary care so that is a bit frustrating*" Respondent, 1, registered nurse.

Discussion

This qualitative study explored organizational readiness to implement a new care model for frail older adults in primary care in Sweden, using the Organizational readiness to change theory (11). Overall, the findings showed a strong commitment to change among nurses and physicians, which was characterized by positive beliefs and expectations regarding the care model. However, findings also suggested that unclear task demands, perceptions of limited resources, and concerns about new collaborative structures compromised change efficacy.

Shared commitment to make a practice change and implement the new care model stemmed from beliefs that the model would bring change that was needed and worthwhile. Indeed, the findings showed that both nurses and physicians could see valued benefits of the care model on both patient and staff levels, and that the new way of working resonated core values: an increasingly proactive and holistic approach to care. Care for frail older adults requires assessments of physical, psychological, and social capacity and function. That is, it is essential to adopt a proactive, multi-professional, and holistic approach rather than focusing on the treatment of disease. Adopting a holistic care approach, including maintaining acceptable levels of functioning and not just preventing death and disease, could have facilitated the respondents' commitment to the change and has been mentioned as a significant cornerstone of health interventions for an aging population (17). The findings showed that the staff members believed that the new care model could offer a valuable framework to work in this way. A review on the effectiveness of care pathways and models showed that they can indeed facilitate standardized care, documentation, professional behavior change, and decision making (18). In addition, a mixed-method study investigating the implementation of a similar care model in Netherlands showed that a similar model provided a useful and feasible structure to deliver geriatric primary care and contributed to similar positive aspects to those found in this study, such as, work satisfaction among staff and patients feeling increasingly acknowledged by clinicians and that patients' care needs were met in a more adequate way (2).

Indeed, the approach of the new care model echoed core values among organizational members which could be an important facilitator for implementation. For example, Self-determination theory posits that the higher an individual values a specific change, and the more intrinsic the motivation is, the more likely it is that change (implementation) will occur (19). Previous research supports the idea that commitment based on "want to" rather than "need to" or "have to" represents a higher level of commitment. It has been shown that individuals with intrinsic commitment also display more cooperative behavior (e.g., volunteering for tasks) and championing behavior (e.g., promoting implementation) (20). Most of the respondents expressed that they "wanted to" use the intervention and exhibited cooperative behavior and took explicit responsibility for the implementation. Also, informants described that they promoted the value of the change to colleagues, thus performing a championing behavior. Early implementation research showed that change champions indeed influence implementation outcomes (21, 22). Recent qualitative research looking at important champion characteristics in successful implementation efforts proposed that long-term commitment, willingness to promote the innovation, credibility, capacity, and social capital were all qualities that could facilitate and drive implementation forward (23). Thus, the model's ability to tap into core values and subsequent champion behaviors among physicians and nurses would probably facilitate implementation in a significant way.

However, findings on beliefs in the collective capability to implement the model revealed some challenges. Informants perceived task demands to be unclear, resources to be limited, and expressed concerns about the need for new collaborative structures that reached outside of the care unit. For example, informants expressed a limited understanding of the roles and responsibilities of the whole chain of care (from identification of at-risk patients to follow-up of care). A scoping review (24) on conditions for implementing care coordination highlight the central theme of complexity, in terms of both care complexity (multiple care providers) and case complexity (patients with multimorbidity). The authors highlight the potential need to both reduce complexity and embrace it to achieve good and equal care. Similarly, our findings suggest that case complexity was mainly embraced illustrated by for instance commitment to a more holistic approach to care. On the other hand, the complexity of care and the need for new collaborative structures was not embraced to the same extent. Indeed, our findings showed concerns that the new care model required collaboration across primary-, home- and social care which was an infrastructure that was perceived to not yet be in place. Strickland (25) draws on system theory and emphasizes that organizational change may not be separated from other organizations but are rather closely connected to their environment. The value of a system perspective on organizational readiness to change is apparent in this type of innovations because it is greatly affected by structures, processes and culture of multiple organizations and divisions. That is, the primary care organization cannot in isolation implement the full range of care because they only have control of one part of the care model (in this case identification and assessment). To fully understand organizational readiness to implement care models such as the one in our study therefore needed a more comprehensive system-approach to readiness.

Thus, the findings suggested discrepancies between the strong commitment of the staff on the one hand and perceived lack of resources and capabilities of the primary care system and culture on the other hand. ORC theory posits that change commitment (willingness) and change efficacy (assessed ability) are inter-related and can influence each other (11). For example, beliefs in poor abilities to implement a change could impair strong commitment for change or vice versa. Scaccia and colleagues (12) propose that organizational readiness for change encompass motivation to implement an innovation, general capacity for change as well as innovation-specific capacity for change. Our findings suggest strong motivation to implement the care model but however, that innovation-specific capacity in terms of change in culture was limited. Indeed, to implement a new approach to care, shifting from predominantly reactive care to a proactive approach may need a cultural change within the primary care system. For example, the care model was described as a long-term ambition which could potentially clash with the short-term realities of everyday practice. More importantly, it has been proposed that high readiness in one area (e.g., motivation) will not compensate for poor readiness in another area (e.g., innovation-specific capacity) (12) which confirms that discrepancies in readiness seen in our findings would need to be carefully considered to optimize conditions for implementation.

Organizational members perceived that they had limited resources to implement new practice routines, and lack of time was mentioned as a hindrance to implementation. However, several respondents mentioned that the intervention was sanctioned and supported by managers, and most participants had time set aside even when the unit was under pressure. Time restraints is an often-cited barrier for implementation (3, 26).

Schein (27) highlighted however the importance of leaders being consistent in imposing what is valued, even during times of organizational strain, arguing that communicating priorities can be more important than added resources.

Lastly, the findings support the notion that organizational readiness to change is a multi-level and multi-faceted construct. Determinants of readiness was found at individual, group and unit levels for example perceptions of the new way of working, multi-professional collaboration and management support. Furthermore, additional determinants were identified for instance difficulties in collaborating with stakeholders outside of the immediate care unit. Thus, the findings showed that this "collective" extends to inter-organizational relationships, patients, and family.

Methodological considerations

To employ a theoretical framework in analysis was useful to understand and structure the data in terms of identifying key aspects of readiness for change for example beliefs among health care professionals that the new care model was needed (change valence in ORC). The research design included multiple primary care units implementing the same new care model. This design allowed for multiple examples of contexts and processes to study and compare, which we believe strengthened the data. However, a limitation was that only physicians and nurses from the primary care units were included. Considering the holistic approach of the care model, it could have been valuable to also investigate the perspectives of other professions such as social workers or psychologists or other actors for instance patients or municipality nurses. However, we adopted a primary care unit approach whereby the organizational readiness of the units was investigated rather than the implementation process of the care model in general. Furthermore, the study was conducted within the Swedish health care system which may have limited the transferablity of the findings to health care organizations outside of Sweden. Finally, the limited number of interviews that were feasible to conduct can have reduced the credibility of the data. However, individuals eligible for interview were restricted. Since only nine units were expected to implement the care model, this resulted in 18 individuals eligible for interview.

Conclusions

Implementing a new care model for frail older adults requires collaborative efforts from primary care, municipalities, patients, and their family members. This study emphasizes the importance of considering implementation as an inter-organizational phenomenon, especially for interventions that span across different health care providers. Readiness to change must thus be considered across the whole patient journey, which requires a deeper understanding of inter-organizational processes. This study further indicates that implementing a proactive, holistic, and multi-professional approach to care demands a change of culture in primary care as much as a change of practice. Further, that implementation required new skills, i.e., working in multi-professional teams, and change of mindset toward a proactive population management and understanding change management. The evolution of patient care models will also need resources; primary care cannot alone front the cost of the transformation needed to support this new approach to care if implementation is to be successful.

Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors upon reasonable request.

Ethics statement

This qualitative study and data collection was part of a larger study which were reviewed and approved by Regional Ethical Review Board at Linköping University (2016/347-31). Participants gave informed consent prior interviews.

Author contributions

KT contributed to the planning of the study, conducted interviews, analyzed the data, and wrote the first draft of the manuscript. PD contributed to the planning of the study, conducted interviews, and analyzed the data. Both authors read and approved the last version of the 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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Use of the consolidated framework for implementation research in a mixed methods evaluation of the EQUIPPED medication safety program in four academic health system emergency departments

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Background: Enhancing Quality of Prescribing Practices for Older Adults Discharged from the Emergency Department (EQUIPPED) is an effective quality improvement program initially designed in the Veterans Administration (VA) health care system to reduce potentially inappropriate medication prescribing for adults aged 65 years and older. This study examined factors that influence implementation of EQUIPPED in EDs from four distinct, non-VA academic health systems using a convergent mixed methods design that operationalized the Consolidated Framework for Implementation Research (CFIR). Fidelity of delivery served as the primary implementation outcome.

Materials and methods: Four EDs implemented EQUIPPED sequentially from 2017 to 2021. Using program records, we scored each ED on a 12-point fidelity index calculated by adding the scores (1–3) for each of four components of the EQUIPPED program: provider receipt of didactic education, one-on-one academic detailing, monthly provider feedback reports, and use of order sets. We comparatively analyzed qualitative data from focus groups with each of the four implementation teams ($n = 22$) and data from CFIR-based surveys of ED providers (108/234, response rate of 46.2%) to identify CFIR constructs that distinguished EDs with higher vs. lower levels of implementation.

Results: Overall, three sites demonstrated higher levels of implementation (scoring 8–9 of 12) and one ED exhibited a lower level (scoring 5 of 12). Two constructs distinguished between levels of implementation as measured through both quantitative and qualitative approaches:

patient needs and resources, and organizational culture. Implementation climate distinguished level of implementation in the qualitative analysis only. Networks and communication, and leadership engagement distinguished level of implementation in the quantitative analysis only.

Discussion: Using CFIR, we demonstrate how a range of factors influence a critical implementation outcome and build an evidence-based approach on how to prime an organizational setting, such as an academic health system ED, for successful implementation.

Conclusion: This study provides insights into implementation of evidence-informed programs targeting medication safety in ED settings and serves as a potential model for how to integrate theory-based qualitative and quantitative methods in implementation studies.

KEYWORDS

implementation science, Consolidated Framework for Implementation Research, mixed methods, emergency medicine, medication safety, older adults

Introduction

Older adults are a vulnerable population at high risk for adverse drug events (ADEs), especially when they are discharged from the Emergency Department (ED) with a newly prescribed medication. Prescribing new medications for older patients outside the primary care setting increases the chances for suboptimal prescribing as well as ADEs, which are both major reasons for repeat ED visits, hospitalization and death (1–8). Recent studies show that more than half of older adults discharged from the ED leave with a new prescription medication (1, 2), and that the risk of it being a potentially inappropriate medication (PIM), one which could cause an ADE due to pharmacotherapy properties, physiological changes in aging, or limited efficacy in older adults, ranges from 5.6 to 13% (2–7). Prescribing safety and medication use among older adults is a public health concern and an important component of the "Medication" focus of the Age-Friendly Health System initiative (9, 10).

EQUIPPED (Enhancing Quality of Prescribing Practices for Older Adults Discharged from the Emergency Department) is an innovative quality improvement initiative designed to reduce PIM prescribing for adults aged 65 years and older (11). EQUIPPED comprises three intervention components: (1) provider education; (2) electronic health record (EHR) clinical decision support *via* specialized geriatric pharmacy order sets and links to online educational content at the point of prescribing; and (3) monthly provider feedback reports that include audit, feedback and peer benchmarking coupled with one-on-one provider academic detailing. EQUIPPED is informed by the Beers Criteria (12), evidence-based recommendations issued by the American Geriatrics Society that are widely used by government agencies and supported by research in various settings (1, 3, 5), to define PIMS and as a marker of prescribing quality in older adults. EQUIPPED is among a group of clinical decision support interventions that have been shown to be effective in changing provider behavior (13, 14). EQUIPPED has been successfully implemented in 20 urban and rural Veterans Affairs (VA) Medical Centers, with the first eight sites reducing PIM rates from a pre-implementation baseline of 7.4–11.9% of all prescriptions to 4.5–9.0% of prescriptions for 2 to 4 years after the initial 12-month implementation (11, 15) and additional results forthcoming. Early results based upon export and expansion of this VA innovation to additional VA and non-VA health systems also demonstrate reduction in PIMs at multiple sites (16–19).

Given the rapidity with which evidence is generated around safety and care of older adults and the often-cited timeframe of 17 years to move this evidence into practice (20, 21), it is vitally important to identify factors that facilitate more efficient and successful implementation and dissemination of evidence-informed interventions such as EQUIPPED into real-world settings. While a number of studies have examined outcomes associated with efforts to decrease PIMs in older adults (22–25), very few have evaluated the process of implementing evidence-informed interventions in EDs (26). Evaluating the implementation process intentionally and systematically using a theory-based approach will build the evidence-base for best practices such as EQUIPPED, and more generally, for common types of interventions such as provider education, clinical decision support, and academic detailing combined with audit, feedback and peer benchmarking across a range of settings and topics. In addition to medication safety for older adults, these strategies are commonly used to promote implementation of a broad range of clinical care guidelines, including for antibiotic prescribing, cancer screening, and mental health care, among other topics (27–29), with applicability in low, middle and high income countries (LMIC) (30, 31).

The Consolidated Framework for Implementation Research (CFIR) (32) is a widely used framework in implementation science designed to synthesize constructs from a range of theories and models (32, 33). It organizes 39 constructs and sub-constructs across five major domains and its consistent use across studies can help to build an evidence-base for factors that influence effective implementation. The majority of studies using CFIR have been qualitative, focusing on categorizing barriers and facilitators to implementation into CFIR domains and/or constructs (34–40). Relatively few studies have examined CFIR constructs quantitatively, in part because until recently there were few valid and reliable measures that clearly corresponded to CFIR constructs (41, 42). Moreover, given the many theories, models, potential measures of related constructs, overlapping definitions of similar constructs, and possible units of analysis, selection of appropriate measures for a specific intervention remains challenging (41, 42). Mixed methods studies of implementation, which capitalize on the strengths of both qualitative and quantitative approaches, have historically used quantitative methods to evaluate outcomes and qualitative approaches to document CFIR constructs related to implementation (43, 44). However, with more recently validated survey measures of CFIR constructs, there is now the opportunity to apply a fully mixed methods approach to understanding facilitators and barriers to implementation outcomes, such as fidelity of intervention delivery to a provider or patient population (45).

The purpose of the current study was to examine CFIR factors that influenced implementation of EQUIPPED in four non-VA, academic EDs from four distinct academic health systems using a mixed methods approach. In addition to providing insights valuable to implementing evidence-informed interventions for older adults in ED settings, this study serves as a potential model for how to integrate theory-based qualitative and quantitative methods in implementation studies.

Methods

This study uses a convergent mixed methods design (46) that includes surveys of ED providers, focus group discussions with implementation team members, and program records as the data source for a measure of fidelity. Fidelity is defined as "the degree to which an intervention was implemented as it was prescribed in the original protocol or as it was intended by the program deliverer, p. 69." (47).

Four EDs from four different academic health systems were purposively selected to extend implementation of EQUIPPED to new ED settings and different EHR platforms outside of the VA system where it was originally developed and tested. Three of the health systems use EPIC as the EHR platform, and these sites implemented EQUIPPED sequentially in successive years (2016–2019) under one funding mechanism. The fourth site uses Cerner and implemented EQUIPPED under a subsequent funding mechanism (2019–2021). Each of the selected sites included a clinical investigator who had been involved with the original evaluation of EQUIPPED in the VA system and who was affiliated with the corresponding academic health system. Each site PI formed a local implementation team that represented the skills needed to implement EQUIPPED, including at least one physician champion in the ED who was also a co-investigator on the research team. Implementation team members varied across sites but typically included geriatricians, ED physicians, pharmacists, EHR/IT experts, and a project coordinator. Implementation was sequential, one occurring each year, across the four sites (see Table 1), building program knowledge over time that could be applied at each subsequent site (48). PIMS-related outcomes for the first three EDs are reported elsewhere (16). The implementation evaluation study protocol was approved by the Emory University Institutional Review Board (IRB00087137).

Data collection

Focus group discussions with implementation teams

The goal of the focus groups was to understand the facilitators and challenges faced in adapting and implementing EQUIPPED in the ED. Focus group discussions were conducted with each individual site at least 6 months after project initiation and after the last program components had been implemented, i.e., ED provider feedback reports distributed and one-on-one academic detailing provided. As mentioned, sites implemented EQUIPPED sequentially, with Site A implementing first in 2017 and Site D implementing last in 2020. All implementation team members at each site were invited to participate in the focus groups. E-mail invitations were sent by the site PI and/or research staff. The participation rate was 59.9% with variation across sites from 33.3 to 87.5%. The first three focus groups were conducted in-person and the last was conducted through ZOOM because of the COVID-19 pandemic. The number of participants from each site varied from 4 to 7, for a total $n = 22$ participants. Written informed consent was obtained from all participants. Each focus group discussion lasted approximately 90 min and was

TABLE 1 Emergency departments characteristics, selected implementation outcomes, and provider survey respondents.

Descriptor	Site A	Site B	Site C	Site D
ED characteristics				
Complexity	Level 1 trauma center	Level 3 trauma center	Level 1 trauma center	Level 1 trauma center
Patient Size (unduplicated)	112,446	88,968	53,324	33,856
Proportion patient population age 65%	15%	19.1%	21.2%	27%
Staff providers	96	60	52	65
Percent attending physician	(55.2%)	(53.3%)	(73.0%)	(50.8%)
Implementation (Fidelity) by component				
Education Session [a]	Medium-2	Medium - 2	Medium-2	Low-1
(estimated attendance)	66% attendance	55% attendance	59% attendance	20% attendance
Order Set Use [a]	Low-1	Low - 1	Low-1	Low-1
(% of discharge prescriptions based on one audit)	1.2%	0.4%	3.4%	6.6%
Provider Feedback Reports	High-3 Went out monthly, but for those with PIMS only. Others received monthly congratulation e-mails.	Low-1 All got initial report, then quarterly for those with PIMs only.	High-3 Went out monthly to all	High-3 Went out monthly to all
One-on-one academic detailing [a]	Medium-2 73%	Low-1 50% physicians and <50% physician assistants	High-3 100%	High-3 96%
Fidelity score	8	5	9	8
Implementation order	1st	2nd	3rd	4th
Provider survey respondents				
Profession, *n*, %				
Physician	25 (69.4%)	19 (65.5%)	19 (90.5%)	12 (70.6)
Nurse practitioner	8 (22.2%)	0 (0%)	0 (0%)	3 (17.7%)
Physician assistant	3 (8.3%)	10 (34.5%)	2 (9.5%)	2 (11.8%)
Male sex, *n*, %	16 (45.7%)	18 (64.3%)	11 (52.4%)	8 (47.1%)
Years at ED, mean, SD	10.7 (8.63)	9.3 (6.98)	9.2 (9.62)	9.5 (7.52)

[a] [High (≥80%), Medium (50–79%), Low (<50%)].

audio-recorded. All participants were compensated $30 for their time.

Provider surveys

The provider survey was administered following distribution of three provider feedback reports, and after one-on-one academic detailing was completed with the majority (>75%) of providers. All ED providers (i.e., attending physicians, nurse practitioners and physician assistants) were invited to complete a web-based survey about the implementation of EQUIPPED. An introductory e-mail was sent to providers to inform them of the survey, followed by a personalized link to a web-based survey programmed in REDCap. Up to five weekly reminders were sent. Overall, 108 of 234 providers completed the survey (response rate of 46.2%), with site-specific response rates ranging from 43.2 to 48.3%. Providers were compensated $20 for their participation.

Program records

Meeting minutes from both local sites and cross-implementation meetings were collected by the research team throughout the project. Implementation records on education (i.e., attendance records) and provider feedback (i.e., delivery logs) were requested from the local ED physician champion. Each individual site implemented its own audit of order set use and we included this as an indicator of fidelity of order set implementation, even though generation of a discharge prescription through use of the order set is not required for the intervention to be effective.

Measures

Focus group discussion guide

The focus group discussion guide was designed to assess selected constructs within the CFIR domains of outer setting, inner setting, characteristics of the intervention, and the implementation process. As recommended by Damschroder et al. (32), a subset of 18 constructs was selected for this study, based on those that were potentially changeable and important (32, 41, 42). Specific focus group questions are listed by CFIR construct in Additional Files 1 and 2 and were adapted from prior qualitative research on evidence-based interventions to promote cancer screening and guidance from CFIR developers (https://cfirguide.org).

Provider survey questions

The provider survey similarly assessed constructs within the CFIR domains. The survey was largely adapted from validated measures and tailored for the ED setting with input from the study team (41, 42). Additional File 1 includes brief definitions, the number of items and sample questions for each construct assessed through the survey. Briefly, within the intervention characteristics domain, we assessed complexity (42, 49), and relative advantage (42, 50). For outer setting, we assessed external policies and incentives (42, 51), and patient needs and resources (42, 52). We assessed 11 constructs from the inner setting, including networks and communication (53, 54), two dimensions of culture (stress and effort) (41, 55, 56), implementation climate (41, 57), tension for change, relative priority (58), goals and feedback (42, 59), learning climate (41, 53), compatibility (42, 49), leadership engagement (41, 53, 60), available resources (41, 59), and access to information and knowledge (53). Within the process of implementation, we assessed engaging through champions (42) and reflecting and evaluating (42, 54). Response options varied from Yes/No to a 5-point Likert scale (1 = strongly disagree to 5 = strongly agree).

Implementation outcome: Fidelity

We used program records, including provider attendance records, audit results, meeting minutes, and program delivery logs, to create a measure of fidelity of delivering the intervention to the provider population. The four key intervention components were assessed for each site as follows: (1) education of providers was documented through attendance records (i.e., percentage of providers attending the session), (2) order set usage was assessed through clinical data warehouse extracts (i.e., percentage of prescriptions for older adults made through order sets during an audit period), (3) provider feedback (i.e., monthly to all providers or not) and (4) provider one-on-one education (i.e., percentage of providers meeting one-on-one with champion). Three of the components were each scored from 1 to 3 based on high, medium or low fidelity as follows: 3 = high (≥80%), 2 = medium (50–79%), 1= low (<50%). Provider feedback was scored as 3 = High (monthly reports or congratulations e-mails to all providers), 2 = Medium (quarterly reports to providers), 1 = Low (quarterly reports to providers with PIMS only). An overall implementation fidelity score was then created by summing component scores, resulting in a possible range of 4 to 12. Once calculated, the scores were presented to site leads to confirm and validate the scoring and relative ranking.

Data analysis

Qualitative analysis

Focus group discussions were recorded and transcribed verbatim. The initial codebook was based on the theoretical domains of CFIR. The codebook and code definitions were refined through coding of the first two transcripts, with additional codes added to capture emergent themes. All transcripts were coded independently by two analysts, with discrepancies resolved through discussion. NVivo 11 (QSR International) was used for data management and analysis.

NVivo reports were generated for each CFIR domain and construct, and these were used to prepare site-specific case studies. One analyst prepared all four case studies. The structure of the case studies was as follows: ED characteristics, implementation data from the provider survey and program records, and then five domain-specific sections. Each domain-specific section had scale scores and standard deviations for each construct from the provider survey, followed by a summary of qualitative findings for each construct. Additional analysis was then conducted using an approach similar to that of Damschroder et al. (61) and Liang et al. (35). Each construct was coded for valence, or the direction of each construct's influence on implementation, as expressed by the implementation team members at each site. Constructs were coded as positive (+), neutral (0), or a negative(-) influence on implementation, or not discussed (ND) per the approach described by Damschroder et al. (61). One analyst completed the initial assessment, with a second analyst reviewing the valence scores and disagreements resolved through discussion. The second analyst had visited three of the sites (not the fourth due to COVID), moderated the focus groups, and carefully reviewed the transcripts. A construct was rated as positive if it was described as a positive influence in the organization or a facilitating influence on work processes and/or implementation efforts. A construct was rated negatively if it was described as a negative influence in the organization or an inhibiting influence on work processes and/or implementation efforts (35, 61–63). A construct was rated neutral if there was no description of either a positive or negative influence and/or if descriptions were both positive and negative. Primary findings for each domain and construct were then placed into matrices ordered by level of implementation (i.e., fidelity) for cross case analysis and pattern identification (i.e., whether valence of a construct varied with the fidelity score).

Provider survey analysis

Data from the provider survey were analyzed descriptively with means, standard deviations and differences across sites calculated for each CFIR construct using the Statistical Analysis System (SAS) 9.4. Scales were formed by summing relevant items and then dividing by the number of items to create a scale score. Cronbach alphas were calculated on scales with three or more items to assess inter-item reliability. We examined differences in CFIR constructs across the four EDs using a ANOVA and Wilcoxon rank sum test. Given we were interested in organizational-level variables and the study had just four EDs, we then used graphical displays with sites ordered by fidelity score (Figure 1) to identify patterns associated with implementation fidelity descriptively. Consistent with a convergent mixed methods design, findings were then compared and contrasted across methods.

Results

Description of EDs and study participants

All four EDs were affiliated with academic health systems, and three of the four EDs were Level 1 trauma centers (Table 1). Numbers of staff providers per site ranged from 52 to 96; number of annual visits from unduplicated patients ranged from approximately 34,000 to 112,500. Proportion of the ED patient population comprising adults ages 65 years and older ranged from 15 to 27%. Table 1 also describes the survey respondents. Across all four EDs, 72.6% of survey respondents were physicians, 10.7% were nurse practitioners, and 16.5% were physicians assistants. The average tenure in the ED was 9.8 years (SD = 8.16) and across all EDs, 52.5% were men.

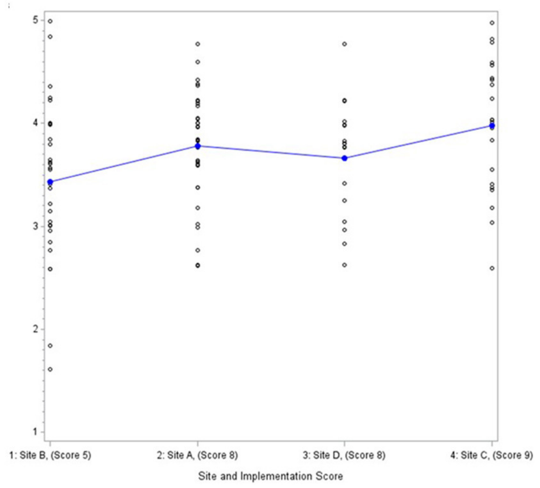

FIGURE 1
Communication and networks mean scores and distribution by site.

Level of fidelity of delivery to provider population

Table 1 also shows fidelity of each intervention component as well as an overall fidelity score. Three of the four EDs had medium levels of provider attendance at the education sessions (range of 55 to 66%), with one ED reporting low attendance. Use of order sets to order medication prescriptions at discharge was low across all four EDs, ranging from 0.4 to 6.6% of all discharge prescriptions for older adults during the period audited. However, use varies by definition; a prior EQUIPPED evaluation indicated that 70% of providers used EQUIPPED order sets when use included consultation of the order sets as needed for a specific medication recommendation (64, 65). Provider feedback reports were categorized as high in three EDs, meaning that reports went out monthly to providers per the intervention design. The ED categorized as low for this component sent out an initial report, but then switched to quarterly distribution. Finally, two sites were classified as having high levels of delivery fidelity for the one-on-one academic detailing component, meeting with almost all of the providers at least once per the intervention design. One ED completed 73% of the one-on-one feedback sessions; and another was able to meet with 50% of their attending physicians and <50% of the physician assistants. Overall, three sites demonstrated higher levels of implementation as operationalized through fidelity (Site A = 8, Site C = 9, and Site D = 8), with one ED exhibiting a lower level (Site B = 5).

Findings by CFIR domain

In keeping with a mixed methods convergent design (46), qualitative and quantitative were first analyzed separately. Findings from the qualitative analysis are summarized in Table 2, with ED sites listed by level of implementation and each CFIR construct categorized as having a positive, negative or mixed influence on implementation within and across the EDs. Constructs that distinguished between high and low levels of implementation are also indicated. Table 3 presents the quantitative results in a site-ordered matrix with mean scores and standard deviation for each construct within each ED, significant differences between the EDs, and Cronbach's alpha when relevant. Table 4 synthesizes the qualitative and quantitative findings, which are discussed in detail below.

Intervention characteristics

None of the intervention characteristics constructs differentiated levels of fidelity in delivery by ED (Tables 2, 3). The provider survey results on relative advantage showed no differences by ED, with respondents across all four EDs somewhat agreeing that EQUIPPED was better than their prior approach for decreasing PIMs (mean score of 3.8 to 4.0). In focus groups with the implementation teams, relative advantage was described as a positive influence in three of the four EDs. For example, in one site, team members stated they did not have anything "*systematic*" in place to address PIMS prior to EQUIPPED and would get "*gentle reminders from pharmacy saying maybe [they] shouldn't do that.*"

Qualitative and quantitative findings also aligned with respect to complexity of the intervention. Provider survey respondents somewhat disagreed with the perspective that EQUIPPED was very complex to implement (mean score of 2.1 to 2.4) (Table 3). Although not asked about explicitly in the focus groups, complexity of the intervention emerged in describing which components were easy or difficult to implement, largely in the context of building the order sets and navigating the approval process for changes to the EHR as opposed to the intervention itself being complex. Members from one team stated the order sets were the hardest to implement because "*there was a lot more red tape to get through and a lot more approval [they] had to get.*"

Of the additional constructs examined qualitatively within the intervention characteristics domain, evidence strength and quality and adaptability were viewed as positive influences in all four EDs (Table 2). For example, implementation team members commented that provider awareness of the Beers criteria, as well as knowledge the intervention was "*evidence-based medicine, that there's been previous… studies and literature that EQUIPPED has worked*" supported provider "*buy in.*" All of the sites described the intervention as adaptable and detailed specific adaptations to fit local needs and context, including changing the provider reports so they were more "*user friendly,*" tailoring the provider education presentation to an available faculty meeting time slot, and aligning the order sets with their work flows, EHR structure, and discharge procedures. These adaptations increased compatibility of the intervention within their settings. Cost was described as a positive influence on implementation in three of the four EDs. One team member emphasized that EQUIPPED cost "*a fraction of the money*" of another one of their initiatives, and they felt it "*was much more impactful*" due to being "*much more… focused.*"

None of the Intervention Characteristic constructs negatively influenced implementation of the intervention, and trialability, or the ability and usefulness of pilot testing, was mixed, in that it was described as positive in some sites and not relevant in others.

Outer setting

One construct within the outer setting domain distinguished level of fidelity as assessed both qualitatively and quantitatively. The EDs varied significantly in the quantitative patient needs and resources measure (mean score of 3.6 to 4.1) (Table 3) in a direction consistent with implementation in that the ED with the highest score on patient needs and resources also had the highest level of fidelity. Patient needs and resources similarly emerged as a distinguishing factor in the qualitative analysis, with the three EDs with higher levels of fidelity describing their older patient populations and associated needs to address PIMs in this group as a facilitator to implementation, while the site with a lower level of fidelity described this factor as neutral (Table 2). For example, in one of the higher implementation EDs, team members indicated their ED has a "*large geriatric population*" and therefore EQUIPPED was a "*unique and great project for* [their] *ED.*" In contrast, one team member in the ED with lower fidelity described how EQUIPPED aligned well with the site's aging population, but that leadership did not recognize those needs or prioritize "*anything geriatric.*"

There were no significant differences in external policies/incentives across EDs on the provider survey, with all four very low on this measure (mean score of 0 to 0.2). Members of the implementation teams described external policies and incentives as a positive influence on implementation, particularly when aligning with quality measures. Some spoke broadly about how the program satisfied several certification and accreditation criteria and aligned with an increased government emphasis on quality, while others spoke specifically about working toward Geriatric ED

TABLE 2 Valence of CFIR constructs by domain as assessed through focus groups with implementation teams, site-ordered by level of implementation.

Construct	Site C	Site A	Site D	Site B	Summary valence
Implementation score	9	8	8	5	NA
Intervention characteristics					
Evidence strength and quality	+	+	+	+	Positive
Relative advantage	+	+	0	+	Positive
Adaptability	+	+	+	+	Positive
Trialability	0	0	+	+	Mixed
Cost	+	0	+	+	Positive
Outer setting					
Patient needs and resources	+	+	+	0	Distinguishing
External policies and incentives	+	+	+	+	Positive
Inner setting					
Structural characteristics	-	Not discussed	+	-	Mixed
Networks and communications	+	+	+	+	Positive
Culture	+	+	+	0	Distinguishing
Implementation climate	+	+	+	0	Distinguishing
Tension for change	-	0	0	-	Mixed
Compatibility	+	+	+	+	Positive
Relative priority	0	+	+	-	Mixed
Organizational incentives/rewards	+	0	+	0	Mixed
Readiness for implementation					
Leadership engagement	0	+	+	-	Mixed
Available resources	0	Not discussed	+	+	Mixed
Access to knowledge and information	+	+	+	+	Positive
Process					
External change agents	+	+	+	+	Positive
Formally appointed implementation team leaders	+	+	+	+	Positive
Champions	+	+	+	+	Positive

+ refers to positive, 0 refers to neutral, - refers to negative valence, or influence on implementation.

certification and how EQUIPPED "*was an easy next step to try to move in that direction.*"

Inner setting

Although operationalized differently, culture distinguished EDs by level of implementation in both the qualitative and quantitative data. Culture varied significantly across EDs from the provider perspective (mean scores of 3.4 to 4.4 for stress and 3.7 to 4.2 for effort), in a direction consistent with level of fidelity for the stress indicator (e.g., site with lower fidelity had higher stress). In the focus groups with implementation teams, a common theme across sites was a culture of research and quality improvement due to having academic faculty as providers and the teaching hospital culture. One participant described a "*good culture*" at their hospital and "*people are receptive to learning, especially if it's evidence based, since [they] are a teaching hospital.*" The site with the lower level of implementation, however, also described shifting priorities, changing leadership, and challenges with overcrowding and delayed hospital admissions. Although each of these fits within other domains, collectively they suggest a more turbulent culture than the other EDs.

Two additional inner setting constructs showed patterns consistent with the level of fidelity as assessed through the provider survey. The higher implementing sites scored higher on networks and communication (Figure 1) (mean scores of 3.4 to 4). In the focus groups, all four implementation teams described networks and communications as facilitating implementation. In one ED, team members stated they "*have a great working relationship in* [their] *department*" with a "*high level of trust among the entire group… including… working with* [PI and study coordinator]." This cohesion makes everyone feel "*comfortable*

TABLE 3 Mean scores of CFIR constructs from ED provider survey by site level of implementation.

Domain and construct	Site C	Site A	Site D	Site B	*p*-value	Cronbach's alpha
Intervention characteristics						
Relative advantage	3.8 (0.81)	3.8 (0.76)	4.0 (0.61)	3.8 (0.98)	0.80	NA
Complexity	2.1 (0.55)	2.3 (0.50)	2.4 (0.55)	2.2 (0.55)	0.26	0.74
Outer setting						
Patient needs/resources	4.1 (0.43)	3.7 (0.56)	3.7 (0.64)	3.6 (0.76)	0.01	0.73
External policies/incentives*	0 (0)	0 (0)	0.2 (0.71)	0.2 (0.37)	0.12[a]	NA
Inner setting						
Networks/communication	4.0 (0.63)	3.8 (0.52)	3.7 (0.58)	3.4 (0.78)	0.02	0.80
Culture-stress	3.4 (0.65)	3.9 (0.86)	3.5 (0.69)	4.4 (0.88)	0.0001	0.92
Culture-effort	4.2 (0.46)	4.1 (0.52)	3.7 (0.49)	3.9 (0.67)	0.03	0.74
Implementation climate	3.7 (0.42)	3.4 (0.58)	3.9 (0.38)	3.5 (0.77)	0.01	0.64
Tension for change	3.6 (0.73)	3.7 (0.67)	3.7 (0.85)	3.4 (0.74)	0.57	NA
Compatibility	4.0 (0.52)	3.7 (0.53)	3.9 (0.46)	3.6 (0.79)	0.09	NA
Relative priority	3.7 (0.41)	3.5 (0.57)	3.5 (0.54)	3.5 (0.63)	0.54	0.55
Goals/feedback	3.2 (0.82)	3.2 (0.75)	3.7 (0.79)	3.3 (0.77)	0.15	NA
Learning climate	4.3 (0.55)	4.2 (0.58)	3.9 (0.55)	3.9 (0.74)	0.04	0.86
Readiness for implementation						
Leadership engagement	4.2 (0.72)	4.0 (0.68)	3.9 (0.61)	3.3 (1.06)	0.001	0.93
Access to info/ knowledge	3.9 (0.54)	3.5 (0.65)	3.7 (0.47)	3.6 (0.77)	0.11	NA
Available resources	4 (0.51)	3.8 (0.38)	3.8 (0.57)	3.8 (0.67)	0.46	0.65
Process						
Champions	3.8 (0.64)	3.3 (0.6)	3.7 (0.58)	3.4 (0.76)	0.0331	NA
Reflecting and evaluating	3.5 (0.77)	2.9 (0.73)	3.8 (0.59)	3.5 (0.72)	<0.0001	NA

Range 1 = strongly disagree to 5 = strongly agree for most items; *Range 0 to 3; [a]Wilcoxon rank sum test.

bringing up issues" and asking questions when they are unsure about anything. Leadership engagement (mean scores of 3.3 to 4.2) similarly distinguished fidelity as assessed through the provider survey, but was viewed as mixed in terms of positive or negative influence from the perspective of the implementation teams, and it did not distinguish higher from lower levels of fidelity.

One additional construct emerged as distinguishing from the qualitative data: implementation climate. Three of the EDs exhibited supportive implementation climates, albeit with different emphases. In one ED, the champion created excitement for the intervention, in others participation in a federally-funded research project helped to smooth implementation (e.g., paid time, higher visibility than a general quality improvement effort). In contrast, focus group participants at the ED with a lower level of fidelity described ED providers' initial concern that quality improvement or research projects might disrupt care; as EQUIPPED was minimally disruptive, it inspired little opposition but also little enthusiasm in this ED.

Compatibility and access to information were each positive influences on implementation in all four EDs and therefore not distinguishing based on the qualitative analysis (Table 2). In describing whether the intervention was compatible, one participant said, "*it's critically important that EQUIPPED was not designed to add time. If anything, it was to be neutral or reduce it, because with all of the pressures that EDs face*," the intervention would not have been successful had it "*impede[d]*" their processes. With respect to accessing needed information, there was generally expertise on the team. As one participant stated, "*Identifying who needs to be on the bus, but that came pretty easily at this organization, and I think we got all the right people on the bus, so it made the process very smooth.*"

Several of the inner setting constructs were mixed in terms of their influence on implementation across the EDs, including structural characteristics, tension for change, relative priority, organizational incentives and rewards, leadership engagement as mentioned above, and available resources.

Process of implementation

None of the constructs assessed within the process domain distinguished level of implementation. The provider survey assessed the constructs of champions, and reflecting and evaluating. Both varied significantly across sites (mean scores of 3.3 to 3.8 for champions, and 2.9 to 3.8 for reflecting

TABLE 4 Integrated results, CFIR construct influence on fidelity as an indicator of implementation quality.

Construct	Qualitative	Quantitative	Distinguishing by both methods
Implementation score			
Intervention characteristics			
Evidence strength and quality	Positive	–	–
Relative advantage	Positive	NS	No
Adaptability	Positive	–	–
Trialability	Mixed	–	–
Cost	Positive	–	–
Complexity	NA	NS	–
Outer setting			
Patient needs and resources	Distinguishing	Distinguishing	Yes
External policies and incentives	Positive	NS	No
Inner setting			
Structural characteristics	Mixed	Differs by Site	No
Networks and communications	Positive	Distinguishing	No
Culture	Distinguishing	Distinguishing (Stress)	Yes
Implementation climate	Distinguishing	Differs by Site	No
Tension for change	Mixed	NS	No
Compatibility	Positive	NS	No
Relative priority	Mixed	NS	No
Organizational incentives/rewards	Mixed	–	–
Goals and feedback	NA	NS	–
Learning climate	NA	Differs by Site	–
Readiness for implementation			
Leadership engagement	Mixed	Distinguishing	No
Available resources	Mixed	NS	No
Access to knowledge and information	Positive	NS	No
Process			
External change agents	Positive	–	–
Formally appointed implementation team leaders	Positive	Differs by site	No
Champions	Positive	Differs by site	No

NS, No significant differences by site; Not assessed (–), Differs by Site (statistically significant but does not correspond with level of implementation).

and evaluating), but not in a pattern consistent with the level of fidelity.

Three of the constructs within the engaging domain were assessed for valence, and all were positive across all four EDs: implementation team leaders, champions and external change agents. Three of the EDs really highlighted their implementation team as using a shared leadership model, describing that while the PI led the implementation of EQUIPPED, they had "*a really distributed leadership model*" with the different team members taking responsibility for different aspects of implementation, depending on their expertise. ED physician champions were designated at the outset of implementation. For example, in one ED, participants spoke about how instrumental the champion was in keeping track of all the various components of EQUIPPED and making sure the project "*moved smoothly*," as well as ensuring the ED was aware of the project and the various components, such as the order sets, so it would be viewed as a priority. The grant recipients (i.e., PI and team) were viewed as the external change agent, and their role was described favorably by all four sites. Evaluating and executing was discussed in terms of how the implementation team will assess whether the intervention was a success, rather than systems for ongoing monitoring and quality improvement.

Discussion

Our mixed-methods analysis identified five CFIR constructs that distinguished the sites with the highest implementation of EQUIPPED from the site with the lowest implementation using fidelity as the implementation outcome of interest. Two constructs emerged consistently across both qualitative and quantitative data (*patient needs and resources* and *organizational culture*), one from the qualitative data only (*implementation climate*), and two from the quantitative data only (*networks and communication*, and *leadership engagement*). Additional factors positively influenced implementation across all four EDs as identified through the qualitative analysis, including: evidence strength and quality, relative advantage, adaptability, and cost from the intervention characteristics domain; external policies and incentives from the external setting domain; networks and communication, compatibility, access to information from the internal setting domain; and external change agent, appointment of a formal implementation team lead, and engagement of champions in the process domain.

Only one of the distinguishing factors was from a domain outside of the inner setting. The finding that *patient needs and resources*, an outer setting construct, was a distinguishing factor in implementation success suggests that EQUIPPED may be easiest to implement at sites which have, or are perceived to have, large geriatric populations with complex care needs that are known and prioritized. Such findings may transfer to analogous programs. Several other studies have similarly noted the salience of patient needs and resources in influencing implementation, sometimes as a distinguishing factor (61–63) and sometimes as salient barriers or facilitators to implementation (34, 35, 37, 39, 44). In environments such as the ED which see a diversity of patients and clinical presentations and have multiple competing priorities, patient subpopulation volumes may be important in driving organizational focus and support. This finding also points to the potential issue of ageism within health systems that may counter attempts to establish an Age-Friendly Health System (9).

The remaining distinguishing factors were from the inner setting domain. The finding that *organizational culture*, including lower stress and higher perceived work ethic, was associated with level of implementation suggests the importance of addressing cultural impediments before attempting to implement a new quality improvement program. For instance, timing of implementation should occur when space and attention can be devoted to it. The EQUIPPED site with the lowest fidelity of delivery reported many unforeseen changes during the period of implementation that may have limited team capacity for new program uptake. In contrast, it is also notable that one of the four sites was in the final stage of EQUIPPED implementation (initiating provider feedback) at the beginning of the COVID-19 pandemic. Despite this significant stressor for ED providers, the pandemic's impact only delayed completion of EQUIPPED implementation by a few months. For this site, the relative strength of the internal organizational culture may have mitigated the impact of a significant external challenge from derailing implementation. Organizational culture is a broad and multi-faceted construct as currently defined in CFIR which makes it challenging to compare findings across studies, with several reporting that it was not assessed or missing from qualitative data (35, 44, 61, 63) or not a distinguishing factor (62). We were able to identify a general "teaching" culture for all sites, with the fourth site also exhibiting a constellation of challenges which we coded as culture qualitatively as they aligned with the quantitative measures which focused on stress and effort.

Implementation climate is an overarching construct with several sub-constructs. Studies that have operationalized the sub-constructs and found some of them to distinguish levels of implementation are most common (35, 61–63). For example, Liang et al. observed that tension for change distinguished sites by level of implementation (35). Damschroder et al. (61) found that four of the sub-constructs distinguished level of implementation, including tension for change, relative priority, goals and feedback, and learning climate. We examined the sub-constructs, as well as an overall implementation climate characterized by overall receptivity to the intervention. Though *implementation climate* distinguished implementation level only qualitatively in our study, it suggests the need for implementation leaders and teams to closely attend to the degree to which its community members are receptive to quality improvement efforts such as EQUIPPED. Being attuned to stress and priorities within the organizational culture may also affect this climate and potentially shut down efforts to implement something new in the ED. The sites with the highest level of implementation were able to generate more enthusiasm among ED providers.

A large number of studies have identified that both networks and communication (61, 62) and leadership engagement (35, 61) are very important influences on implementation. Our study affirms that attention should be given to *networks and communication* and to *leadership engagement* as part of the implementation process, although identified only through the quantitative provider data. Those sites with higher perceived teamwork and regular communication among ED providers, and more engaged and supportive leaders, were able to implement the program more fully than the site with lower levels of these factors.

While we could not identify studies that specifically applied CFIR to understand implementation of medication safety programs for prescribers treating older adults in the ED, these findings may be considered in the context of other studies evaluating implementation of programs to influence prescribing behavior. A narrative review by Baumgartner et al. (26) highlighting factors abstracted from studies focused on de-prescribing inappropriate medications noted that *networks and* communication and patient needs and resources were important factors influencing implementation. Future research should examine whether different factors influence implementation based on setting (e.g., inpatient vs. outpatient), type of intervention (e.g., provider education, audit and feedback), implementation vs. de-implementation, or country context. For example, would culture, networks and communication, and leadership engagement still emerge as major influences on implementation of a medication safety program in LMIC, or would these factors be dwarfed by limited "available resources" in a low-income country? A recent review of CFIR use in over 30 LMIC countries reported general applicability across country context, along with recommendations for increased focus on characteristics of systems (e.g., systems architecture, resource continuity) (66).

Limitations

This study has several limitations that should be considered when interpreting the results. In addition to a small number of EDs, we used just one implementation outcome for the comparative analysis: fidelity of delivery. Although the implementation science and CFIR literature is calling for more precise definitions and measurement of implementation (45), a more general measure of implementation outcomes may have led to different conclusions. Additionally, program records were used to determine delivery levels and these varied in quality. Focus groups did not include all members of the implementation teams and were therefore subject to the perspectives of those present. It is possible our finding would have differed if we had been able to include perspectives on implementation and CFIR constructs by role or position in the ED. Provider surveys too were a subsample of the entire provider sample and there could have been selection bias. Finally, this study did not examine whether increased fidelity or uptake of the intervention by providers was associated with improved PIMS outcomes. Despite these limitations, our data on implementation is representative for EQUIPPED based upon the balanced response rate across sites and the range of detailed data sources leveraged in this mixed methods analysis.

Conclusion

Few studies have evaluated implementation factors for geriatric care programs in the ED setting (26). Our mixed methods analysis triangulates not only different data sources (surveys and focus groups) but also differing perspectives (the implementation team vs. ED providers). Organizational culture, the extent to which the needs of older patients are known and prioritized, strong networks and communication, and leader engagement emerged as particularly important in successful implementation of EQUIPPED. As the Age-Friendly Health System movement grows, programs like EQUIPPED provide clinical leaders in the ED with a blueprint for optimizing prescribing behavior toward older adults. Because there are few implementation studies of quality improvement programs in the ED focused on geriatric care, the current findings are an important first step toward advancing best practices to enhance health care delivery for older adults in the ED.

Data availability statement

The datasets presented in this article are not readily available because one of the datasets generated and/or analyzed during the current study is not publicly available due to its qualitative nature and difficulty in making it non-identifiable. The survey data are available from the corresponding author on reasonable request. Requests to access the datasets should be directed to mkegler@emory.edu.

Ethics statement

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

Author contributions

MK designed the study and data collection instruments, drafted major sections of the manuscript, collected the qualitative data, analyzed qualitative and quantitative data, and edited the full manuscript. SR coordinated data collection, analyzed qualitative data, wrote parts of the results, and edited the full manuscript. AV helped design the study, drafted sections of the introduction and discussion, and edited the full manuscript. SH helped design the study, co-coordinated implementation of the intervention in one ED, and edited the full manuscript. UH helped design the study, coordinated implementation of the intervention in one ED, and edited the full manuscript. SE co-coordinated implementation of the intervention in one ED and edited the full manuscript. CV helped design the study, oversaw implementation of the intervention as overall PI, wrote part of the discussion section, and edited the full manuscript. All authors approved the final version of the paper.

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Conflict of interest

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

Publisher's note

Supplementary material

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/frhs.2022.1053489/full#supplementary-material

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Prerequisites for implementing physical activity on prescription for children with obesity in paediatric health care: A cross-sectional survey

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Background: Physical inactivity is a main driver of childhood obesity that tracks into adulthood, making it crucial to address early in life. Swedish physical activity on prescription (PAP) is an effective intervention for increasing physical activity levels in adults and is being implemented in primary care in Sweden. Before implementing PAP for children, both intervention effectiveness and implementation prerequisites need to be examined. Framed by the Normalization Process Theory (NPT) domains, this study aimed to investigate perceptions of PAP amongst paediatric staff and managers working with children with obesity, as well as acceptability, appropriateness, feasibility, and barriers and facilitators for implementing PAP in paediatric health care.

Methods: Staff and managers in 28 paediatric outpatient clinics in western Sweden were surveyed using validated implementation instruments and open-ended questions. Data were analysed using Mann–Whitney U tests and Kruskal–Wallis tests. Qualitative data were categorised into NPT domains.

Results: The survey response rate was 54% (125/229). Most respondents (82%) reported PAP to be familiar and many (56%) perceived it as a normal part of work; nurses and physiotherapists to a greater extent ($p < 0.001$). This was anticipated to increase in the future (82%), especially amongst those with the longest work experience ($p = 0.012$). Respondents reported seeing the potential value in their work with PAP (77%), being open to working in new ways to use PAP (94%), and having confidence in their colleagues' ability to use PAP (77%). Barriers and facilitators were found in all the NPT domains, mainly collective action and reflexive monitoring, where, for example, inadequacies of education, resources, and research on PAP for children were reported as barriers. Most respondents agreed that PAP was acceptable, appropriate, and feasible (71% to 88%).

Abbreviations
AIM, Acceptability of Intervention Measure; FIM, Feasibility of Intervention Measure; IAM, Intervention Appropriateness Measure; IQR, Interquartile range; NPT, Normalization Process Theory; PAP, Physical activity on prescription; PC, Paediatric clinic; SD, Standard deviation; NoMAD, Normalization MeAsure Development.

Conclusions: PAP is familiar and perceived as an acceptable, appropriate, and feasible intervention, and by many viewed as a normal part of clinical routines in paediatric outpatient clinics in western Sweden, especially by physiotherapists and nurses. Barriers and faciliators are mainly related to collective action and reflexive monitoring. The wide acceptance demonstrates receptiveness to PAP as an intervention to promote an active lifestyle for children with obesity.

KEYWORDS
obesity, physical activity on prescription, children, feasability, implementation, determinants, normalization process theory (NPT), survey

Introduction

Childhood obesity has increased dramatically in recent decades and prevalence remains high in many countries (1, 2), making it an urgent public health concern. The prevalence of obesity in European children aged 5–9 years was 11.4% in 2016 (3). In Sweden, 6% of children aged 6–9 had obesity in 2019, an increase by 4% since 2016 (4). Additionally, the COVID-19 pandemic has driven weight gain amongst children (5–9), caused for example by decreased physical activity, increased screen time, and increased dietary intake (10). Obesity is considered a complex multifactorial condition (11), which tracks into adulthood and is associated with cardiometabolic and psychosocial comorbidity as well as premature mortality (12–15). One of the main behavioural drivers and an important risk factor, is physical inactivity (16, 17), making it critical to address this issue early in life.

For children who are overweight or obese, studies have shown positive effects of physical activity on weight-related outcomes, e.g., body fat and insulin resistance (18, 19), while evidence for interventions to increase children's overall physical activity levels remains inconsistent (20, 21). However, research highlights that although there is evidence for physical activity interventions, implementation strategies to translate evidence-based results into practice are lacking (22, 23). In paediatric health care, behaviour-changing interventions are commonly used with the aim to improve dietary intake, increase physical activity, and reduce sedentary time (16). Physical activity on prescription (PAP) is one such intervention that is being implemented in many countries, including Sweden, to promote lifestyle change in the form of increasing physical activity (24) and decreasing sedentary time (25). The Swedish PAP intervention comprises three core components: a person-centred dialogue, individually tailored activity recommendation with a written prescription, and a structured follow-up (26).

Studies of PAP have shown effectiveness in adults, including patients with overweight or obesity, measured as increased physical activity levels (27), but for children there is a paucity of studies. One study (28) showed PAP to be both feasible and increasing physical activity levels amongst children with cerebral palsy, and one study (29) showed effects on BMI scores in children with obesity after a web-based intervention of which PAP was one component. The Swedish National Board of Health and Welfare's National Guidelines for Methods of Preventing Disease posit PAP as an evidence-based practice targeting adults (30). Because an inactive lifestyle amongst Swedish children and youth is a common health concern (31), several regions in Sweden have started to use PAP for physically inactive children. As part of a combined lifestyle treatment, PAP might be a potentially behaviour-changing and structured intervention for children with obesity, in accordance with the description of requirements and needs in the national guidelines for treatment of childhood obesity in Sweden (32).

Several barriers and facilitators for implementation of health promoting interventions have been identified. A recent review showed that implementation support strategies, such as educational materials and meetings, opinion leaders, small incentives or grants, and tailored interventions may improve implementation of programmes to prevent obesity and promote physical activity for young children (23). For adults, identified barriers for implementing PAP include practitioners' lack of knowledge about the intervention and lack of organisational support (33–36). Reports including paediatric contexts also identified lack of time, lack of evidence for PAP for children, and limited collaboration with activity organisers as barriers (37, 38). Facilitators include affirmative attitudes amongst practitioners' and central and local supporting structures. However, no study has investigated the prerequisites amongst staff and managers for implementing PAP for children with obesity in paediatric health care.

Identifying implementation determinants before implementing a new intervention is crucial for implementation success. Especially in the highly complex healthcare context (39), implementing new interventions can be challenging. It is also important to understand what works and does not work in the implementation process, for which using a theory is recommended (40, 41). The Normalization Process Theory (NPT), especially developed for use in health care, was designed to help us understand how complex interventions become implemented in routine healthcare practice (39). This theory is concerned with explaining the work people do during the implementation process, and comprises four core constructs, or domains (42). The constructs/domains can be described as a set of mechanisms that energise and shape implementation processes, with a focus on how an intervention can become part of everyday practice (43), making them relevant to assess before implementing a new intervention.

Other implementation determinants that are important to assess before implementing a new intervention are the acceptability, appropriateness, and feasibility of the intervention; three determinants often used during early-stage implementation and seen as leading indicators of implementation success (44). There is a lack of knowledge about whether PAP is perceived as a suitable intervention for children with obesity. To address this knowledge gap, it is important to investigate the prerequisites, barriers and facilitators amongst staff and managers for implementing PAP for childhood obesity in paediatric health care. This knowledge is highly warranted before the intervention is implemented more widely.

The aims of this study were to examine (1) how staff and managers perceive PAP for children with obesity in terms of the NPT domains coherence, cognitive participation, collective action, and reflexive monitoring; (2) what barriers and facilitators they report for working with PAP for children with obesity; and (3) how they perceive acceptability, appropriateness, and feasibility of PAP for children with obesity.

Methods

Study design and setting

The study design was a cross-sectional survey, guided by the NPT and collecting quantitative and qualitative data using a web-based questionnaire. Findings are reported, when applicable, according to the STROBE checklist (45).

The study was conducted in the paediatric healthcare organisations in Region Västra Götaland, Sweden, comprising 26 clinics, and four rehabilitation clinics providing healthcare services for children with obesity. The organisations all cater to children with obesity and offer specialist health services. Region Västra Götaland is Sweden's second largest county council, providing healthcare services to approximately 1.7 million residents in western Sweden. One major city, Gothenburg, is located in the region, while the rest of the region comprises three smaller cities, medium-sized towns, and rural areas located in four regional areas (**Table 1**). In Gothenburg, PAP has already been introduced amongst healthcare professionals, through for example education, tutoring, networking, and PAP clinics supporting families whose children have been prescribed physical activity.

Participants

The inclusion criterium for participating in the survey was to be either staff or manager at a paediatric healthcare clinic or a rehabilitation clinic providing outsourced rehabilitation services for children with obesity, in Region Västra Götaland. No prior experience of working with PAP was required. Approximately 240 eligible participants were identified with the assistance of managers and administrative staff. The heads of departments approved the clinics' participation in the study; all 30 clinics accepted the invitation to participate.

Data collection and outcomes

All eligible participants were invited to answer a web-based questionnaire comprising four validated instruments measuring implementation outcomes. The questionnaire was distributed *via* e-mail during a three-week period in February and March 2021. To increase response rate and reduce the risk of non-response bias, three reminders at one-week intervals were sent.

TABLE 1 Participating clinics by geographic location ($n = 30$).

Gothenburg	Regional area			
	Södra Bohuslän	Fyrbodal	Skaraborg	Södra Älvsborg
POC Frölunda	POC Kungälv	POC Dalsland	POC Lidköping	POC Alingsås
POC Hisingen	POC Mölndal	POC Lysekil	POC Mariestad	POC Lerum
POC Kungshöjd	POC Mölnlycke	POC NÄL	POC SkaS	POC Skene
POC Öckerö	POC Partille	POC Strömstad	POC Skövde	POC Ulricehamn
Obesity centre at Queen Silvia's Children's Hospital	POC Stenungssund			POC Viskan
Primary care rehabilitation clinic, Angered	POC Tjörn			Primary care rehabilitation clinic, Lerum
Primary care rehabilitation clinic, Gamlestaden				Primary care rehabilitation clinic, Sörhaga
Specialist centre for children and youth, Angered				
Specialist centre for children and youth, Gamlestaden				

POC, paediatric outpatient clinic.

In this study, the NPT was used to investigate and understand the collective work with PAP for children with obesity at the paediatric healthcare clinics. To assess the implementation process from the perspective of staff directly involved in the work of implementing PAP and their managers, the Normalization MeAsure Development tool (NoMAD) (42) was used. This instrument was specifically developed for implementation in healthcare contexts (42) and can be applied at any stage of an implementation process (46). It is adaptable to different interventions and settings, and can be combined with other measurements focusing on other dimensions of implementation (42).

The NoMAD instrument consists of 23 items, of which three general questions are indicators of normalisation answered on 11-point Likert-type scales ranging from "still feels very new" to "feels completely familiar" for item 1 and from "not at all" to "completely" for items 2 and 3 (46). Twenty items target the four core NPT domains: (1) coherence, that is the "sense-making" work people do to initiate a new intervention or practice; (2) cognitive participation, described as the relational work around the practice; (3) collective action, the work to perform/operationalise the practice; and (4) reflexive monitoring, the appraisal work to understand the new practice (42). Each item has two options, A and B. Option A is answered on 5-point Likert-type scales with response options “strongly agree”, “agree”, “neither agree nor disagree”, “disagree”, and “strongly disagree”. Option B is applicable only to those who found no relevance in answering option A (46).

In this study the validated Swedish version S-NoMAD (47) was used. The word “intervention” was replaced by “PAP for children with obesity” or just “PAP”. Although the instrument was developed for healthcare professionals directly involved in the intervention, we wanted to address the perspectives of both staff and managers. Some items were slightly modified by adding wording addressing managers, e.g., “Do you feel PAP is currently a normal part of your work/area of responsibility?” and “Management supports/I as a manager support PAP for children with obesity”.

To supplement NoMAD, the implementation determinants acceptability, appropriateness, and feasibility of implementing PAP in paediatric health care were assessed, adding the staffs’ and managers’ perceptions and attitudes towards PAP. Acceptability is defined as the perception amongst stakeholders that a given treatment, service, practice, or innovation is agreeable, palatable, or satisfactory (44). Appropriateness is the perceived fit, relevance, or compatibility of the innovation or evidence-based practice for a given practice setting, provider, or consumer; and/or perceived fit of the innovation to address a particular issue or problem. Feasibility is the extent to which a new treatment, or an innovation, can be successfully used or carried out within a given agency or setting (44). These outcomes were measured with the Acceptability of Intervention Measure (AIM), Intervention Appropriateness Measure (IAM), and Feasibility of Intervention Measure (FIM) (48). All three are validated instruments with the purpose of assessing the fit and match of a practice or intervention to a given context, targeting different criteria (48). The measures comprise four items each, answered on 5-point ordinal scales with response options “strongly agree”, “agree”, “neither agree nor disagree”, “disagree”, and “strongly disagree”. The instruments were translated and cross-culturally adapted into Swedish, adapted to children with obesity, and validated (49).

In addition, we collected demographic data and data on PAP experience and prescribing frequency. Two open-ended questions explored barriers and facilitators, in which the respondents were given the opportunity to describe their own experiences and thoughts regarding determinants for implementing PAP.

Data analysis

The quantitative variables are presented descriptively using frequencies and percentages and medians and interquartile ranges. To facilitate future comparisons with other studies, means and standard deviations (SD) are also presented. The respondents’ practice location was categorised into Gothenburg and other regional areas of the Region Västra Götaland (**Table 1**). Work experience in the organisation was categorised into (1), <2 *years;* (2), 2–5 *years;* (3), 6–10 *years; and* (4), >10 *years.* Professions were categorised into six groups: (1), *nurse;* (2), *physician;* (3), *dietician;* (4), *physiotherapist*; (5), *manager* and (6), *other*. Number of years working with/taking decisions about PAP was categorised into (1), <3 *years*; (2), 3–5 years; and (3), >5 *years or longer.* Missing data analyses were performed using chi-square tests to examine proportion of managers and practice location amongst non-responders vs. responders.

To facilitate presentation and interpretation, response categories were merged into fewer categories. Responses to the three general items were coded as: 0–4 = *not familiar* and 5–10 = *familiar* for item 1; 0–4 = *not a normal part of work* and 5–10 = *a normal part of work* for item 2; and 0–4 = *it will not become a normal part of work* and 5–10 = *it will become a normal part of work* for item 3. For the NoMAD items, the *disagree/strongly disagree* response categories were merged into *disagree,* and the *strongly agree/agree* response categories were merged into *agree*. Item 3.2 was reverse-scored due to its negative wording. One item (2.2) was not analysed since it was accidentally removed from the questionnaire. For the AIM/IAM/FIM suite of instruments, the response categories *completely disagree/disagree* were merged into *disagree* and *agree/completely agree* were merged into *agree*.

Comparative analyses of participants from the Gothenburg clinics in which PAP has already been introduced vs. clinics in the rest of the region were performed using chi-square tests for the dichotomised general questions. Because the assumptions of the chi-square tests were not met for the NOMAD and AIM/IAM/FIM items, we performed Mann–Whitney *U* tests using the original 5-point scales. Differences between years of work experience in the organisation and between professions in all variables were performed using Kruskal–Wallis tests with pairwise comparisons, applying Bonferroni correction. For variables where there were significant differences in the main Kruskal-Wallis test, we only report significant differences in the pairwise comparisons. Because age and work experience correlated, no comparisons were made between age groups. A p-value of ≤ 0.05 was considered statistically significant. All cases for which all items in at least one instrument were completed, were included in the analyses.

Internal consistency of the NoMAD items was acceptable for coherence (Cronbach’s $\alpha = 0.748$), and questionable for cognitive participation ($\alpha = 0.600$), collective action ($\alpha = 0.638$), and reflexive monitoring ($\alpha = 0.687$). For the the AIM/IAM/FIM measures, internal consistency was excellent for acceptability and appropriateness (Cronbach’s $\alpha = 0.924$ and 0.943, respectively) and good for feasibility ($\alpha = 0.892$). Quantitative data were analysed using IBM SPSS, version 28 (IBM Corp, Armonk, NY).

The barriers and facilitators described in free text answers to the open-ended questions were coded and sorted into categories corresponding to the NPT domains. This was done in an iterative process by the first author together with two physiotherapist colleagues with experience of working with PAP for children.

Results

A total of 229 healthcare professionals (of whom 30 managers) were invited to participate in the survey, and 125 responded (response rate 54.5%). Of the 104 non-responders, 18 were managers. Missing data analysis showed no significant differences between responders and non-responders related to the proportion of managers or practice location in the Gothenburg area vs. other regional areas. Item-level missing values ranged from 7 to 12 (5.6%–9.6%) for S-NoMAD and from 0 to 8 (0.0%–6.4%) for AIM, IAM, and FIM. Mean age of the respondents was 48.2 years (SD 9.6). Respondent characteristics are presented in Table 2.

TABLE 2 Respondent demographic characteristics ($n = 125$).

Characteristic	*n* (%)
Age (years)	
<30	4 (3.2)
30–39	21 (16.8)
40–49	44 (35.2)
50–59	37 (29.6)
>59	19 (15.2)
Work experience in the organisation (years)	
<2	26 (20.8)
2–5	42 (33.6)
6–10	27 (21.6)
>10	30 (24.0)
Profession	
Nurse, including paediatric nurse	43 (34.4)
Physician, including paediatrician	32 (25.6)
Dietician	13 (10.4)
Physiotherapist	9 (7.2)
Manager	12 (9.6)
Other[a]	16 (12.8)
Role in relation to PAP	
Works with PAP	68 (54.4)
Is aware of PAP but does not work with it	56 (44.8)
Is not aware of PAP	1 (0.8)
Experience of working with PAP (years)	
<3	62 (49.6)
3–5	31 (24.8)
>5	32 (25.6)
Frequency of prescribing PAP	
Prescribers	64 (51.2)
Daily	2 (1.6)
Once per week	10 (8.0)
Once per month	27 (21.6)
Once per year	25 (20.0)
Non-prescribers	61 (48.8)

PAP, physical activity on prescription.

[a] Other = psychologist, social counsellor, occupational therapist, and nursing assistant.

General questions about PAP

A majority of the respondents (81.1%) reported being familiar with PAP (Table 3). A higher proportion of respondents in the Gothenburg area reported being familiar with PAP than those in regional areas (90.0% vs. 70.6%, $\chi^2 = 6.772$, $p = 0.009$). Physiotherapists reported familiarity with PAP to a greater extent than "other" professions (Mdn 9 vs. Mdn 5, U = 55, $p = 0.025$). Fifty-six percent described PAP as currently being a normal part of their work; a higher proportion of respondents from the Gothenburg area reported this than those in the regional areas (70.0% vs. 40.7%, $\chi^2 = 9.882$, $p = 0.002$). Nurses reported feeling PAP was a normal part of their work to a greater extent than "other" professions (Mdn 6.5 vs. Mdn 0.5, $U = 38$, $p < 0.001$), as did physiotherapists (Mdn 9 vs. Mdn 0.5, $U = 53$, $p < 0.001$). A majority (82.0%) reported believing that PAP will become a normal part of their work. Respondents with >10 years of work experience in the organisation reported this belief to a greater extent than those with 2–5 years' experience (Mdn 9 vs. Mdn 6, $U = 23$, $p = 0.012$).

Coherence

Most respondents (67.9%) agreed that they could distinguish between PAP and their usual ways of working, and 56.1% reported that they have a shared understanding of its purpose (Table 4). Respondents in the Gothenburg area agreed to a greater extent than those in regional areas to having a shared understanding of PAP (Mdn 4 vs. Mdn 3, $U = 1170$, $p = 0.005$) and of how the intervention affects the nature of their work (Mdn 4 vs. Mdn 3, $U = 1104$, $p = 0.017$) (Table 5). About three quarters of the respondents (76.6%) agreed on the potential value of PAP. No differences were seen related to work experience in the organisation or profession in this domain. Option B responses were selected by 3–8 respondents (2.6% to 6.8%).

A barrier for using PAP described in the open-ended questions was the respondents' experiences of not knowing the PAP intervention well enough and working with single components alone, particularly the written prescription for physical activity. The opposite, a comprehension of the PAP intervention and considering and including all of its components, was described as a facilitator. Statements like "I consider it important that PAP is well supported by a good assessment so it will be at the right level, for example goal setting, activity, duration, and that the patient is motivated. If not, then it might just be 'another piece of paper' for the individual." were typical.

Cognitive participation

Almost half (47.2%) agreed that there are key people who drive PAP forward and get others involved. Respondents in Gothenburg

TABLE 3 General questions about physical activity on prescription.

Items	*N* (missing)	0–4 1. Not familiar 2. Currently not a normal part of work 3. Will not become a normal part of work *n* (%)	5–10 1. Familiar 2. Currently a normal part of work 3. Will become a normal part of work *n* (%)	Median (IQR)[a]	Mean (SD)[a]
1. When you use PAP, how familiar does it feel?	111 (14)	21 (18.9)	90 (81.1)	7 (5–9)	6.53 (2.61)
2. Do you feel PAP is currently a normal part of your work/*area of responsibility?*	114 (11)	50 (43.9)	64 (56.1)	5 (2–8)	4.99 (3.40)
3. Do you feel PAP will become a normal part of your work/*area of responsibility?*	89 (36)	16 (18.0)	73 (82.0)	7 (6–9)	7.08 (2.62)

Text in italic font are adjustments made so that the item would be answerable also by managers.
[a]Medians and means are calculated on the original 11-point scale.
IOR, interquartile range; PAP, physical activity on prescription; SD, standard deviation.

agreed to a greater extent than those in regional areas that there are key people driving PAP forward and involving others (Mdn 4 vs. Mdn 3, $U = 1000$, $p = 0.003$). Most reported being open to working with colleagues in new ways to use PAP (94.5%) and agreed to continuing to support PAP (85.7%). No differences were seen related to work experience or profession in this domain. Option B responses were selected by 1–8 respondents (0.9% to 6.8%).

A reported barrier in this domain for using PAP was the absence of physiotherapists at the clinics and the perceived uncoordinated pathways to healthcare units offering PAP support. Facilitators for using PAP were colleagues being supportive of PAP and successful healthcare collaboration. Statements like “In my clinic we have divided the tasks between us a little. However, I could prescribe PAP more often, but mostly it’s done by my colleague who is a nurse.” were reported.

Collective action

Over half of the respondents (57.8%) agreed they can easily integrate PAP into their existing work and only 1.8% agreed that PAP disrupts working relationships. A majority (77.2%) reported having confidence in their colleagues’ ability to use PAP. Over half (56%) agreed that work is assigned to those with skills appropriate to PAP. One fourth (26%) agreed that sufficient training is provided to enable staff and managers to implement PAP. Respondents in Gothenburg agreed to a greater extent than those in regional areas that work is assigned to those with skills appropriate to PAP (Mdn 4 vs. Mdn 3, $U = 1116$, $p = 0.032$), that sufficient training to implement PAP is provided (Mdn 3 vs. Mdn 2, $U = 704$, $p < 0.001$), and that sufficient resources to support PAP are available (Mdn 3 vs. Mdn 3, $U = 1121$, $p = 0.029$). No differences were seen related to work experience or profession. One fourth (26.9%) reported that sufficient resources are available to support PAP and half (51.1%) agreed that management adequately supports PAP. Option B responses were selected by 1–22 respondents (0.9% to 19.5%).

Barriers from the open-ended questions were inadequate education and insufficient time to use PAP. Statements like “I would like to learn more about PAP, but I have too many duties to have time to plunge into it. It’s not my most prioritised task, instead it’s something I do on the side, a few times a month” were typical. Facilitators were staff taking on the role of using PAP and having more time with patients when delivering PAP.

Reflexive monitoring

Thirty-seven percent reported being aware of reports about the effects of PAP. Managers agreed to a higher extent than “other” professions that they were aware of reports (Mdn 4 vs. Mdn 3, $U = 45$, $p = 0.013$) and respondents with more than 10 years of work experience in the organisation agreed to a higher extent than those with 6–10 years of experience that they were aware of reports (Mdn 4 vs. Mdn 2, $U = 30$, $p = 0.007$). Sixty percent agreed that PAP is worthwhile and 48.5% valued the effects PAP has had on their work. Respondents in the Gothenburg area agreed to a greater extent than those in regional areas that they valued the effects (Mdn 4 vs. Mdn 3, $U = 890$, $p = 0.011$). The respondents agreed that feedback about PAP can be used to improve it in the future (81.2%). No differences were seen related to work experience. Option B responses were selected by 2–22 respondents (1.7% to 12.1%).

A reported barrier for using PAP was the lack of research on PAP for children. Statements like “I’d like to see randomised studies that are large enough to show the effectiveness of PAP if I am to become positive about the intervention” are illustrative. The opportunity to provide discounted activities was reported as an important facilitator.

Acceptability

Most respondents stated that PAP meets with their approval (85.6%), is appealing (85.6%), and that they like (84.0%) and welcome (83.2%) PAP (Table 6). Respondents in the Gothenburg area agreed to a greater extent than those in regional areas that PAP meets their approval (Mdn 5 vs. Mdn 4, $U = 1528$, $p = 0.022$).

TABLE 4 Responses to NoMAD by Normalization Process Theory domain.

Domain	Option A						
	N (missing)	*n* Option A	Agree *n* (%)	Neutral *n* (%)	Disagree *n* (%)	Median (IQR)^a	Mean (SD)^a
Coherence							
I can see how PAP differs from usual ways of working	117 (8)	112	76 (67.9)	28 (25.0)	8 (7.1)	4 (3–4)	3.8 (0.87)
Staff in this organisation have a shared understanding of the purpose of PAP	117 (8)	114	64 (56.1)	45 (39.5)	5 (4.4)	4 (3–4)	3.6 (0.77)
I understand how PAP affects the nature of my own/ *my staff's* work	114 (11)	108	52 (48.1)	50 (46.3)	6 (5.6)	3 (3–4)	3.5 (0.72)
I can see the potential value of PAP for my work	115 (10)	107	82 (76.6)	22 (20.6)	3 (2.8)	4 (4–4)	3.92 (0.71)
Cognitive participation							
There are key people who drive PAP forward and get others involved	115 (10)	108	51 (47.2)	42 (38.9)	15 (13.9)	3 (3–4)	3.4 (1.0)
I'm open to working with colleagues/ staff in new ways to use PAP	117 (8)	109	103 (94.5)	6 (5.5)	0 (0.0)	4 (4–5)	4.4 (0.59)
I will continue to support PAP	115 (10)	112	96 (85.7)	16 (14.3)	0 (0.0)	4 (4–5)	4.3 (0.7)
Collective action							
I can easily integrate/*take decisions about PAP into my existing work*	116 (9)	109	63 (57.8)	38 (34.9)	8 (7.3)	4 (3–4)	3.7 (0.88)
PAP disrupts working relationships^b	118 (7)	110	2 (1.8)	15 (13.6)	93 (84.5)	4 (4–5)	4.24 (0.79)
I have confidence in *my colleagues/staff's* ability to use PAP	118 (7)	114	88 (77.2)	24 (21.0)	2 (1.8)	3 (1–2)	4.04 (0.75)
Work is assigned to those with skills appropriate to PAP	117 (8)	107	60 (56.0)	40 (37.4)	7 (6.5)	3 (2–3)	3.6 (0.75)
Sufficient training is provided to enable staff/managers to implement PAP	116 (9)	100	26 (26.0)	40 (40.0)	34 (34.0)	4 (2–4)	2.9 (0.93)
Sufficient resources are available to support PAP	118 (7)	108	29 (26.9)	48 (44.4)	31 (28.7)	4 (2–4)	2.93 (1.02)
Management/*I as a manager* adequately supports PAP	113 (12)	90	46 (51.1)	39 (43.3)	5 (5.6)	3 (2–3)	3.6 (0.78)
Reflexive monitoring							
I am aware of reports about the effects of PAP	116 (9)	113	42 (37.1)	37 (32.7)	34 (30.1)	3 (2–4)	3.08 (1.06)
The staff agree that PAP is worthwhile	17 (8)	113	68 (60.2)	40 (35.4)	5 (4.4)	2 (2–3)	3.7 (0.75)
I value the effects that PAP has had on my work	116 (9)	99	48 (48.5)	46 (46.5)	5 (5.1)	3 (2–3)	3.51 (0.75)
Feedback about PAP can be used to improve it in the future	115 (10)	109	89 (81.2)	18 (16.5)	2 (1.8)	2 (2–2)	4.02 (0.73)
I/*the staff* can modify how I/*they* work with PAP	117 (8)	104	63 (60.6)	36 (34.6)	5 (4.8)	2 (2–3)	3.63 (0.78)

IQR, interquartile range; SD, standard deviation.

[a] Medians and means are calculated on the original 5-point scale.

[b] Item reverse scored. In the survey most of the items were formulated as *PAP for children with obesity.* Text in italic font are adjustments made so that the item would be answerable also by managers.

Respondents with more than 10 years of work experience agreed to a higher extent than those with 2–5 years of experience that they welcome working with PAP (Mdn 5 vs. Mdn 4, $U = 23$, $p = 0.019$). No differences were found by profession.

Appropriateness

Most agreed that PAP seems fitting (81.6%), suitable (83.2%), applicable (80%), and like a good match (78.4%) for children with obesity (**Table 6**). No differences were seen by practice location, profession, or years of work experience.

Feasibility

Most respondents reported PAP being implementable (78.4%), possible (88%), doable (82.4%), and easy to use (71.2%) (**Table 6**). No differences were found by practice location, profession, or years of work experience.

TABLE 5 NoMAD responses by Normalization Process Theory domains and practice location.

Areas	Gothenburg ($n = 66$)			Regional ($n = 59$)			p value*
	n (missing)	Median (Q1;Q3)	Mean	*n* (missing)	Median (Q1;Q3)	Mean	
Coherence							
I can see how PAP differs from usual ways of working	56 (10)	4 (3;4)	3.88	56 (3)	4 (3;4)	3.73	0.407
Staff in this organisation have a shared understanding of the purpose of PAP	57 (9)	4 (3;4)	3.79	57 (2)	3 (3;4)	3.40	**0.005**
I understand how PAP affects the nature of my own/*my staff's* work	56 (10)	4 (3;4)	3.64	52 (7)	3 (3;4)	3.29	**0.017**
I can see the potential value of PAP for my work	55 (11)	4 (4;4)	3.98	52 (7)	4 (3;4)	3.87	0.544
Cognitive participation							
There are key people who drive PAP forward and get others involved	52 (14)	4 (3;4)	3.63	56 (3)	3 (3;4)	3.09	**0.003**
I'm open to working with colleagues/*staff* in new ways to use PAP	54 (12)	4 (4;5)	4.33	55 (4)	4 (4;5)	4.44	0.325
I will continue to support PAP	57 (9)	4 (4;5)	4.30	55 (4)	4 (4;5)	4.24	0.675
Collective action							
I can easily integrate/*take decisions* about PAP into my existing work	55 (11)	4 (3;4)	3.73	54 (5)	4 (3;4)	3.63	0.488
PAP disrupts working relationships[a]	56 (10)	2 (1;2)	1.71	54 (5)	2 (1;2)	1.81	0.680
I have confidence in my colleagues/*staff's* ability to use PAP	58 (8)	4 (4;5)	4.12	56 (3)	4 (3;5)	3.95	0.296
Work is assigned to those with skills appropriate to PAP	54 (12)	4 (3;4)	3.74	53 (6)	3 (3;4)	3.43	**0.032**
Sufficient training is provided to enable staff/*managers* to implement PAP	49 (17)	3 (3;4)	3.24	51 (8)	2 (2;3)	2.55	**<0.001**
Sufficient resources are available to support PAP	55 (11)	3 (3;4)	3.13	53 (6)	3 (2;3)	2.74	**0.029**
Management/*I as a manager* adequately supports PAP	41 (25)	4 (3;4)	3.73	49 (10)	3 (3;4)	3.45	0.059
Reflexive monitoring							
I am aware of reports about the effects of PAP	56 (10)	3 (2;4)	3.11	57 (2)	3 (2;4)	3.05	0.995
The staff agree that PAP is worthwhile	56 (10)	4 (3;4)	3.73	57 (2)	4 (3;4)	3.58	0.406
I value the effects that PAP has had on my work	53 (13)	4 (3;4)	3.68	46 (13)	3 (3;4)	3.30	**0.011**
Feedback about PAP can be used to improve it in the future	56 (10)	4 (4;5)	4.05	53 (6)	4 (4;4)	4.00	0.761
I/*the staff* can modify how I/*they* work with PAP	54 (12)	4 (3;4)	3.63	50 (9)	4 (3;4)	3.64	0.864

[a] Item reverse scored. *PAP* Physical activity on prescription. In the survey most of the items were formulated as *PAP for children with obesity.*

**p*-values are derived from Mann-Whitney U tests of differences between practice locations.

Discussion

This study reports prerequisites and determinants for implementing the PAP intervention for children with obesity amongst healthcare professionals at paediatric clinics in western Sweden. Our findings suggest that those prerequisites are good, and that, in fact, implementation is underway to various extents. Main findings are that most respondents perceive PAP as familiar and many, in particular nurses and physiotherapists, as a normalised part of their work. Barriers and facilitators for working with PAP were identified across all NPT domains, especially related to collective action and reflexive monitoring. The respondents perceived PAP as highly acceptable, appropriate, and feasible, regardless of profession and experience of working in the organisation.

Respondents from the Gothenburg area perceived PAP as more normalised than those in regional areas; a geographical difference seen in all the NPT domains as well as regarding acceptability of the intervention. Identified facilitators for PAP use were comprehension of the PAP intervention, taking on the role of using PAP, and the interventions's ease of use. Barriers were inadequate education, insufficient time, uncoordinated pathways to other healthcare units, poor collaboration with activity organisers, and the lack of research on PAP for children.

The geographical differences are likely attributed to the PAP support structure that has been in place in Gothenburg for several years. Gothenburg represents a unique context in Sweden, with a PAP support structure in the form of education, networking, and PAP clinics to which patients are referred for extra support in changing their physical activity patterns. None of these support structures are established elsewhere in the region or in Sweden, and there are considerable regional variations across Sweden in the support for work with PAP (37).

TABLE 6 Acceptability, appropriateness and feasibility of physical activity on prescription.

Statement	*N* (missing)	Agree *n* (%)	Neutral *n* (%)	Disagree *n* (%)	Median[a] (IQR)	Mean (SD)[a]
Acceptability						
PAP meets my approval	125	107 (85.6)	17 (13.6)	1 (0.8)	5 (5–5)	4.36 (0.75)
PAP is appealing to me	124 (1)	107 (85.6)	16 (12.8)	1 (0.8)	4.5 (4.5–5)	4.35 (0.74)
I like PAP	125	105 (84.0)	18 (14.4)	2 (1.6)	4 (4–5)	4,31 (0.78)
I welcome PAP	124 (1)	104 (83.2)	18 (14.4)	2 (1.6)	5 (5–5)	4.35 (0.79)
Appropriateness						
PAP seems fitting	123 (2)	102 (81.6)	16 (12.8)	5 (4.0)	5 (5–5)	4.24 (0.90)
PAP seems suitable	123 (2)	104 (83.2)	15 (12.0)	4 (3.2)	4 (4–5)	4.32 (0.81)
PAP seems applicable	121 (4)	100 (80.0)	19 (15.2)	2 (1.6)	5 (5–5)	4.25 (0.78)
PAP seems like a good match	117 (8)	98 (78.4)	12 (9.6)	7 (5.6)	4 (4–5)	4.24 (0.87)
Feasibility						
PAP seems implementable	118 (7)	98 (78.4)	16 (12.8)	4 (3.2)	4 (4–5)	4.23 (0.81)
PAP seems possible	122 (3)	110 (88.0)	12 (9.6)	0 (0.0)	5 (5–5)	4.43 (0.67)
PAP seems doable	122 (3)	103 (82.4)	16 (12.8)	3 (2.4)	4 (4–5)	4.25 (0.78)
PAP seems easy to use	117 (8)	89 (71.2)	26 (20.8)	2 (1.6)	4 (4–5)	3.99 (0.77)

IQR, interquartile range; PAP, physical activity on prescription; SD, standard deviation. In the survey the items in appropriateness were formulated as PAP for children with obesity.

[a]Medians and means are calculated on the original 5-point scales.

Nurses and physiotherapists perceived PAP as normalised to a great extent. Both professions have worked with PAP for many years in Sweden, particularly for adults. Studies in adult populations have also shown nurses' engagement in PAP and other types of physical activity referrals (33, 35, 36). In paediatric health care, nurses have a central role in the work with children and families, including counselling about physical activity and following up intervention effects.

Most respondents perceived PAP as acceptable, appropriate and feasible for children with obesity. Feasibility of PAP as part of an internet-based intervention for children with obesity was recently reported in another Swedish study (29). However, as PAP was one of three intervention components, it is not possible to attribute the results to PAP alone. Amongst adults, feasibility and effects of PAP have recently been shown in two studies, of which one showed sustained results five years after the intervention (50, 51). Although not yet evaluated as a stand-alone intervention in children with obesity, the high acceptability, appropriateness and feasibility of PAP found in our and other studies are important prerequisites for future studies on effectiveness in this population.

Both staff and managers perceived PAP as a possible intervention, implying an understanding of the feasibility of using it in routine clinical practice and the possibility of implementing it in paediatric health care. The high acceptability of PAP by managers is an important prerequisite to the normalisation of PAP. This finding is in contrast to previous studies on PAP, which have identified lack of supportive management (35) and organisational support (33, 35, 36, 38) as problematic.

One reason for the high scores on appropriateness of PAP may be the intervention's person-centredness and individually tailored components, which correspond well with a respectful and structured obesity management according to Swedish national guidelines (32). Another reason might be the discounts offered for many of the prescribed physical activities, which can enable the child's participation in an activity. Families with obese children are often socio-economically disadvantaged (52), so this financial incentive could be an important facilitator.

The collective and individual understanding of an intervention and how it differs from usual ways of working is important for clinical practice (42). In the domain coherence, almost two thirds of the respondents reported they could "make sense" of PAP and understand how it affected their work. These findings were nuanced by qualitative data where respondents expressed insufficient knowledge of PAP and uncertainty about its clinical use. Similar findings have been shown in previous research on PAP for adults, where lack of information and knowledge about PAP and its application was found amongst practitioners (34, 35).

Patients have described not receiving sufficient information about PAP during an intervention period (53). Our findings show a variation in the respondents' perceptions of PAP and its usability in paediatric health care. It is natural for healthcare professionals to experience uncertainty regarding the rationale and clinical use of PAP, particularly in a context for which the intervention has not primarily been developed. This variation in perceptions might reflect that the work with PAP has been transferred from an adult context to the paediatric context without having been fully developed and adapted for children with obesity, which may contribute to uncertainty about its application.

For successful integration into practice, the collective contribution to enact and sustain the work with a new intervention is important. Regardless of profession and years of working in the organisation, most items in the cognitive participation domain were scored high amongst the respondents in our study. In the open-ended questions, respondents described how PAP work was organised in their own clinic and amongst other clinics with licensed practitioners. In the Gothenburg area, key people were driving the PAP work forward and could share good experiences with new colleagues.

The lack of physiotherapists in the paediatric healthcare organisation was described as a barrier, implying that physiotherapists are viewed as one of the most legitimate professions for working with PAP. Physiotherapists' familiarity with PAP and their perception that PAP is already a normal part of their work also corroborate this view. Physiotherapist is a profession with skills for working with physical activity (54), but that is largely missing in paediatric health care. To access these skills and competency, some staff referred patients onward to physiotherapists in PAP clinics or rehabilitation clinics. This uncoordinated referral system between prescribers and physiotherapists was seen as a barrier for working with PAP. Nevertheless, another study described a similar referral setup in primary and secondary care for adults, in which patients perceived PAP to be both feasible and increasing physical activity (50). Hence, the need for formal and coordinated referral pathways between clinics may be greater for children and their families than for adults. The lack of coordination between clinics has been identified earlier as a considerable barrier for families (38).

To improve work with PAP, many respondents called for more training. In the collective action domain, lack of training, structure, and time was described as barriers to efficiently delivering PAP. Similar barriers have also been reported for adult populations managed in primary care (33, 35, 36), as well as for children with intellectual developmental disorders (38). A recent systematic review of implementation of obesity prevention interventions for children also identified lack of knowledge, e.g., concerning physical activity recommendations, as a barrier amongst primary care nurses and physicians (55).

Only half of our respondents, including managers, agreed that management adequately supports PAP. However, in view of the high acceptability and feasibility of PAP reported by both staff and managers, the perceived lack of management support may imply poor communication between staff and managers rather than an actual lack of support. Improved communication and collaboration amongst staff and managers would likely improve chances for an intervention to become normalised in routine practice. Insufficient training, managerial support, and resources were reported as important barriers for implementing physical activity prevention interventions for children with obesity also in primary care (55).

In the reflexive monitoring domain almost 40% of the respondents agreed they were aware of reports about the effects of PAP. This finding is difficult to interpret since research is mostly lacking on PAP for children, but communal or individual evaluations may have been undertaken in clinical practice. Managers reported being aware of effects to a greater extent than other professions, possibly implying they might be better informed by policy documents and national guideline recommendations (30, 56) about the health benefits of physical activity for children. Although lack of research on PAP for children was reported as a barrier, staff might also recognise PAP as an evidence-based intervention for adults and could have gained knowledge through networking, education, and information material for both adults and children.

Strengths and limitations

A main strength of the study is the use of a theory-based framework and instrument to assess and categorise the factors that might influence implementation of PAP in the paediatric context. A particular strength in using the NPT is its focus on the implementation work healthcare professionals actually do, rather than their cognitions, e.g., beliefs and attitudes. Another strength is our use of validated instruments, which are also pragmatic and easy to use. The NoMAD was particularly helpful in pointing out problems that can be addressed when implementing PAP for children with obesity, enabling improvements related to collective action and reflexive monitoring. Assessing the dual perspective of practitioners and managers also strengthens the findings. Supplementing NoMAD with the AIM, IAM, and FIM instruments to assess important implementation determinants provided a comprehensive overview of aspects necessary to address in a future implementation of PAP for children with obesity. Several efforts were made to reduce bias. Sampling bias was minimised since the survey was distributed to all staff and managers at all paediatric clinics in the study population. We attempted to reduce non-response bias by sending several reminders to answer the questionnaire.

There were some limitations to the study. The intention to capture multiple perspectives meant that not all participants had practical experience of PAP, making several questions irrelevant for some respondents and likely contributing to both unit-level and item-level missing data. The use of self-reported data entails a risk for both self-selection bias and social desirability bias. We did not perform sensitivity analyses, but believe our analyses are robust enough with the used tests. We did not investigate gender, because a vast majority of both practitioners and managers in the population studied are women. The low alpha values for some of the NoMAD items indicate low internal consistency, which might have affected the results of the statistical analyses.

There is an obvious need for research on effectiveness of physical activity promoting interventions for childhood obesity, as well as implementation process and outcome evaluations of such interventions. To improve the understanding of barriers and facilitators for using PAP, further research is needed from the perspective of staff and managers, as well as that of the children and their parents.

Our study can provide helpful information to develop support structures for PAP work, streamline the use of the intervention, and inform future implementation strategies. The broad inclusion criteria of the study, including all professions and managers involved in paediatric health care, and the study setting – Region Västra Götaland which is Sweden's second largest county council – enhances generalisability of our findings to other paediatric populations and to other regions in Sweden, and possibly also to other countries with similar paediatric healthcare systems.

Conclusions

The prerequisites for implementing PAP for children with obesity in paediatric health care in western Sweden can be considered good. The intervention is familiar and perceived as acceptable, appropriate, and feasible by paediatric healthcare practitioners and managers, constituting important facilitators for implementing PAP. For many participants, PAP was already perceived as a normal part of their work, and a majority believed it would become a normal part of their work in the future. The wide acceptance demonstrates receptiveness to PAP as an intervention to promote an active lifestyle for children with obesity. Barriers and facilitators for working with PAP exist in all NPT domains, particularly in the domains collective action and reflexive monitoring where main barriers are the lack of education, resources, and research on PAP for children.

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 Swedish Ethical Review Authority issued an advisory statement that the authority has no ethical objections to the study (Reference no. 2020-05693). Because no intervention was involved and no sensitive personal data were collected, ethics review was not required for this study (SFS 2003:460). Participants provided their informed consent by checking a box within the survey.

Author contributions

CB contributed to study design, led data collection, data analysis, and drafted the manuscript. SB, KL, SL and KM contributed to study design, data collection, data analysis and revised the manuscript. All authors contributed to the article and approved the submitted version.

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Conflict of interest

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

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A conceptual model for building program sustainability in public health settings: Learning from the implementation of the program sustainability action planning model and training curricula

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Background: The emergence of implementation science has driven an increase in research examining the implementation of evidence-based programs and policies. However, there has been less attention through program sustainability. To achieve the full benefit of investment in program development and implementation, there must be an understanding of the factors that relate to sustainability; additionally, there is a need for a robust set of tools and trainings to support strategic long-term program sustainability. This paper presents results of our sustainability training intervention and a new conceptual model of sustainability. The proposed conceptual model builds upon the intervention design, further specifying the implementation strategy, strategy-mechanism linkages, and effect modifiers.
Methods: This research is part of the larger randomized control trial evaluating the effectiveness of the Program Sustainability Action Planning Model and Training Curricula. Specifically, this multimethod study establishes a conceptual model for program sustainability and related capacity-building interventions. The training intervention was delivered through workshops and technical assistance to 11 state tobacco control programs, principally entailing the development and implementation of a sustainability action plan. We utilize descriptive statistics and participant perspectives to evaluate the training intervention and propose an empirically-grounded conceptual model for sustainability capacity-building interventions in public health settings.
Results: Participants found intervention components (workshop, workbook, instructor and resources) to be effective. Overall, participants found the intervention improved their ability to develop sustainability action plans and assess their program and partners. Throughout the study, program managers emphasized the importance of the workshop in providing direction for their sustainability work and the value of robust, ongoing technical assistance. Program managers identified several factors that interfered with intervention reception including staff turnover, competing priorities, partnership challenges, and the COVID-19 pandemic.

Conclusion: The present study documents the development and implementation of a novel Program Sustainability Action Planning Model and Training Curricula, one of the first interventions designed to improve program sustainability. In addition, we present an empirically-grounded conceptual model for program sustainability. Considering the paucity of research in this understudied and undefined topic area, this is an important contribution that can serve as a framework for similar intervention designs and implementation efforts.

Clinical Trail Registration: ClinicalTrails.gov identification number is NCT03598114.

KEYWORDS

program sustainability, implementation science, conceptual model, tobacco control programs, agile science

Introduction

The emergence of dissemination and implementation (D&I) science has driven an increase in theoretical and empirical understanding of evidence-based program and policy implementation. However, D&I science has paid less attention through the post-implementation period of sustainability. To achieve the full and continued benefits of significant investment in public health research and program development, there must be an understanding of the factors that relate to program sustainability in the post-implementation period; additionally, there is a need for a robust set of tools and trainings to support strategic long-term program sustainability (1).

Despite a burgeoning implementation science literature, there is still a lack of planning for sustainability of evidence-based programs. In a recent review of dissemination and implementation research studies funded by the National Institutes of Health, Johnson et al., found that only only 67.1% of the studies made references to sustainability and none referred to sustainability planning (2). Similarly, there remains a lack of a formally agreed upon definition or elements of sustainability. In Johnson et al.'s review, researchers who actually referenced sustainability in their study, conceptualized sustainability as the "continued delivery of interventions, programs, or implementation strategies," (2) but there was no formal consensus on the definition. Shediac-Rizkallah and Bone conceptualize sustainability broadly as "*the maintenance of health benefits over time*" (3). Scheirer and Dearing focus exclusively on the organizational and programmatic elements: "*the continued use of program components and activities for the continued achievement of desirable program and population outcomes*" (1). In an attempt to define a more formal definition, Moore et al. (4) abstracted sustainability definitions from 209 articles and mapped constructs from the definitions to create a revised definition of sustainability: "*after a defined period of time, a program, clinical intervention, and/or implementation strategies continue to be delivered and/or individual behavior change (i.e., clinician, patient) is maintained; the program and individual behavior change may evolve or adapt while continuing to produce benefits for individuals/systems*" (4).

We have adopted a more comprehensive definition that considers program organizational components, the evidence for program effectiveness, as well as the process or system in which a program is implemented over time. Comprehensively defined, sustainability is the existence of structures and processes within an adaptive system that allow a program to effectively implement and maintain evidence-based policies and activities that improve health over time (5). This definition is deliberately broad, and moves beyond the characteristics of the program itself to include organizational and other system characteristics. This sustainability definition contains three key elements. First, sustainability is an ongoing (cyclical) change process that requires action-oriented planning to strengthen system capacity (6, 7). Systems include the program, the auspice organization, the community, and the funder. Second, programs rely on structures and processes that contribute toward adequate system capacity as a necessary condition for program sustainability (8). A sustainable program must be integrated into normal organizational operations (9). The characteristics of these programmatic and organizational structures, processes, and community and funder supports (10) build programmatic capacity for sustainability and institutionalization, over time. Finally, what is to be sustained is an evidence-based innovation which is part of a prevention system. Because the innovation is evidence-based, sustainability is essential in attaining positive health impacts (11).

In addition to consensus on one formal definition of sustainability, there remains a lack on congruence in defining "what" factors contribute toward sustainability and "how" programs can achieve sustainability. In considering the factors that contribute toward sustainability Luke et al., identifies 17 frameworks suggesting a variety of factors (with some similarity) that influence program sustainability (12). In addition, only a few conceptual models focus exclusively on the "how" or the programmatic process for building capacity for sustainability. While these frameworks exist, few are actually utilized in D&I research; few researchers funded by the National Institutes of Health referenced frameworks with sustainability constructs and offered limited information on how they operationalized frameworks (2). The Dynamic Sustainability Framework offered by Chambers et al., considers the context in which an intervention is implemented and operationalized within a system (13). However, it does not offer an implementation strategy or mechanism for which programs should engage to improve sustainability of the intervention. May et al.'s, Normalization Process Theory explains how new ideas, ways of acting, and ways of working become routinely embedded or normalized in practice settings (14). It has been utilized in studying program implementation and sustainability (15) and found useful in identifying processes that are likely to enhance sustainability, but again does not offer a mechanism for which programs should engage to improve sustainability. The Program Sustainability Framework (5), which was utilized for our study, outlines eight domains of sustainability including organizational capacity, funding stability, strategic planning, external environment, partnerships, communication, program adaptation, and program evaluation. These domains have been proven to affect the capacity for sustainability among public health programs (5); however, understanding of how these domains interact to improve program sustainability or how to determine how success in one domain might improve other domains is not yet understood.

This paper outlines the development and assessment of the *Program Sustainability Action Planning Model and Training Curricula*, an intervention which aimed to build capacity for sustainability in state tobacco control programs (TCPs) (16). Specifically, we developed the *Program Sustainability Action Planning Model and Training Curricula* as an action-oriented training model (defined by Kolb's experiential learning theory) (17) that addressed the internal and external program-related domains outlined in the Program Sustainability Framework (5) proven to affect the capacity for sustainability among public health programs. For the purposes of this paper, the "intervention" is the *Program Sustainability Action Planning Model and Training Curricula*. We also provide an assessment of the implementation strategy (i.e., use of experiential learning) of this intervention. Using results from this study, including participant perspectives regarding the implementation strategy including intervention component utility and suitability as well as programmatic outcomes, we propose an empirically-grounded conceptual model for implementing sustainability capacity-building interventions in public health settings. The proposed model builds upon and refines the original intervention model used in the development of the intervention, further specifying the implementation strategy, strategy-mechanism linkages, and effect modifiers (preconditions, mediators, and moderators).

Methods

Study design

The Plans, Actions, and Capacity to Sustain Tobacco Control (PACT) study utilized a multiphase approach to develop and assess the effectiveness of a novel intervention, the *Program Sustainability Action Planning Model and Training Curricula*, to increase the capacity for sustainability among state level tobacco control programs. In the first phase of the PACT study, the intervention was developed through a rigorous multidisciplinary literature review process and a series of expert consultations. We used SCOPUS, ERIC (ProQuest), PubMed, Education Full Text, and PsychINF databases to conduct a formative literature review to inform the development and evaluation of the training intervention. Specifically, we performed formative literature reviews regarding experiential models of learning (i.e., duration and components) and technical assistance (type and duration) to design the intervention. To design the evaluation of the intervention, we conducted formative review to assess previous metrics of experiential learning and technical assistance effectiveness. We also consulted with our PACT advisory team which was comprised of two academic experts in sustainability, two state tobacco control program directors, and three officials from the Centers for Disease Control and Prevention Office of Smoking or Health to determine the final *Program Sustainability Action Planning Model and Training Curricula*.

In the second phase of this study, a multiyear randomized control trial was conducted to assess the effectiveness in improving the capacity for sustainability [as defined by organization outcomes and Program Sustainability Assessment Test (PSAT) scores] among 24 State Level Tobacco Control Programs (TCP). Ultimately, 11 intervention and 12 control TCPs participated. The *Program Sustainability Action Planning Model and Training Curricula* was delivered to 11 TCPs through tailored workshops at baseline and ongoing, robust technical assistance through their participation in the multiyear randomized control trial (2018–2022). This paper presents only the results of the evaluation of the training and technical assistance delivered to the 11 intervention states as these data were used in defining the proposed conceptual model.

The program sustainability action planning model and training curricula

The intervention consisted of a two- day workshop to design a program sustainability action plan, two years of tailored technical assistance for implementing the action plan and sustainability outcome assessment. Participants of the workshops actively engaged in developing state TCP-specific sustainability action plans. Each state action plan outlined one or two domain-focused objectives, matched with time-specific activities to be shared across stakeholders present. One person at each workshop claimed responsibility for overseeing the implementation process. Sustainability plans were designed to be implemented over the course of two years. All Program Sustainability Action Planning Training workshops followed the same structure, but were tailored to each state depending on the Program Sustainability Framework domain chosen for the action plan. The two-day workshop involved the TCP staff and as well as a number of stakeholders (i.e., advocates, coalition members, voluntary organizations, grantees, local level health department staff) actively participating to design a sustainability action plan and develop an implementation strategy. Inclusion of and participation by all stakeholders engaged was an important component of the sustainability action plan development process and ensuring all components of the state TCPs were considered. Table 1 outlines the intervention components of this study.

TABLE 1 Components of the sustainability action planning training intervention.

Intervention Components	Dose
Introduction to Sustainability Webinar	1 h, 1 time
Access to Program Sustainability Assessment Test Sustainability Report	1 h, 3 time points
State program-level PSAT results follow-up correspondence	2 h, 3 time points
In-person Program Sustainability Action Planning Training	48 h, in person, 1 time point
Technical Assistance	1 h, 9–12 time points (quarterly for 3 years)
Access to final Sustainability Action Planning Training and Curricula tools and resources	as needed

Assessing intervention components

Quantitative data methods

Following receipt of the workshop, TCP staff and stakeholders ($n = 106$) completed a 29-item survey evaluating intervention components for their utility and suitability. Survey items assessing the workshop, workbook, and the instructors utilized a Likert-type scale with anchors “strongly disagree” (1) and “strongly agree” (5). Survey items were grouped by component, forming evaluation areas: Workshop Evaluation, Workbook and Workshop Usefulness, Workbook Satisfaction, and Instructor Evaluation. Survey items were based on the theory of change that allows for study on how a change (intervention) has influenced the design, implementation, and institutionalization of a program and were designed specifically to assess outcomes related to Kolb experiential learning components (17). Descriptive statistics were calculated at the item- and component-level to analyze evaluation survey data.

Qualitative data methods

Workshop and workbook evaluation. Included in the evaluation survey of the intervention were two open-ended questions, (1) *What were the three most important things you learned at this training? Please explain* and (2) *What suggestions do you have for improving this workshop?* A total of 220 answers were recorded in response to most important things learned at the training. Responses such as, *None*, and *Not applicable*, were excluded from analysis ($n = 13$). The remaining 207 responses were reviewed and grouped into themes. A total of 100 answers were recorded in response to suggestions for improvement. Responses such as, *None*, and *Not applicable*, were excluded from analysis ($n = 37$). The remaining 63 responses were reviewed and grouped into themes.

Technical assistance (TA) calls. From December 2018 to January 2022, staff from the 11 intervention TCPs participated in TA calls to assess their progress on implementing their sustainability plans and to determine challenges and resource needs. Each state received an average of 2 calls/year during their two years of study participation ($n = 46$). These calls lasted about 30–45 min and were audio recorded.

Each TA call record was professionally transcribed using an online service (Rev.com). Transcripts were reviewed for accuracy and uploaded to NVivo 20 (released in March 2020) for coding. We used an inductive approach for thematic analysis. We developed a codebook based on the items addressed in the TA calls. The codes and sub-codes of the initial codebook were revised throughout the coding of transcripts. The final codebook consisted of four codes and sixteen sub-codes.

For the coding process, three research team members coded transcripts until they reached substantial inter-rater reliability (kappa = .72) (18). Differences between coders were discussed and addressed. Remaining transcripts were coded by a single research team member. This work focuses on the themes from two parent codes: (1) developing capacity for sustainability and (2) overall study feedback.

Diagram modelling

Quantitative and qualitative intervention component data were fit to the original intervention model through an Agile Science-informed causal pathway diagram modeling process to propose a generalizable, empirically-grounded conceptual model for implementing sustainability capacity-building interventions in public health settings. An Agile Science informed process was utilized due to the focus on intervention modularity and condition specification. As outlined by Lewis et al. (19), in implementation research this process entails specifying implementation strategies, strategy-mechanism linkages, effect modifiers, and distal and proximal outcomes (19). In the present study, the research team carried out the diagram modeling process over multiple working sessions. The research team presented results to the PACT advisory team, to ensure face and content validity.

Results

Assessing intervention components

Quantitative results

Workshop evaluation

The workshop evaluation area comprised nine survey items assessing logistics, utility, suitability, and outcomes. At the component level, the workshop was favorably assessed by intervention participants ($M = 4.24$, SD = 0.81). At the item level, participants indicated that the workshop augmented their understanding of the action planning process and their capacity to move these plans forward ($M = 4.34$, SD = 0.69; $M = 4.37$, SD = 0.65), and was overall beneficial for their program ($M = 4.35$, SD = 0.69). Participants indicated that they planned to translate workshop learning objectives into their tobacco control work ($M = 4.47$, SD = 0.59). See **Table 2**.

Workbook and workshop usefulness

The workbook and workshop usefulness area comprised 6 survey items assessing the usefulness of intervention component modules: Defining Program ($M = 4.21$, SD = 0.74), Understanding Sustainability ($M = 4.30$, SD = 0.61), Reflecting on Results ($M = 4.26$, SD = 0.70), Building an Action Plan

TABLE 2 Program sustainability action planning model and training curricula evaluation.

Training Component and Evaluation Indicator	Mean	Standard Deviation
Workshop Evaluation		
The quality of this workshop was excellent	4.39	0.66
The length of the workshop was just right	4.26	0.86
The objectives were clearly articulated	4.34	0.76
The objectives were achieved	4.33	0.67
The workshop was beneficial for my program	4.35	0.69
I understand the process of action planning completely	4.34	0.69
I feel capable of helping move the action plan forward	4.37	0.65
I plan to use what I learned from this workshop in my tobacco control work	4.47	0.59
I could successfully complete an action plan without this workshop	3.36	1.02
Workshop and Workbook Usefulness		
Defining the program	4.21	0.74
Understanding sustainability	4.3	0.61
Reflecting on results	4.26	0.7
Building an action plan	4.49	0.61
Continuing progress	4.14	0.69
Appendix resources	3.89	0.83
Workbook Satisfaction		
Design	4.48	0.65
Organization of content	4.50	0.59
Legibility and ease of use	4.55	0.63
Clarity of activity instructions	4.41	0.65
Instructor		
Demonstrated a thorough knowledge of the subject matter	4.68	0.56
Were well prepared for class	4.75	0.56
Presented material in a clear and organized manner	4.67	0.53
Used effective teaching/facilitating techniques	4.58	0.66
Respected and encouraged other's viewpoints	4.86	0.35
Discussed how the information can be applied in an actual situation	4.57	0.62
Made time for questions, answers, and discussion	4.79	0.43

Survey items were measured using a Likert-type scale with anchors "strongly disagree" (1) and "strongly agree" (5). Data were collected from September 18 to October 19 from 106 recipients.

($M = 4.49$, SD = 0.61), Continuing Progress ($M = 4.14$, SD = 0.69), and Appendix Resources ($M = 3.89$, SD = 0.83). At the component level, participant responses indicate that the workbook and workshop were useful ($M = 4.22$, SD = 0.72) (see Table 2).

Workbook satisfaction

*The workbook satisfaction a*rea comprised 4 survey items assessing design ($M = 4.48$, SD = 0.65), content organization ($M = 4.50$, SD = 0.59), ease of use ($M = 4.55$, SD = 0.63), and instructional clarity ($M = 4.41$, SD = 0.65). At the component level, participants were highly satisfied with the workbook ($M = 4.48$, SD = 0.63) (see Table 2).

Instructor evaluation

To evaluate the workshop training instructor, we used seven survey items assessing their subject matter expertise and professionalism. At the item level, participants reported that workshop instructors demonstrated a thorough knowledge of the subject matter ($M = 4.68$, SD = 0.56), used effective teaching and facilitating techniques ($M = 4.58$, SD = 0.66), and discussed how workshop learning objectives could be applied to their tobacco control work ($M = 4.57$, SD = 0.62). At the component level, instructors were favorably assessed ($M = 4.70$, SD = 0.53) (see Table 2).

Thematic analysis results

Workshop and workbook evaluation

Overall, participants found that the sustainability training intervention provided them with a better understanding of program sustainability and improved their ability to develop sustainability action plans. Participants noted it was useful to have a common language around sustainability and a shared action plan to be completed collaboratively by the TCP and its partners.

> *It was very important and helpful to have common language and definitions for the domains –State Health Department staff*

Participants also shared that the workshop enhanced their ability to assess the strengths and weaknesses of their program. The workshop also helped participants gain a better understanding of their partners, noting how valuable it was to have dedicated time with their partners and include them in their sustainability action plan.

> *…just working through the actual action plan because we're all so busy and so being able to do that and get that started in that meeting. I don't how long it would have taken us to get that done otherwise. –State Health Department, Director*

Program managers emphasized the importance of the workshop in providing direction for their sustainability work throughout the study.

Technical assistance

The TCP managers often commented on the importance of robust, ongoing technical assistance to continue implementing their sustainability plan. Ongoing access to program sustainability resources and intervention-facilitated peer learning were frequently requested during TA calls to further implementation of their action plans.

> *I think it's always been nice to have timely reminders to focus on the strategic planning process and make sure that we're continually looking at how we're tracking against those milestones, the way outlined in the sustainability plan. That's been really useful for me… –State Health Department, Program Manager*

Managers also felt that the alignment of their action plan with other grant requirements facilitated implementation. Strong partner engagement was also identified by program managers as a factor which augmented sustainability training and technical assistance effectiveness.

> *I appreciate the technical assistance and all of the tools that you put together for us to use. It was really, really helpful and it helped catalyze some really robust conversations at some of the stakeholder meetings we've had… –State Health Department, Program Manager*

Program managers identified several factors that interfered with their progress in implementing their plans throughout the study. Most notable were high levels of staff turnover, competing priorities, partnership challenges, and the COVID-19 pandemic. In discussing staff turnover, program managers shared they were responsible for covering the duties of the vacant positions in their TCP making it difficult to prioritize their action plan. They also noted the vacancies they experienced in their program were at times the individuals directly responsible for aspects of the action plan, which slowed down and at times halted their progress.

> *While that position is vacant, I'm kind of doing double duty, which just makes it hard to be focused on longterm just because of dealing with the day to day. We still try to do that as much as we possibly can, but I'm definitely looking forward to getting that position filled so we can share that workload a little bit. –State Health Department, Policy Section Manager*

Regarding competing priorities, managers discussed the prioritization of funding and contractual agreements, as well as emergency bans on tobacco products which required immediate attention.

> *Plus we had that emergency ban on vapor products, flavored vapor products that kind of inundated our time. So, we had to push a lot of our dates back, and so that's what we did. So, we spent a lot of time revising the action plan in terms of dates and really moving towards completing some of the activities that we had said that we would do by January. – State Health Department, Unit Manager*

Some program managers noted they struggled to maintain engagement with their partners throughout their participation in the study, leading to slower responses to communication and lack of follow through on action plan responsibilities.

> *Trying to make sure that partners were continually engaged and that when they left the meeting, that they felt empowered enough to actually follow through on activities that have been discussed. Because sometimes we would have meetings and everybody would leave with what they were supposed to do but when we met again there hadn't been any movement on anything. – State Health Department, Program Director*

Finally, the COVID-19 pandemic impacted the overall capacity of TCPs, as public health staff were reassigned to work on pandemic response activities.

> *And we also were impacted with COVID and capacity, so we definitely had a plan and we had a product to share with legislators, but one of our staff has been and remains full-time on COVID… –State Health Department, Program Manager*

> *…I'm sure you've heard this from other people, but partners are dealing with COVID too… they don't have the time or ability to sit in on some of the meetings that they normally would with us. So that's been somewhat of an issue as well. –State Health Department, Program Director*

When asked about recommendations for sustainability training and technical assistance intervention improvement, participants wanted it to be more adaptable to the changing needs and priorities of their TCP. They also requested additional opportunities to interact with other states enrolled in the study to further peer learning.

> *I think, as we go through the strategic planning process, if you have seen strategic plans from other States that you think look amazing, feel free to send them… if you've been working with other States and you're really impressed with the caliber of work that they're doing, they have innovative ideas, I definitely think it's a good idea to learn from the best so that we might be able to emulate. –State Health Department, Program Manager*

The conceptual model

Using quantitative and qualitative data we engaged in an Agile Science-informed causal pathway diagram modeling process (19) to develop our conceptual model (**Figure 1**). The implementation strategy consisted of the *Program Sustainability Action Planning Model and Training Curricula*. The mechanism through which the Program Sustainability Action Planning Model and Training Curricula intervention was implemented was through action oriented, participatory training, as defined by Kolb's experiential learning theory (17). Both quantitative and qualitative results indicate the *Program Sustainability Action Planning Model and Training Curricula* was an effective intervention in developing and implementing a sustainability action plan.

Moderating factors or factors that increase or decrease the level of influence of the implementation of the state TCP sustainability action plans included high levels of staff turnover, competing priorities, partnership challenges, and the COVID-19 pandemic. While the pandemic was specific to this project's timing, other major public health events could be considered.

Mediating factors or variables that influence the outcome of the implementation strategy included programmatic and organizational factors, community partner support and funder

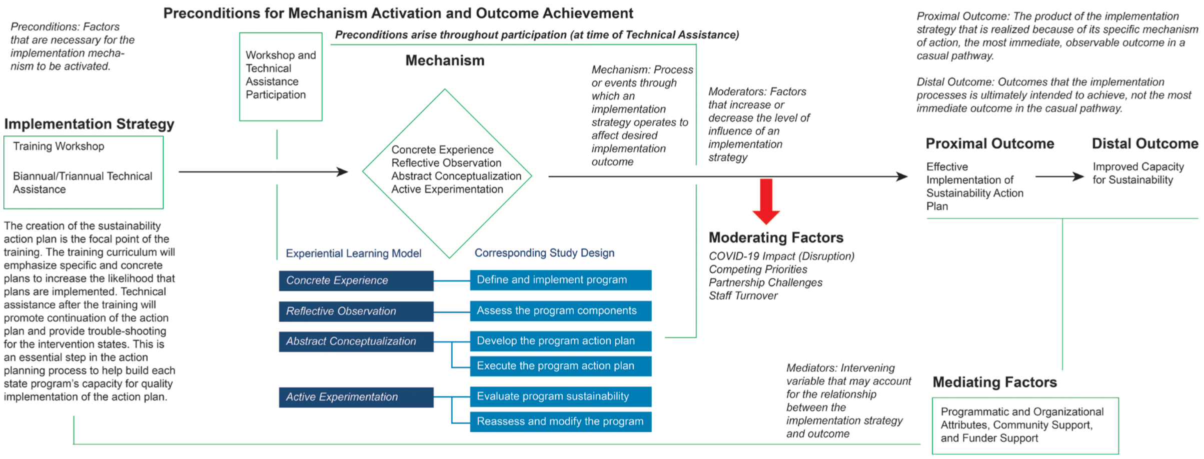

FIGURE 1
Conceptual model for building program sustainability in public health settings.

support. Programmatic factors contributing toward the success of sustainability action plan implementation included dedicated time to work on sustainability plan activities and leadership support in continuing to work on the plans in spite of other competing priorities. Those state TCPs experiencing staff vacancies, especially involving those staff responsible for implementing the plan, slowed the ability to complete plan activities. Qualitative results indicated TCPs with strong partner engagement throughout their implementation process were more successful in completing their objectives and goals outlined in their sustainability plans. Likewise, some programs were unable to complete certain objectives outlined because they struggled to maintain engagement of their partners throughout their participation in the study. Competing priorities or lack of budgetary funding support for TCPs deterred progress on TCP sustainability action plan implementation (see **Figure 1**).

Discussion

The present study makes several important contributions to implementation science. Notably, the present study documents the development and implementation of the novel *Program Sustainability Action Planning Model and Training Curricula*, one of the first proposed training interventions for improving the capacity for program sustainability in public health. We also propose an empirically-grounded conceptual model for implementing sustainability capacity-building interventions in public health settings. The proposed model builds upon previous work and specifies the implementation strategy, strategy-mechanism linkages, and effect modifiers (preconditions, mediators, and moderators).

Our results indicate that *Program Sustainability Action Planning Model and Training Curricula* was an effective capacity building intervention in developing and implementing a sustainability action plan. Those in receipt of the *Program Sustainability Action Planning Model and Training Curricula* assess it favorably in regards to its utility and suitability, across all evaluation areas. Thematic analysis further qualified quantitative results: participants indicated that the *Program Sustainability Action Planning Model and Training Curricula* enhanced their understanding of program sustainability and related program-specific characteristics as well as the role of TCP partners. In addition, throughout the study, program managers emphasized the importance of the workshop in providing direction for their sustainability work and the value of robust, ongoing technical assistance. Ongoing access to program sustainability resources and intervention-facilitated peer learning and partner engagement were also noted as factors augmenting *Program Sustainability Action Planning Model and Training Curricula* intervention component effectiveness.

We used both qualitative and quantitative results in refining a conceptual model for implementing sustainability capacity-building interventions in public health settings. Other studies focused on understanding sustainability have recognized similar components (mediators and moderators) identified in our proposed model but none have considered the complete process including the implementation strategy and mechanism for which to plan for and improve program sustainability. For instance, when utilizing the Normalization Process Theory in evaluating the implementation of an evidence-based violence screening model, Hooker et al., found several organizational components that mediated program "normalization" or programmatic sustainability including lack of staff capacity (15). Similar to our results, authors also noted the importance of partner and community interaction (collective action) in achieving desired results. Finally, authors also noted the importance of tracking (reflective monitoring) results. This is similar to the idea of the inclusion of active tracking of sustainability action plans in this study. Though not broadly applied, The Dynamic Sustainability Framework also defines similar components to our conceptual model. Specifically, the idea that systems are not static, but rather dynamic forcing programs to be adaptive and ready to respond to a constantly changing environment to be sustainable (13). In addition to the advent of new programmatic components or evidence invoking the need for change of a program, there exist external factors and events that require a dynamic response by programs. COVID-19 and changes in tobacco regulatory requirements were found to influence sustainability in this study.

Limitations

There are several limitations to this study. First, although evidence-informed and developed through a systematic process, the proposed model has not been empirically tested. The present study also utilized programmatic data and the perspectives of individuals at 11 state TCPs. Although this is of sufficient size to statistically evaluate the intervention for its effectiveness, findings may not be completely generalizable across all state TCPs. Further work is therefore needed to establish generalizability. Finally, our data were generated throughout the COVID-19 pandemic, and therefore are not unaffected by the unprecedented conditions the event produced. Throughout this time state TCPs operated in nonroutine ways, and the extent to which emergent phenomena in our study were products of this is unknown. While we feel that any public health event might disrupt the state health department system, one may not have the same magnitude effect.

Conclusion

By establishing a method for action planning and technical assistance for program sustainability, the present study supports public health programs broadly in their understanding of and achievement in sustainability, an outcome that has become increasingly critical given the environmental complexity. In addition, this work advances the field of study regarding action planning and technical assistance, which contributes to implementation science beyond the topic area of sustainability. Finally, the present study advances implementation science by establishing an empirically-grounded conceptual model for program sustainability and related capacity-building interventions. Considering the paucity of research in this understudied and undefined topic area, this is a significant contribution that can serve as a framework for similar intervention designs and implementation efforts. Future research in the application of this framework will be beneficial in defining its utility and refining its components.

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 Human Research Protection Office, Washington University. Written informed consent for participation was not required for this study in accordance with the national legislation and the institutional requirements.

Author contributions

SMR guided study design and led and contributed to writing the manuscript. JG managed the development of the interview guide, conducted interviews, coded interview transcripts, analyzed and interpreted interview themes, and was a contributor in writing the manuscript. EJ analyzed quantitative data and was a contributor in writing the manuscript. All authors contributed to the article and approved the submitted version.

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Conflict of interest

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

Publisher's note

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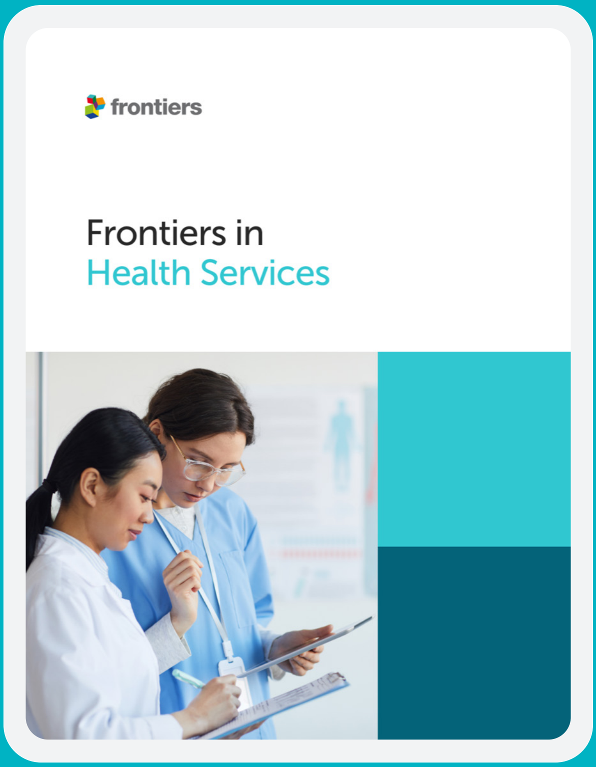

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